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 001-40407

Vera Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**81-2744449**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2000 Sierra Point Parkway, Suite 1200 Brisbane, California	**94005**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 770-0077

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, $0.001 par value per share	VERA	The Nasdaq Stock Market LLC

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

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

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

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

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

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

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

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

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

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 ☒

The aggregate market value of the Registrant's Class A common stock held by non-affiliates of the Registrant as of June 30, 2025, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $1.3 billion based on the closing price of the Registrant's Class A common stock on the Nasdaq Global Select Market of $23.56 per share.

As of February 23, 2026, the registrant had 71,355,667 shares of Class A common stock, $0.001 par value per share, and no shares of Class B common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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 not 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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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the Annual Report) may contain "forward-looking statements" within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under Part I, Item 1A, "Risk Factors" in this Annual Report. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise. These statements, which represent our current expectations or beliefs concerning various future events, may contain words such as "may," "will," "expect," "anticipate," "intend," "plan," "believe," "estimate" or other words indicating future results, though not all forward-looking statements necessarily contain these identifying words. Such statements may include, but are not limited to, statements concerning the following:

- our financial performance;
- the sufficiency of our existing cash to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- the scope, progress, results and costs of developing our product candidates and conducting nonclinical studies and clinical trials;
- the timing and costs involved in obtaining and maintaining regulatory approval of our product candidates and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations for our product candidates for various diseases;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and our ability to grow a sales team;
- the ability to license additional intellectual property relating to any future product candidates and to comply with our existing license agreements;
- the impact of unfavorable geopolitical and macroeconomic conditions on our business and operations;
- the implementation of our strategic plans for our business and current product candidates or any other product candidates we may develop;
- the size of the market opportunity for our product candidates in each of the diseases we target;
- our reliance on third parties to conduct nonclinical research activities, and for the manufacture of our product candidates;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our estimates of the number of patients in potential commercial markets who suffer from the diseases we target and the number of subjects that will enroll in our clinical trials;
- the progress and focus of our current and future clinical trials, and the reporting of data from those trials;
- our ability to advance product candidates into and successfully complete clinical trials;
- the ability of our clinical trials to demonstrate the safety and efficacy of our product candidates, and other positive results;
- the success of competing therapies that are or may become available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;

- our plans relating to the further development and manufacturing of our product candidates, including additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our potential and ability to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
- the rate and degree of market acceptance of our product candidates, as well as the pricing and reimbursement of our product candidates, if approved;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates;
- our plans and ability to obtain and protect intellectual property rights;
- the scope of protection we are able to establish and maintain for intellectual property rights, including our product candidates and any other product candidates we may develop; and
- our ability to retain the continued service of our key personnel and to identify, hire, and then retain additional qualified personnel.

Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. You should be aware that the occurrence of any of the events discussed under Part I, Item 1A, "Risk Factors" and elsewhere in this Annual Report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our Class A common stock (common stock) could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this Annual Report are intended to be applicable to all related forward-looking statements wherever they may appear in this Annual Report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report. Except as required by law, we assume no obligation to update our forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

An investment in shares of our common stock involves a high degree of risk. Below is a list of some of the material risks associated with our business. This summary does not address all of the risks that we face. Additional discussion of the risks listed in this summary, as well as other risks that we face, is set forth under Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K:

- We have completed a limited number of clinical trials for our lead product candidate, atacicept, and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs of our product candidates or future commercialization efforts.
- We have incurred net losses since inception, and have never generated revenue from product sales. We expect to continue to incur net losses at least until we have one or more approved products that achieve commercial success.
- The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.
- We are substantially dependent on the success of our product candidates. If we are unable to complete development of, obtain regulatory approval for and commercialize our product candidates in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.
- Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with immunoglobulin A nephropathy, the availability of competitive products, and significant competition for recruiting participants in clinical trials.
- The incidence and prevalence for target patient populations of our product candidates in specific indications are based on estimates and third-party sources. If the market opportunities for our product candidates, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.
- Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more participant data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than us.
- Changes in methods of manufacturing or formulation of our product candidates may result in additional costs or delays.
- Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.
- Even if any product candidate we develop receives regulatory approval, it could be subject to significant post-marketing regulatory requirements and will be subject to continued regulatory oversight.
- Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations, or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, and prevent new or modified products from being developed, reviewed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

- Biosimilars to our product candidates may provide competition sooner than anticipated.
- Unfavorable geopolitical and global economic conditions, including tariffs and trade tensions, could adversely affect our business, financial condition and results of operations.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers, employees and key consultants.
- We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- If we breach our license agreement with Ares Trading S.A., an affiliate of Merck KGaA, Darmstadt, Germany, related to atacicept, the license agreement with Novartis International Pharmaceutical AG related to MAU868, or the license agreement with the Board of Trustees of Leland Stanford Junior University related to VT-109, we could lose the ability to continue the development and commercialization of atacicept, MAU868, or VT-109, respectively.
- We may be required to make significant payments under our license agreements related to our product candidates.
- If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.
- Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations, to conduct certain aspects of our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition, results of operations and prospects could be significantly harmed.
- The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our product for patients, if approved, could be delayed or prevented.
- If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.
- The price of our common stock may be volatile, and you could lose all or part of your investment.
- If we experience material weaknesses in internal control over financial reporting in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.
- Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.
- We may be subject to securities litigation, which is expensive and could divert management attention.

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PART I

Item 1. Business.

Overview

We are a late clinical-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases. Our lead product candidate, atacicept, is currently being evaluated for the treatment of immunoglobulin A nephropathy (IgAN) and other autoimmune kidney diseases. Atacicept is a native human TACI-Fc fusion protein that binds both the B-cell activating factor (BAFF) and A proliferation-inducing ligand (APRIL) cytokines and is self-administered subcutaneously at home. We are conducting ORIGIN 3, the pivotal Phase 3 trial of atacicept 150 mg in IgAN. The trial met the primary efficacy endpoint of reduction in proteinuria as measured by 24-hour urine protein-to-creatinine ratio (UPCR) at week 36, where participants treated with atacicept achieved a 46% reduction from baseline in UPCR with a statistically significant and clinically meaningful 42% reduction in UPCR compared to placebo ($p<0.0001$). The incidence of adverse events was generally balanced between the atacicept and placebo groups, with fewer serious adverse events reported with atacicept (n=1 [0.5%]) than placebo (n=11 [5%]), no safety signals indicating immunosuppression, and no deaths in either treatment group. In November 2025, we submitted a Biologics License Application (BLA) for atacicept for the treatment of adults with IgAN to the U.S. Food and Drug Administration (FDA) through the Accelerated Approval Program. On January 7, 2026, the FDA granted priority review to the application and assigned a Prescription Drug User Fee Act (PDUFA) target action date of July 7, 2026. If approved, atacicept would be the first B-cell modulator inhibiting both BAFF and APRIL for IgAN, offering patients an autoinjector for at-home self-administration. The ORIGIN 3 key secondary endpoint to support full approval is estimated glomerular filtration rate (eGFR) at 104 weeks, with results expected in 2027.

The ORIGIN Phase 2b clinical trial evaluated the safety and efficacy of atacicept in 116 participants with IgAN and reported positive results at 24 weeks in January 2023, 36 weeks in June 2023, and 96 weeks in October 2024. The trial remained blinded through 36 weeks, after which all participants were eligible for the open label extension portion of the study and received atacicept 150 mg through 96 weeks. Atacicept met its primary endpoint at 24 weeks with a statistically significant reduction in UPCR. Through 36 weeks, participants treated with atacicept demonstrated reductions in galactose-deficient IgA1 (Gd-IgA1, the autoantigen produced by B cells in patients with IgAN), hematuria, and UPCR, with stable eGFR. The improvements in Gd-IgA1, hematuria, UPCR and eGFR represent the quartet of findings consistent with IgAN disease modification. The 96-week open label extension results showed consistent and sustained reductions in Gd-IgA1, hematuria, and UPCR, with continued eGFR stabilization at a rate similar to the general population without kidney disease. Atacicept's safety profile appeared favorable, and comparable to placebo, across the ORIGIN program in IgAN.

We believe that atacicept has pipeline-in-a-molecule potential, with expected application in multiple diseases. Based on data from the ORIGIN Phase 2b trial, the FDA granted Breakthrough Therapy Designation to atacicept for the treatment of IgAN. We have also committed to providing long-term access to atacicept for ORIGIN participants through ORIGIN EXTEND, a long-term Phase 2 extension study that offers atacicept to participants who completed ORIGIN Phase 2b or 3 until, if approved, commercial availability in their country or region. We are evaluating atacicept in other autoimmune kidney diseases, including primary membranous nephropathy (pMN), focal segmental glomerulosclerosis (FSGS) and minimal change disease (MCD), in patients with anti-phospholipase A2 receptor (PLA2R) or anti-nephrin autoantibodies in the Phase 2 PIONEER clinical trial. Potential future indications include anti-neutrophil cytoplasmic antibody-associated vasculitis (AAV), lupus nephritis (LN), Sjogren's disease, systemic lupus erythematosus (SLE), systemic sclerosis, generalized myasthenia gravis, and idiopathic thrombocytopenic purpura.

We also hold worldwide, exclusive development and commercial rights to MAU868, a potentially first-in-class monoclonal antibody to treat reactivated BK virus (BKV) infections, for which we completed a Phase 2 clinical trial in 2022. In January 2025, we acquired worldwide, exclusive development and commercial rights to VT-109, a novel, next-generation dual BAFF/APRIL inhibitor that is in preclinical development. We believe that our current pipeline programs leverage the deep expertise of our team and have strong potential commercial synergies.

Pipeline

Beyond our lead indication in IgAN, we have several late-stage opportunities for potential patient benefit – including indication expansion opportunities for atacicept, the development of VT-109 in B-cell–mediated diseases, and MAU868 for BK viremia among kidney transplant recipients. We are currently evaluating these opportunities for future development.

As part of our life cycle management strategy for atacicept, we are actively enrolling participants in a monthly dose range finding study to evaluate extended dosing intervals. As discussed above, there are also multiple indications in which blocking BAFF and APRIL may offer therapeutic benefit and which offer an attractive commercial opportunity, some of which we are evaluating in the PIONEER phase 2 clinical trial.

In January 2025, we announced a license agreement (Stanford Agreement) with the Board of Trustees of Leland Stanford Junior University (Stanford) to acquire global rights to VT-109, a novel, next generation fusion protein targeting BAFF and APRIL that is in preclinical development with wide therapeutic potential across the spectrum of B-cell-mediated diseases. These rights are for all therapeutic, prophylactic, diagnostic, and treatment uses in humans.

Finally, we have exclusive worldwide rights, pursuant to the license agreement (Novartis License) with Novartis International Pharmaceutical AG (Novartis), to the investigational drug MAU868 for BK viremia among kidney transplant recipients. BKV is a common polyoma virus in adults (90%) that remains latent except in severely immunocompromised populations such as kidney transplant recipients. BKV infection or reactivation can cause BKV nephropathy (BKVN), a condition in which BK infection (first identified as BK viremia) triggers inflammation, then progresses to fibrosis and tubular injury; BKVN is a leading cause of allograft loss. Approximately 15% of kidney transplant recipients develop BK viremia; 3–4% of kidney transplant recipients develop BKVN. Currently, there are no approved treatment options for BK viremia or BKVN. Final results from the Phase 2 clinical trial of MAU868 versus placebo were presented at ASN Kidney Week 2022 and showed that MAU868 was well tolerated and it demonstrated clinically meaningful reductions in BK antiviral activity through 36 weeks in kidney transplant patients with BK viremia. Following feedback from the FDA on the Phase 2 clinical trial, we are evaluating strategies for continued development, including a potential next clinical trial. We believe that MAU868 has the potential to become standard of care for the treatment of reactivated BK infection in order to prevent devastating consequences following kidney transplantation such as BKVN and graft loss.

Our business principles and strategy

Our goal is to develop and commercialize transformative treatments for patients suffering from severe immunological diseases. We believe the successful translation of biomedical science into innovative therapeutic products for patients with immunological diseases will enable outsized growth over the next decade and beyond. Specifically, our strategy is based on the following business principles:

- **Develop disease-modifying medicines to improve patients' lives.** Our team seeks to bring transformative medical products to patients with severe immunological diseases, who often receive steroids as the current standard of care. The non-specific immunosuppressive effect of steroids, with known acute and chronic side effects, presents an important opportunity for innovation. We aim to develop and commercialize disease-modifying drugs that target the source of disease, minimize side effects, and have high potential to meaningfully change standard medical care and improve patients' lives.
- **Establish clear line-of-sight to successful products.** We apply our deep drug development experience, scientific rigor, and disciplined decision making to establish clear line-of-sight along the full spectrum of drug development. We pursue biologic targets, product candidates, and disease indications with a strong scientific rationale, de-risked profile, and capital-efficient development pathway, and optimize for high probability of clinical, regulatory, and commercial success.
- **Build a leading biotech company that delivers innovative medicines to patients.** We believe our team's expertise and our business culture are fundamental to our success. Our Research and Development and Commercial teams are led by experienced drug development executives with proven track records in clinical and commercial development who have led or been involved in the approvals of more than 15 medicines from leading companies, including Gilead Sciences and Amgen. We leverage our team's know-how with additional outsourced resources and enable focused clinical development of our product candidates with the goal of improving patients' lives.

These principles have guided us to the successful in-licensing of atacicept from Ares Trading S.A. (Ares), VT-109 from Stanford, and obtaining the rights to MAU868 via the Novartis License from Amplyx Pharmaceuticals, Inc. (Amplyx), a wholly-owned subsidiary of Pfizer, in each case with worldwide rights for development and commercialization. We take a gated-capital raise approach and scale product candidate investment and exposure in close step with key development milestones to ensure high return on development costs.

Our near- and long-term objectives in pursuit of our goal include:

- **Complete global development of atacicept in IgAN.** Our BLA for atacicept in IgAN was granted Priority Review by the FDA, with a PDUFA target action date of July 7, 2026. We have also committed to providing access to atacicept through the ORIGIN EXTEND study for ORIGIN participants until atacicept is available in their region. The PIONEER study is evaluating atacicept in an expanded IgAN population beyond the ORIGIN program. We anticipate clinical results from the ORIGIN EXTEND and PIONEER studies in 2026.
- **Build and scale organizational capabilities to support commercialization of atacicept.** Under the leadership of our experienced management team, we are building a specialized commercial organization with deep launch experience in nephrology, B cell, and autoimmune therapeutics, to successfully launch atacicept in the United States and other key markets, if approved.
- **Explore additional disease areas where atacicept holds significant therapeutic promise.** By targeting BAFF and APRIL, atacicept's ability to reduce disease-causing autoantibodies may provide clinical benefit. We are exploring additional immunologic diseases where BAFF and APRIL are involved in the pathophysiology of disease, or where autoantibodies play an important role.
- **Advance the development of VT-109 and explore its potential in multiple B-cell–mediated diseases.** We acquired rights to this novel, next-generation dual BAFF/APRIL inhibitor in January 2025 and plan to leverage our research, translational medicine, clinical development and commercial expertise in developing this program.

- **Identify next clinical trial for MAU868 in BK viremia in kidney transplant recipients and align with regulatory authorities.** We reported positive final results from our Phase 2 clinical trial in kidney transplant recipients in 2022 and are evaluating strategies for continued development, including a potential next clinical trial.
- **Expand our pipeline by acquiring or in-licensing product candidates for immunologic diseases with unmet needs.** We believe our expertise and track record will enable us to identify and acquire or in-license additional product candidates that represent opportunities to expand the potential value of our pipeline. We will leverage our lean clinical development operation to bring to market additional product candidates to address kidney and immunologic diseases.

Atacicept in IgAN

We are developing atacicept as a potential treatment for patients with IgAN, a serious and progressive autoimmune disease of the kidney with a high unmet medical need and limited treatment options available. IgAN is driven by the B-cell production of Gd-IgA1 and its corresponding autoantigen. We reported positive topline 24-week results in January 2023, 36-week results in June 2023, and 96-week results in October 2024 from the ORIGIN 2b trial. Our pivotal Phase 3 clinical trial, ORIGIN 3, met the primary endpoint in June 2025, leading to a BLA filing with a PDUFA date of July 7, 2026. We believe that atacicept has the potential to be the best-in-class, leading B-cell modulator therapy for IgAN.

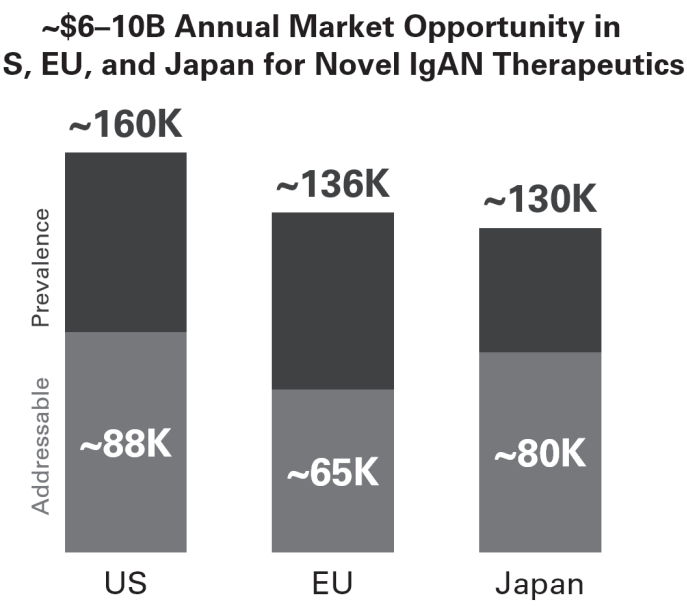
Disease burden, diagnosis, and predictors of disease progression

IgAN is considered a rare disease in the United States and Europe, but it is the predominant cause of primary glomerulonephritis. Patients with IgAN are most often diagnosed in the second and third decades of life. Diagnosis often occurs when patients present with visible signs of chronic kidney disease (CKD), such as hematuria, proteinuria, and hypertension; in the US, most IgAN patients are in stage 3 CKD or greater at diagnosis. Once IgAN is suspected based on clinical history and laboratory data, kidney biopsy is performed for a definitive diagnosis. IgAN is associated with a high risk of kidney-related morbidity and mortality. Patients with IgAN consistently report lower quality of life, even with optimized supportive care. At least 50% of patients diagnosed with IgAN develop end-stage kidney disease (ESKD) within 10 to 20 years from diagnosis, requiring dialysis or kidney transplant. In addition to considerable morbidity and impact on patients' lives, ESKD represents a significant health economic burden estimated to be greater than or equal to ~$3.8 billion over ten years in the U.S. based on a retrospective 2023 study of U.S. patients with IgAN.

IgAN market opportunity

We estimate there will be approximately 160,000 biopsy-confirmed IgAN patients in the United States, 136,000 in Europe, and 130,000 in Japan, at estimated peak year of sales, and that growth in the diagnosed prevalent population is due to overall population growth. Underlying genetic differences may contribute to the significantly higher rate in Japan. As therapies become commercially available, however, an increase in diagnosis rate or longer time to progression, due to better treatments, may increase the diagnosed population over time. We estimate the global market opportunity for novel, disease-modifying therapeutics in IgAN is approximately $6.0 billion to $10.0 billion annually, based on the disease prevalence and the segment of IgAN patients at high risk of progressing to ESKD.

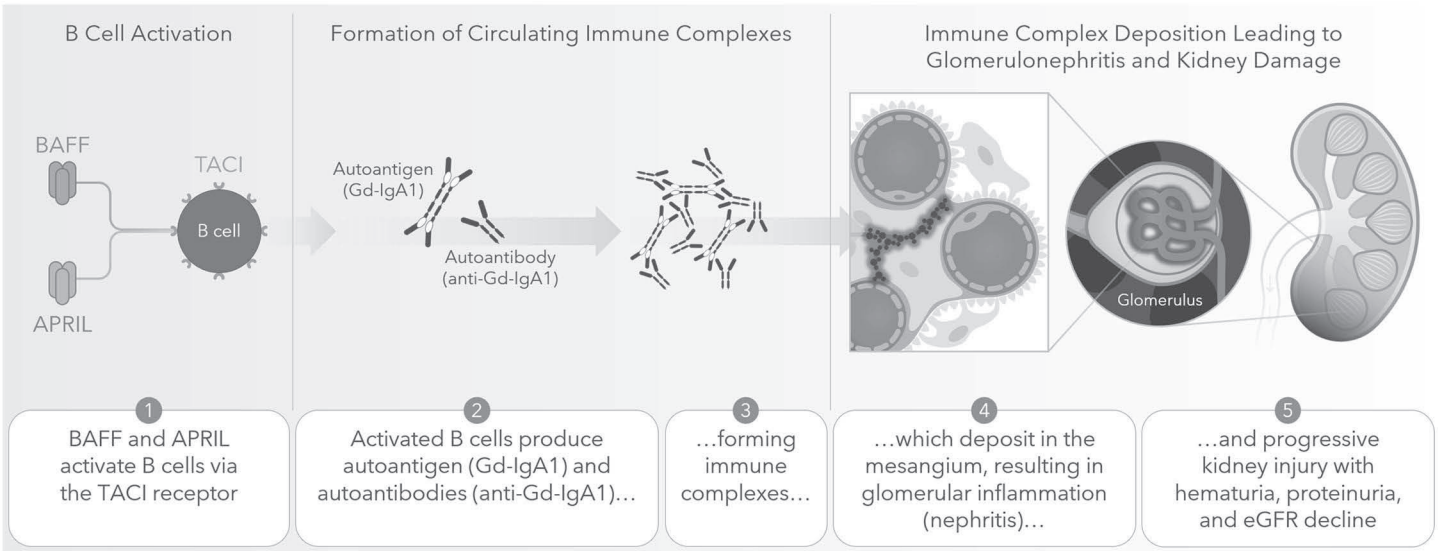
Figure 1: Estimated IgAN epidemiology at estimated peak year of sales



Pathophysiology of IgAN

As shown in Figure 2 below, B cell activation by BAFF and APRIL drives a process that leads to the ultimate development of progressive kidney injury.

Figure 2: IgAN pathophysiology



(1) BAFF and APRIL activate B cells by binding to TACI, a receptor on the surface of B cells. This leads to B cell maturation and survival, and antibody class switching, a mechanism that changes cells' production from one immunoglobulin to another, causing an increase in the production of immunogenic Gd-IgA1.

(2) The Gd-IgA1 antibodies are immunogenic when found in the systemic circulation, and are recognized as an autoantigen by autoantibodies, or antibodies created by B cells in response to a constituent of the body's own tissue.

(3) Gd-IgA1 and anti-Gd-IgA1 autoantibodies combine to form pathogenic immune complexes, or clusters of antibodies.

(4) Pathogenic immune complexes are deposited and become trapped in the mesangium of the kidney's glomeruli. This initiates an inflammatory response that damages the membranes.

(5) As the glomeruli are destroyed, the kidney's ability to remove waste products from the blood is reduced, and protein and blood leak into the urine. Over time, the decline in kidney function as measured by eGFR can result in potentially life-threatening complications that lead to the need for dialysis or kidney transplant in many patients.

Findings consistent with disease modification in IgAN

We believe that a therapy that may comprehensively address treatment goals outlined in current clinical guidelines, and offer potential for disease modification, would be designed to address the underlying autoimmune drivers of disease progression. Such a treatment would ideally achieve 1) a reduction in the burden of the immune complexes, which can be indirectly measured via reductions in the autoantigen, Gd-IgA1; 2) resolution of inflammation, which can be simply measured using a point of care device, urine dipstick, for hematuria; 3) reductions in proteinuria, and most importantly, 4) achievement of a stabilized kidney function profile, as measured by eGFR, consistent with that of the general population.

(1) Gd-IgA1 antibodies have been shown to be the target autoantigen for autoantibodies. A histopathological hallmark of IgAN is deposition of Gd-IgA1 in the glomerular mesangium, either alone or in combination with immunoglobulin G (IgG) and/or immunoglobulin M (IgM). Clinical trials of patients with IgAN have correlated higher serum levels of Gd-IgA1 with greater disease severity, suggesting that reduction in serum Gd-IgA1 may slow disease progression. In a prospective study of 275 patients with IgAN published in Kidney International, higher serum Gd-IgA1 levels were correlated with a higher likelihood of developing progressive kidney failure. A separate clinical trial of patients with IgAN of varying severity found that higher titers of autoantibodies specific for Gd-IgA1 corresponded to both absolute renal risk score and risk of ESKD or death.

(2) Hematuria, a clinical manifestation of glomerular inflammation seen in over 70% of patients with IgAN, correlates with worse clinical outcomes, such as greater rates of kidney failure, highlighting its potential as a marker of disease. Evidence from recent studies suggests that persistent heavy microscopic hematuria in IgAN likely reflects glomerular capillary wall damage caused by the deposition of immune complexes and is a contributing factor for proteinuria and disease progression.

Patients with persistent hematuria in addition to persistent proteinuria are at higher risk than those with proteinuria alone, suggesting that hematuria should be considered when assessing the risk of disease progression. Patients with persistent microscopic hematuria are more likely to have a greater decline in kidney function during follow up compared to those with minimal or no hematuria. Resolution of microscopic hematuria has been associated with improved kidney outcomes in patients with IgAN

(3) Proteinuria is considered an appropriate surrogate endpoint to assess treatment response and monitor disease progression in IgAN. Current clinical guidelines define patients at risk for progressive disease as those with proteinuria >0.5 g/day. Although baseline proteinuria is predictive of eGFR decline, recent data have shown that even lower levels of proteinuria (0.44 to <0.88 g/g) are associated with an increased risk of kidney failure.

(4) eGFR stabilization is the ultimate treatment goal in order to minimize risk of disease progression and kidney function loss. Even with an eGFR decline of 1 mL/min/1.73m2/year, ~40% of patients diagnosed before age 50 will reach kidney failure. Reducing the rate of eGFR decline to ≤1 mL/min/1.73m2/year to be consistent with the general population without kidney disease is recommended by current clinical guidelines in order to minimize risk of disease progression and kidney function loss.

For these reasons, we believe a fusion protein that blocks both BAFF and APRIL, which has the potential to reduce serum Gd-IgA1, would address the upstream source of IgAN, and represent the first disease-modifying approach for IgAN.

Current standard of care for IgAN patients

Despite the high unmet medical need in IgAN, there are limited treatment options available. Current clinical guidelines recommend simultaneous use of the following two approaches for patients with IgAN:

- Non-specific measures to manage the consequences of existing kidney damage (i.e., CKD), including the use of renin-angiotensin system (RAS) inhibitors (e.g., angiotensin-converting enzyme [ACE inhibitors] or angiotensin II receptor blockers [ARBs]) and sodium-glucose cotransporter-2 (SGLT2) inhibitors.
- Treatments that have been proven to reduce immune complex formation and immune-complex-mediated glomerular injury, such as steroids with or without other immunosuppressive agents to non-specifically reduce inflammation resulting from immune complex deposition in the glomeruli.

Simultaneous use of both approaches is recommended to meet the key treatment goal of reducing the rate of loss of kidney function to that of the general population (i.e., 1 mL/min/year or less) in order to minimize the lifetime risk of ESKD. Treatment is selected based on perceived risk of progressive kidney disease, and clinical measures such as hematuria, proteinuria, and eGFR are used to monitor patients while on treatment. Even the combination of these treatments is currently seen as insufficient by physicians and patients; these treatment approaches have limited clinical efficacy and are not well tolerated. The use of steroids may cause significant side effects, including serious infections, high blood pressure, weight gain, diabetes, and osteoporosis. As such, there is a high unmet medical need for targeted therapies that address the underlying disease pathophysiology and have a more tolerable safety profile than systemic steroids.

Treatment landscape of approved and emerging therapies

The hypothesis of IgAN pathophysiology offers potential target points and approaches for therapeutic intervention. As of January 2026, there are five agents approved for the treatment of IgAN and several additional treatments are in clinical development. Most therapeutic candidates in clinical development have employed various approaches to target inflammation and the downstream effects.

These agents can be grouped mechanistically into the following categories: glucocorticoid receptor agonists, endothelin receptor antagonists (ERAs), complement inhibitors, B-cell modulators, and a variety of other approaches that are in the early stages of clinical development.

Glucocorticoid receptor agonists. Glucocorticoid receptor agonists are a well-known class of molecules that have broad anti-inflammatory effects, and well-established acute and chronic side effects. Though reduction in the risk of eGFR decline was shown in clinical trials, there is no consensus on whether glucocorticoids may improve kidney survival. The glucocorticoid budesonide has been reformulated to concentrate steroid effects locally on the gut mucosa, theoretically suppressing the abnormal B cell activity and reducing systemic steroid toxicity. Reformulated budesonide, a delayed-release corticosteroid developed by Asahi Kasei Corp., is currently approved by the FDA as TARPEYO® and European Commission as KINPEYGO® for reducing the loss of kidney function in adults with IgAN who are at risk for disease progression, though systemic steroid side effects have been observed in clinical trials.

ERAs. Aberrant endothelin signaling is implicated in structural podocyte changes and increased mesangial proliferation in chronic kidney diseases, including IgAN. ERAs block endothelin-induced cell proliferation and hence may reduce renal perfusion pressure and proteinuria. Since this mechanism of action works downstream of disease-related immune activities, it is not expected to reduce Gd-IgA1 or the resulting immune complexes that cause the disease. ERAs have previously been approved for the treatment of pulmonary arterial hypertension and erectile dysfunction and make use of a vasodilatory effect. ERAs have been associated with edema, significant

liver toxicity and increased risk of heart failure. Sparsentan, a dual endothelin angiotensin receptor antagonist developed by Travere Therapeutics, is currently approved by the FDA and European Commission as FILSPARI®, with a boxed warning for hepatotoxicity and embryo-fetal toxicity and a Risk Evaluation and Mitigation Strategies (REMS) assigned for liver toxicity. Atrasentan is an endothelin A receptor antagonist developed by Novartis and approved by the FDA as VANRAFIA®.

Complement inhibitors. Increased complement activation is commonly observed in patients with IgAN. It is hypothesized that immune-complex deposition in glomeruli may contribute to complement activation, though the exact mechanism is not well understood. Iptacopan is a complement inhibitor developed by Novartis and approved by the FDA as FABHALTA®. Several other agents that inhibit complement activation are in early stages of clinical development for IgAN. As complement inhibition works downstream of immune complex formation, these agents are not expected to impact the upstream cause of disease and reduce Gd-IgA1 or the resulting immune complexes that cause inflammation and complement activation in the kidney.

B-cell modulators. B-cell modulators, including atacicept, are an important category of emerging therapies for IgAN. The disease-causing Gd-IgA1 is predominantly produced by B cells. Therefore, control of B cell activation may reduce production of Gd-IgA1 and the downstream formation of autoantibodies and immune complexes. Preclinical models have shown that dual inhibition of BAFF and APRIL offers improved suppression of B cell activities over blocking BAFF or APRIL alone. Sibeprenlimab is an APRIL-specific monoclonal antibody developed by Otsuka Pharmaceuticals and approved by the FDA as VOYXACT®.

Our solution: Atacicept

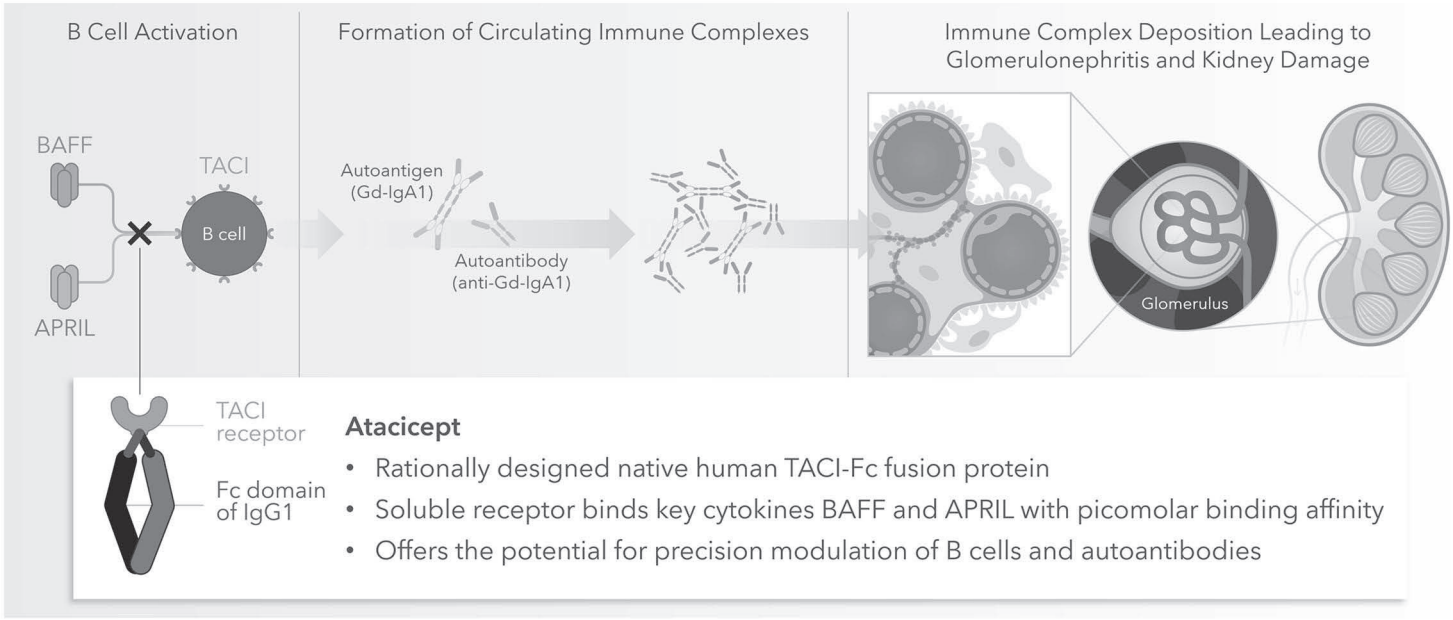
Atacicept is a fusion protein that blocks both BAFF and APRIL, which play key roles in the upstream pathways that cause IgAN and other autoimmune diseases, and is dosed once weekly via a 1-mL subcutaneous injection, self-administered at home. We believe that atacicept's mechanism has the potential for clinically meaningful improvements in measures designed to assess efficacy in IgAN and other immunologic diseases. BAFF inhibition has been clinically and commercially validated through the approval of BENLYSTA (belimumab) in both SLE and LN. Preclinical and clinical evidence support that atacicept's mechanism of dual inhibition of BAFF and APRIL may provide improved clinical outcomes, compared to inhibiting either signal alone, as measured by endpoints designed to assess efficacy.

Importantly, atacicept is the first agent in development to demonstrate Gd-IgA1 reductions, hematuria improvements, and UPCR reductions with eGFR stabilization at a rate of decline similar to the general population without kidney disease through 96 weeks, suggesting atacicept may offer a potential long-term, disease-modifying treatment for IgAN with a favorable safety profile. As a result, we believe atacicept has the potential to be the first disease-modifying therapy which inhibits both BAFF and APRIL for IgAN. Atacicept has a well-characterized clinical safety profile with >1,900 participants across all completed and ongoing clinical trials to date. We completed enrollment of participants in the ORIGIN 2b trial in 2022, and we reported positive results at 24 weeks in January 2023, 36 weeks in June 2023, 72 weeks in January 2024, and 96 weeks in October 2024. We are conducting a multinational, randomized, double-blind, placebo-controlled Phase 3 clinical trial in IgAN (ORIGIN 3). We completed enrollment for the primary endpoint cohort in September 2024 and completed full enrollment of the study in April 2025. In June 2025, we announced that atacicept met the primary endpoint of UPCR reduction at week 36, with a 46% reduction from baseline and a statistically significant and clinically meaningful 42% reduction compared to placebo ($p<0.0001$; atacicept n=106, placebo n=97). In November 2025, we presented additional results from the 36-week interim analysis in a featured oral presentation during the ASN Kidney Week opening plenary session, with simultaneous publication in The New England Journal of Medicine. We submitted a BLA for atacicept in IgAN to the FDA in November 2025. The FDA granted priority review to the application and assigned a PDUFA target action date of July 7, 2026. If approved, atacicept would be the first B cell modulator targeting both BAFF and APRIL for IgAN, offering patients an autoinjector for at-home self-administration.

Our approach to IgAN: B-cell modulation to reduce Gd-IgA1 and autoantibodies

Atacicept is a native human TACI-Fc fusion protein that is designed to modulate the B cell pathway, which has well characterized implications in immunologic diseases. Specifically, as shown in Figure 3 below, atacicept contains the soluble extracellular domain of the native TACI receptor fused with the inactivated Fc domain of IgG1. TACI is a native receptor for BAFF and APRIL, members of the tumor necrosis factor family that promote B cell survival and autoantibody production associated with IgAN and other immunologic diseases. Dual blockade of BAFF and APRIL by TACI has been shown to be more potent than blocking BAFF alone or APRIL alone and has the benefit of targeting long-lived plasma cells, in addition to B cells, thus reducing production of Gd-IgA1 and its autoantibodies. Therefore, atacicept is designed to precisely modulate B cell activity by binding both BAFF and APRIL, and follows a long history of impactful agents that are logically designed Fc fusion proteins. This mechanism acts directly on the source of IgAN, which we believe will significantly mitigate the downstream effects of the disease.

Figure 3: Atacicept is the result of rational drug design to target the upstream source of disease



(1) Atacicept inhibits BAFF and APRIL, leading to decreased Gd-IgA1 production by B cells.

(2) This leads to a reduction in the autoantibodies that bind to Gd-IgA1.

(3) Therefore, formation of pathogenic immune complexes is greatly reduced.

(4) This, in turn, reduces immune complex deposition in glomeruli and glomerular inflammation is reduced.

(5) Ultimately, progressive renal injury is attenuated, with reductions in hematuria and proteinuria, and stabilization of eGFR, which we believe will significantly lower the morbidity and mortality associated with IgAN.

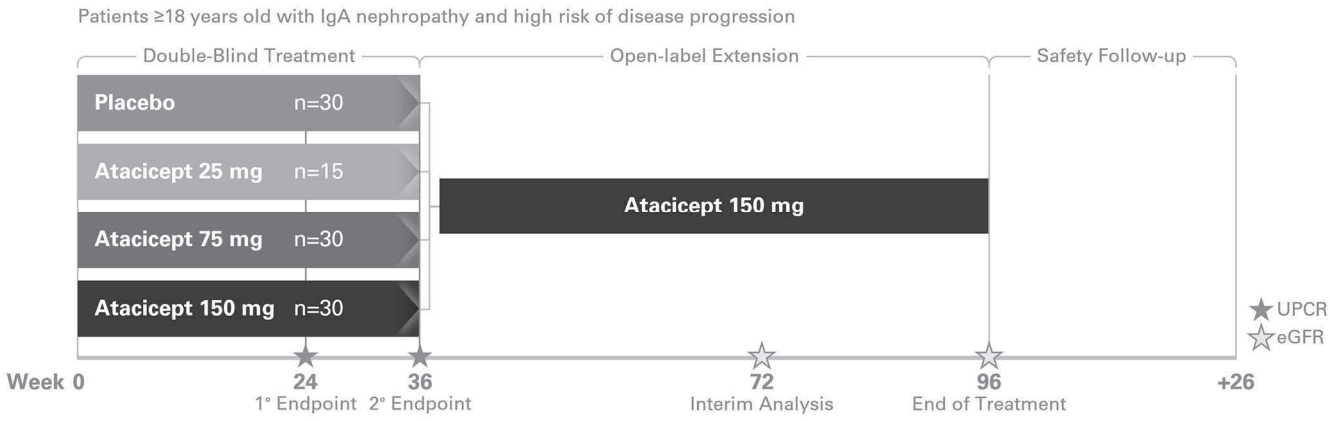
Atacicept's potential disease-modifying mechanism addresses the upstream processes that cause IgAN, while other therapies act on downstream processes. Therefore, we believe that the clinical outcomes of atacicept, measured by endpoints designed to assess efficacy and durability, will be favorable over competitors, with a tolerability profile assessed in a rigorous clinical development program of >1900 patient exposures to date. At home dosing with a once weekly, 1-mL subcutaneous injection via autoinjector also provides an attractive target product profile for patients.

Atacicept in IgAN: clinical development

Atacicept was the subject of a collaboration agreement between Ares and ZymoGenetics, Inc. in 2001, and was licensed on an exclusive basis to Ares in 2008. It was advanced by Merck KGaA (Merck), Darmstadt, Germany, in clinical trials for several autoimmune diseases, including rheumatoid arthritis (RA), multiple sclerosis, SLE, and IgAN. We have worldwide, exclusive rights to atacicept from Ares, an affiliate of Merck, pursuant to a license agreement (Ares Agreement), which advanced atacicept in randomized, double-blind, placebo-controlled clinical trials for several autoimmune diseases in over 1,500 patients, in which it was well tolerated. Previously, Merck conducted a randomized, double-blind, placebo-controlled Phase 2a trial in IgAN known as JANUS. Results from the JANUS trial showed a dose-dependent effect of atacicept 25 mg and 75 mg weekly on serum Gd-IgA1, proteinuria, and key biomarkers, including serum Ig levels. As reported at the American Society of Nephrology (ASN) Kidney Week conference in 2022, atacicept is also the first therapeutic candidate in IgAN to show reduction in all first three hits of pathophysiology—serum Gd-IgA1, anti-Gd-IgA1 autoantibody, and immune complex levels.

Atacicept was studied in the ORIGIN 2b clinical trial, a multinational, randomized, placebo-controlled, double-blind trial for the treatment of IgAN (Figure 4). The ORIGIN 2b trial was designed to evaluate the efficacy and safety of atacicept in participants with biopsy-proven IgAN and persistent proteinuria despite stable and maximum-tolerated renin-angiotensin-aldosterone (RAAS) inhibitor regimen for at least 12 weeks. The clinical trial consisted of a 36-week double-blind treatment period, followed by a 60-week open-label treatment period and a 26-week safety follow-up period. The trial assessed three doses (25 mg, 75 mg and 150 mg) of once-weekly 1-mL subcutaneous injections, administered at home, of atacicept versus placebo, for impact on kidney function as measured by proteinuria and eGFR. The primary endpoint was change from baseline in UPCR at 24 weeks based on 24-hour urine collection, with a secondary endpoint of UPCR at 36 weeks. Other secondary endpoints included UPCR and eGFR at multiple timepoints, and safety and tolerability. Exploratory endpoints included Gd-IgA1 change from baseline and hematuria resolution. We completed enrollment in mid-2022, enrolling a total of 116 participants at multiple global sites.

Figure 4: ORIGIN 2b trial design



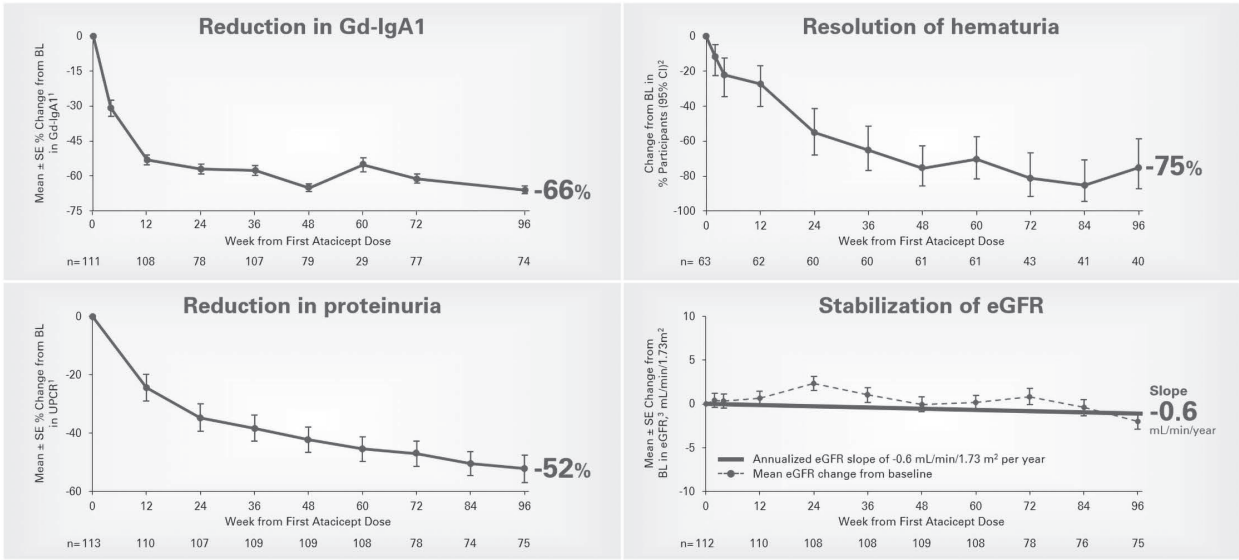
Results from the 36-week double-blind period were presented in a late-breaking oral presentation at the European Renal Association 2023 conference and published in *Kidney International* in 2024. The primary endpoint was met at 24 weeks as the mean UPCR was reduced from baseline by 31% in the combined atacicept group (defined as atacicept 75 mg and 150 mg groups) vs 8% with placebo, resulting in a statistically significant 25% reduction with atacicept vs placebo.

The results of the 36-week randomized period were consistent with a profile of disease modification in IgAN:

- Gd-IgA1 reduction of 64% from baseline with atacicept 150 mg.
- Hematuria resolution in 80% of participants on atacicept 150 mg vs 5% on placebo.
- Atacicept 150 mg achieved a 35% reduction vs placebo.
- Stable eGFR observed for participants on atacicept, with clinically meaningful difference of 5.8 mL/min/1.73m^2 vs placebo.
- Atacicept was well tolerated, with a similar safety profile to placebo.

In October 2024, long-term results from the ORIGIN Phase 2b trial were simultaneously presented in a late-breaking oral presentation at ASN Kidney Week and published in the Journal of the American Society of Nephrology (JASN). Over 96 weeks, participants treated with atacicept demonstrated a 66% reduction in Gd-IgA1, resolution of hematuria in 75% of participants, a 52% reduction in proteinuria, and a mean annualized eGFR slope of -0.6 mL/min/1.73m2/year. This eGFR slope profile is consistent with the aging-related decline observed in the general population without biopsy-proven kidney disease.

Figure 5: ORIGIN Phase 2b long-term 96-week results with atacicept was consistent with disease-modifying IgAN profile



Atacicept group includes all participants receiving any atacicept dose at each timepoint, with baseline (BL) defined as the last available measurement prior to the first dose of atacicept. Data from weeks 0 to 60 includes participants who switched from placebo to atacicept. 1. Percentage changes from BL computed using FDA-endorsed mixed-effects modeling; 2. Percentages represent change from BL in number of participants with hematuria at each visit divided by number with BL hematuria; 3. Changes from BL in eGFR were analyzed using MMRM analysis and LS estimation and SE were estimated from the model directly; eGFR slope was analyzed using mixed-effects model with random intercept and random slope and mean slope and SE were estimated from the model directly.

In the randomized phase of the ORIGIN Phase 2b clinical trial, the clinical safety profile was similar between atacicept and placebo. The cumulative generally favorable safety profile of atacicept remained consistent with that observed during the randomized period (Figure 6), with a 90% completion rate of atacicept treatment in the open-label extension period. We believe these data support the potential for atacicept to offer long-term, comprehensive IgAN disease modification and provide further confidence in the ongoing pivotal ORIGIN 3 trial of atacicept in IgAN.

Figure 6: Phase 2b ORIGIN clinical trial adverse events profile

	Double-Blind Baseline to Week 36		Open-Label Extension Week 36 to 96[1]
Participants, n (%)	**Placebo n=34**	**All Atacicept n=82**	**Atacicept 150 mg n=111**
TEAEs	28 (82)	60 (73)	85 (77)
Infections and infestations	11 (32)	35 (43)	43 (39)
Study drug-related TEAEs[2]	14 (41)	42 (51)	52 (47)
Serious TEAEs[3]	3 (9)	2 (2)	12 (11)
TEAEs leading to study drug discontinuation[4]	1 (3)	1 (1)	2 (2)
Deaths	0	0	0

TEAE = treatment-emergent adverse event.
1. Week 96 cut-off includes all safety data as of June 03, 2024, including visits past Week 96. AEs were considered treatment-emergent during the open-label extension period if they started after the first dose of open-label atacicept 150 mg through the end of the trial. n=111 represents 80 atacicept and 31 placebo who entered the open-label extension.
2. Mostly injection site reactions.
3. Serious TEAEs during double-blind period were previously reported (Lafayette R, et al. Kidney Int. 2024;S0085-2538(24)00236-9); serious TEAEs during the OLE: excess abdominal fat and left basal bronchopneumonia (n=1), acute kidney injury (n=1), angioedema (n=1), termination of pregnancy (n=1), post cricoid ulcer (n=1), pancreatitis, passed out common bile duct stone, and acute cholecystitis (n=1), tonsillitis (n=1), pneumonia (n=1), acute coronary syndrome required hospitalization (n=1), left 5th metatarsophalangeal joint gout (n=1), mild flare of IgA nephropathy (n=1), and urethral stricture worsening (n=1).
4. Reasons for discontinuation during double-blind period were previously reported; discontinuations during the OLE were due to: pneumonia in a heavy smoker, resolved (n=1); and worsening alanine aminotransferase and aspartate aminotransferase, resolved and unrelated to study treatment (n=1).

Ongoing Phase 3 ORIGIN clinical trial

We advanced atacicept 150 mg into a pivotal Phase 3 trial in IgAN in the second quarter of 2023, using the same formulation from the Phase 2b trial and learnings from the Phase 2b subgroup analyses to reduce risk in the design of a Phase 3 trial that aims to accurately assess treatment efficacy while minimizing potential confounders for proteinuria measure.

Figure 7: Phase 3 ORIGIN 3 trial design

ORIGIN 3 is a Phase 3 global, multicenter, randomized, placebo-controlled, double-blind trial (Figure 7) in participants with IgAN who have persistent proteinuria and remain at high risk of disease progression despite being on a stable prescribed regimen of renin-angiotensin system inhibitors (ACE inhibitors or ARBs) for at least 12 weeks that is the maximum labeled or tolerated dose, with the use of SGLT2 inhibitors (SGLT2i) also allowed. The clinical trial consists of a 104-week double-blind treatment period which is currently ongoing, followed by a 52-week open-label extension and a 26-week safety follow-up period. The trial assesses at-home self-administered once weekly 1-mL subcutaneous injections of atacicept 150 mg versus placebo for impact on kidney function as measured by proteinuria and eGFR. The primary endpoint is change from baseline in UPCR at 36 weeks based on 24-hour urine collection and the key secondary endpoint is change from baseline in eGFR at 104 weeks. Additional secondary endpoints are change in Gd-IgA1, hematuria resolution, change in eGFR at 52 weeks, and time from randomization to first occurrence of composite kidney failure endpoint event. In accordance with guidance from regulatory authorities to sponsors of registrational trials in IgAN, eGFR results are not reported while the trial is ongoing.

We completed enrollment for the Phase 3 primary endpoint cohort in September 2024 and full enrollment of the study in April 2025. In June 2025, we announced that atacicept met the primary endpoint. In November 2025, we presented additional results from the 36-week interim analysis in a featured oral presentation during the ASN Kidney Week opening plenary session, with simultaneous publication in *The New England Journal of Medicine.*

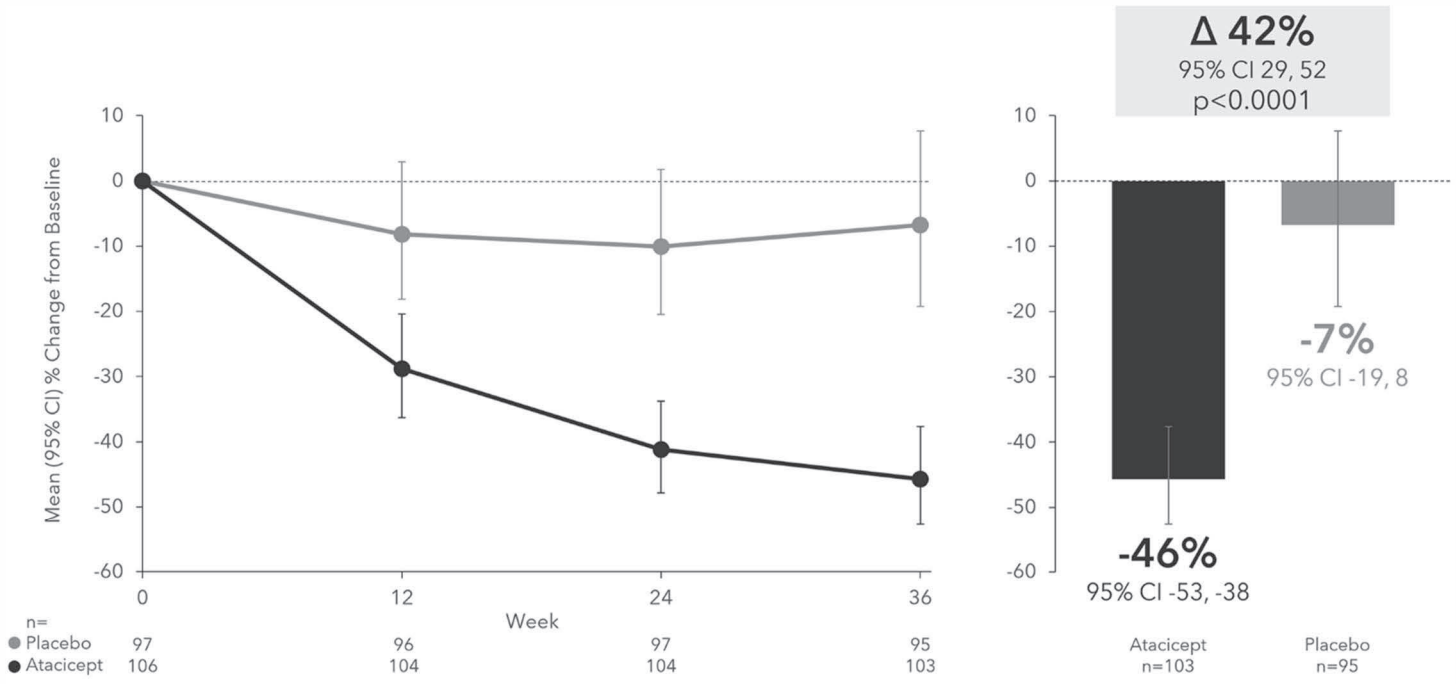
A total of 428 participants were randomized and treated, with 214 in the atacicept group and 214 in the placebo group. Of the 203 patients included in the 36-week interim efficacy analysis, 99/106 (93%) in the atacicept group and 84/97 (87%) in the placebo group remained on treatment after 36 weeks. The baseline demographics and characteristics for the ORIGIN 3 participants were similar to the previous ORIGIN 2b trial, with the exception of a higher percentage of patients on SGLT2i in the Phase 3 trial, reflecting evolving clinical practices.

Figure 8: Demographics and baseline characteristics of ORIGIN 3 and ORIGIN 2b

	ORIGIN 3 Interim Analysis Set			ORIGIN 2b
	Atacicept n=106	Placebo n=97	Total n=203	Total N=116
Age, median (range), years	40 (18, 72)	39 (19, 70)	40 (18, 72)	37 (18, 67)
Male sex, n (%)	57 (54)	58 (60)	115 (57)	69 (59)
Race, n (%)				
White	46 (43)	42 (43)	88 (43)	62 (53)
Asian	59 (56)	52 (54)	111 (55)	51 (44)
Black or African American	0	1 (1)	1 (0.5)	0
Native Hawaiian or other Pacific Islander	0	1 (1)	1 (0.5)	1 (1)
Other/not reported	1 (1)	1 (1)	2 (1)	2 (2)
Hispanic/Latino ethnicity, n (%)	14 (13)	6 (6)	20 (10)	4 (3)
eGFR, mean ± SD, mL/min/1.73 m^2	65 ± 28	65 ± 29	65 ± 28	63 ± 27
UPCR by 24h urine, mean ± SD, g/g	1.7 ± 0.9	1.8 ± 1.2	1.7 ± 1.0	1.6 ± 0.9
Time since biopsy, mean ± SD, years	2.5 ± 2.6	2.5 ± 2.4	2.5 ± 2.5	2.8 ± 2.8
SGLT2i use, n (%)	59 (56)	49 (51)	108 (53)	16 (14)

The primary endpoint for the interim analysis was the change in UPCR at 36 weeks. Participants receiving atacicept had a 46% reduction in UPCR and the placebo-treated participants had a 7% reduction. Using a mixed effects model, the difference between the groups was statistically significant at 42% ($p<0.0001$).

Figure 9: Primary endpoint of UPCR reduction through 36 weeks

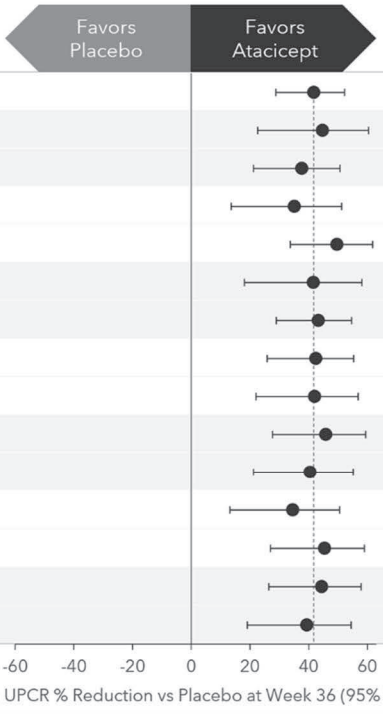


Interim Analysis Set (IAS) included the first 203 randomized participants who received ≥1 dose of trial drug. Change from baseline in natural-log transformed UPCR at Week 36 was analyzed using a mixed-effects model with repeated measurement (MMRM), including fixed effects for treatment group, visit as a categorical variable, treatment-by-visit interaction, baseline natural-log transformed UPCR, baseline eGFR category, SGLT2i use at baseline, and region, with participant as a random effect. log-transformed change from baseline in UPCR was estimated with use of least-squares means. To facilitate interpretation of the result, the least-squares means estimate was back-exponentiated to obtain the equivalent geometric mean percentage change. MMRM analysis included double-blind period data up to Week 36, regardless of treatment discontinuation or initiation of rescue treatment for IgAN or prohibited therapy; missing values after study withdrawal were imputed with jump to reference (placebo) approach for 100 times. The Rubin rule was used to combine results estimated from each of 100 imputation datasets by MMRM analysis.

The effect of atacicept on UPCR reduction was consistent across prespecified subgroups of age, sex, region, race, baseline proteinuria, baseline eGFR, and baseline SGLT2i use (Figure 10).

Figure 10: UPCR reduction across prespecified subgroups at 36 weeks

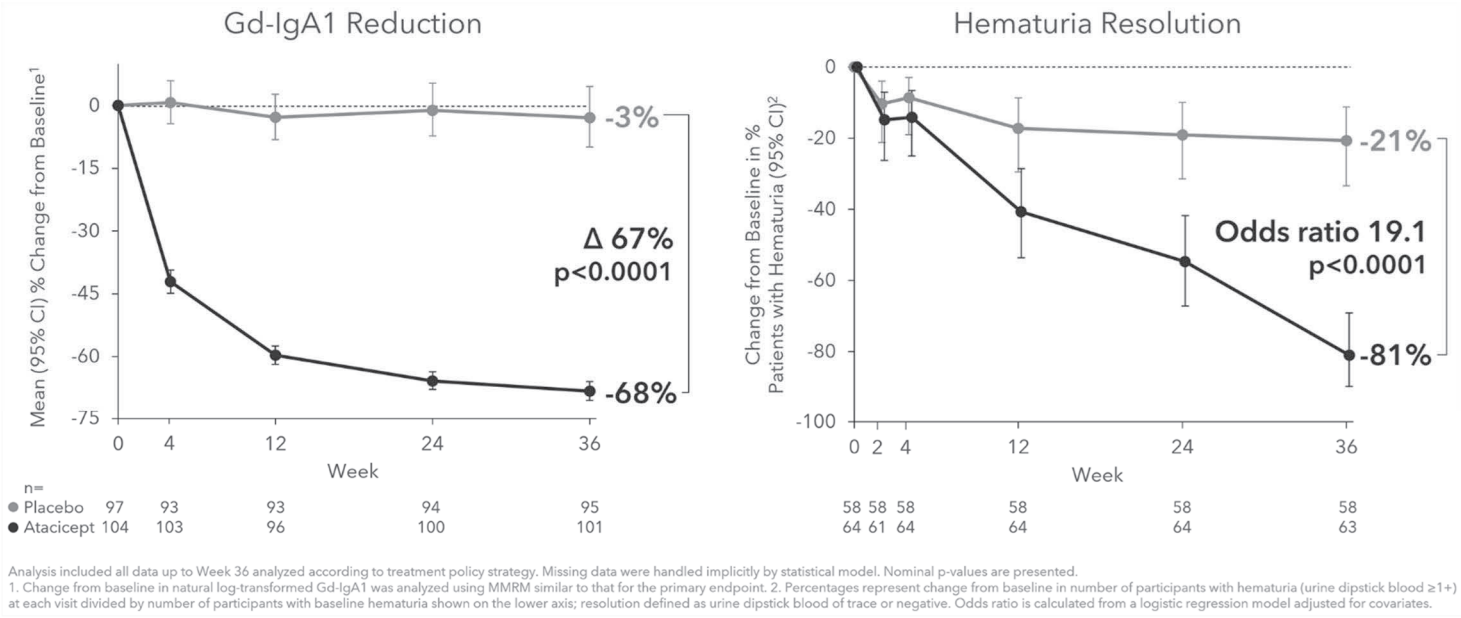
		n (%)		Mean UPCR % Change at Week 36		Mean UPCR % Reduction vs Placebo (95% CI)
		Atacicept	Placebo	Atacicept	Placebo	
Overall		106	97	-46%	-7%	42% (29, 52)
Age, years	<40	48 (45)	49 (51)	-44%	+0.5%	45% (23, 60)
	≥40	58 (55)	48 (49)	-46%	-14%	38% (21, 51)
Sex	Male	57 (54)	58 (60)	-41%	-9%	35% (14, 51)
	Female	49 (46)	39 (40)	-51%	-2%	50% (34, 62)
Region	Asia	50 (47)	48 (49)	-50%	-14%	42% (18, 58)
	Other	56 (53)	49 (51)	-42%	+1%	43% (29, 55)
Race	White	46 (43)	42 (43)	-42%	+0.1%	42% (26, 55)
	Non-white	60 (57)	55 (57)	-48%	-11%	42% (22, 57)
BL UPCR, g/g	<1.5	53 (50)	47 (48)	-44%	+3%	46% (28, 59)
	≥1.5	53 (50)	50 (52)	-48%	-13%	41% (21, 55)
BL eGFR, mL/min/1.73m^2	<60	50 (47)	52 (54)	-35%	-1%	34% (13, 51)
	≥60	56 (53)	45 (46)	-53%	-14%	45% (27, 59)
SGLT2i use at BL	Yes	59 (56)	49 (51)	-48%	-7%	44% (26, 58)
	No	47 (44)	48 (49)	-43%	-6%	39% (19, 54)



Subgroup analyses were conducted using the same imputed data sets and the same MMRM model as for the primary analysis for each subgroup category, separately. If the subgroup was one of the covariates in the model, the covariate was removed from the model statement when the model was performed for the particular subgroup.

Secondary endpoint results with atacicept were consistent with the Phase 2b study, with a 67% reduction in Gd-IgA1, and an 81% reduction in hematuria in participants with baseline hematuria (Figure 11).

Figure 11: Gd-IgA1 reduction and hematuria resolution through 36 weeks



Analysis included all data up to Week 36 analyzed according to treatment policy strategy. Missing data were handled implicitly by statistical model. Nominal p-values are presented.
1. Change from baseline in natural log-transformed Gd-IgA1 was analyzed using MMRM similar to that for the primary endpoint. 2. Percentages represent change from baseline in number of participants with hematuria (urine dipstick blood ≥1+) at each visit divided by number of participants with baseline hematuria shown on the lower axis; resolution defined as urine dipstick blood of trace or negative. Odds ratio is calculated from a logistic regression model adjusted for covariates.

Across the ORIGIN program in IgAN, the safety profile of atacicept appears favorable, and comparable to placebo. In the ORIGIN 3 safety analysis set (atacicept n=214, placebo n=214), the incidence of adverse events was generally balanced between the atacicept and placebo groups, with numerically fewer serious adverse events reported with atacicept (n=1 [0.5%]) than placebo (n=11 [5%]). There were more discontinuations due to adverse events in placebo treated participants, and the rates of infections were balanced. The one adverse event that was higher in atacicept treated individuals was the rate of injection site reactions; these were mild to moderate, and did not lead to discontinuation. There was a higher number of hypersensitivity reactions in placebo treated individuals.

Atacicept treatment led to reductions in serum immunoglobulin (Ig) levels consistent with its mechanism of B-cell modulation, but without evidence of B-cell depletion or immunosuppression: there were no reported cases of hypogammaglobulinemia (IgG <3 g/dL) and no serious, severe, or opportunistic infections. There were no deaths in either treatment group. (Figure 12)

Figure 12: Adverse event profile

Participants, n (%)	Atacicept n=214	Placebo n=214
Adverse events	127 (59)	107 (50)
Serious adverse events[1]	1 (0.5)	11 (5)
Adverse events leading to drug discontinuation[2]	2 (1)	8 (4)
Adverse events of infections and infestations	68 (32)	60 (28)
Serious or severe infections and infestations	0	3 (1)
Opportunistic infections	0	0
Study drug related adverse events[3]	63 (29)	22 (10)
Adverse events associated with injection site reactions[4]	51 (24)	11 (5)
Hypersensitivity reactions	8 (4)	14 (7)
Adverse events leading to death	0	0

Analysis of safety population (all participants randomized and treated) as of interim data cut on 15-May-2025.
1. Atacicept: cholecystitis, determined by site investigator to be unrelated to treatment; Placebo (n=1 each): gastroenteritis, lower respiratory tract infection, pneumonia, pyelonephritis, IgA nephropathy, renal impairment, acute myocardial infarction, transplant rejection, hyponatremia, osteonecrosis, ovarian epithelial cancer, carotid artery aneurysm, hypertension, acute cholecystitis. 1 placebo serious adverse event was deemed related to study drug.
2. Discontinuations in the 2 atacicept participants were due to eczema and erythema.
3. Majority were mild to moderate injection site reactions that did not lead to discontinuation.
4. Injection site reactions among atacicept recipients were largely characterized by injection site erythema, bruising, and pruritis.
No observed hypogammaglobulinemia (IgG <3 g/dL).

The FDA granted priority review to the BLA for atacicept in IgAN and assigned a PDUFA target action date of July 7, 2026. If approved, atacicept would be the first B cell modulator targeting both BAFF and APRIL for IgAN, offering patients an autoinjector for at-home self-administration.

ORIGIN EXTEND Phase 2 clinical trial

We initiated the ORIGIN EXTEND trial, a Phase 2 extension study in participants who complete ORIGIN Phase 2b or Phase 3. The objectives of the trial are to 1) capture longer-term safety and efficacy data of atacicept treatment, 2) evaluate the effect of reinitiation of atacicept treatment following an off-treatment period and 3) provide eligible participants with extended access to atacicept prior to commercial availability in their country or region. We anticipate clinical results from the trial in 2026.

PIONEER Phase 2 clinical trial to assess Atacicept in pMN, FSGS, and MCD

Due to the positive results of the ORIGIN program, in August 2025 we initiated the PIONEER trial, a global, open label, Phase 2 basket trial evaluating the safety and initial signals of efficacy of atacicept in an expanded cohort of IgAN patients and other autoimmune-mediated glomerular diseases. The expanded IgAN cohort includes participants aged 10 years or older, IgA vasculitis nephritis, and lower baseline thresholds for proteinuria and eGFR than were studied in ORIGIN 3. The trial also includes cohorts with additional autoimmune glomerular diseases characterized by the presence of antibodies to glomerular antigens, including pMN, FSGS, and MCD. We anticipate clinical results from the trial in 2026.

Atacicept in pMN

pMN Pathophysiology and Disease Overview

pMN is an autoimmune disease characterized by glomerular membrane thickening and long-term proteinuria. pMN patients are initially treated with ACEi / ARBs, and upon progression typically are treated with either immunosuppressive or CD20 therapies. Despite proper management, patients still progress to ESKD, highlighting the need for a more effective standard of care.

pMN Market Opportunity, Current Standard of Care, and Our Proposed Solution

There are approximately 50,000 patients in the United States with pMN. In 70-80% of cases, inflammation of the renal glomeruli is caused by autoantibodies targeting PLA2R and thrombospondin type 1 domain-containing 7A (THSD7A). The remaining 20-30% of cases develop as a secondary condition due to underlying issues such as infections, other autoimmune diseases, tumors, or drug poisoning. Most patients with biopsy-confirmed pMN have circulating anti-PLA2R autoantibodies, with approximately 70% of pMN cases associated with anti-PLA2R+ antibodies, and 65% of these cases considered moderate-to-severe. According to current KDIGO guidelines, PLA2R is recognized as a crucial diagnostic marker, eliminating the need for a kidney biopsy if the patient is seropositive for PLA2R and exhibits clinical symptoms. Additionally, the concentration of anti-PLA2R antibodies provides insights into disease activity and progression, serving as a clinical criterion for assessing the risk of progressive renal failure in pMN patients: 1) higher antibody concentrations indicate more active pMN and a greater risk of kidney failure, and 2) monitoring antibody levels can predict phases of clinical remission and relapses, as changes in anti-PLA2R antibody levels typically precede improvements or worsening of the disease.

Current treatments tackle the autoimmune aspect of pMN through B-cell depletion (e.g., agents such as rituximab) or immunosuppression via cyclophosphamide / high dose steroids; these therapies have been associated with significant toxicity. With no FDA-approved pMN therapies, significant unmet need remains for efficacious and safe agents, including those that can reduce adverse events associated with immunosuppressant therapy, offer benefit for the ~40% of patients that are refractory to rituximab, and further reduce disease progression to CKD and ESKD.

A more targeted approach that focuses on modulating autoimmune B-cell production, rather than broad immunosuppression, may offer a potential solution. Autoreactive B-cells are implicated in the immunopathogenesis of pMN, with PLA2R identified as the target antigen for the typical IgG deposition observed in renal biopsies. While immunosuppressive treatments have shown reductions in PLA2R autoantibody (PLA2R-Ab) levels, patients with higher serum levels of both BAFF and APRIL are less likely to achieve clinical remission on standard immunosuppressive therapy. Additionally, the BAFF-targeting immunomodulator belimumab has been shown to improve proteinuria and PLA2R titers in an open-label trial. This supports the rationale for using other treatments involving B-cell modulation, such as atacicept. Atacicept's ability to block pathogenic B-cell activation via BAFF and APRIL cytokine binding suggests it may be effective in treating pMN, particularly in patients who have been treated with immunosuppressive therapies but still maintain high BAFF and APRIL serum levels.

Atacicept in FSGS and MCD

FSGS and MCD Pathophysiology and Disease Overview

FSGS is characterized by histological lesions (scarring) on kidney glomeruli, manifestations of proteinuria & hypoalbuminemia, and chronic kidney disease, which can present at any age. FSGS often presents with nephrotic syndrome manifestations, including high-grade proteinuria (>3.5 g/day), hypoalbuminemia, and edema, with 30 – 40% progressing to ESKD by 10 years. Nephrin is a transmembrane protein found in kidney podocytes, plays a significant role in maintaining the integrity and function of the glomerular filtration barrier, and it can be used as a biomarker for early glomerular injury, since elevated levels of nephrin in the urine (nephrinuria)

can indicate damage to the podocytes and the filtration barrier. Recently, anti-nephrin antibodies were identified in ~10% of primary FSGS patients, indicating potential autoimmune involvement in the disease pathology and demonstrating a strong correlation to urine albumin-to-creatinine ratio (uACR).

MCD is a kidney disorder that leads to glomeruli damage and is characterized by sudden onset of nephrotic syndrome, including increased proteinuria, edema, and hypoalbuminemia. Immune dysregulation, including the presence of autoantibodies against nephrin and other podocyte components, contributes to podocyte injury and disease progression. MCD accounts for 70 – 90% of pediatric and 15% of adult idiopathic nephrotic syndrome patients. MCD is distinguished from other nephrotic diseases based on sudden onset of clinical features such as proteinuria (i.e., days/weeks vs. months) and distinct morphological features (e.g., podocyte effacement, normal glomerulus) based on kidney biopsy. Approximately two-thirds of adult patients with MCD and active nephrotic syndrome have anti-nephrin autoantibodies, while this figure rises to about 90% in children with idiopathic nephrotic syndrome.

FSGS and MCD Market Opportunity, Current Standard of Care, and Our Proposed Solution

There are approximately 44,000 diagnosed primary FSGS patients in the United States, of which approximately 7,000 may be identified as auto-immune assuming improved diagnostic methods. Primary FSGS patients are typically treated with background ACEi / ARBs, followed by sequencing steroids, calcineurin inhibitors (CNIs), immunosuppressive therapies (ISTs), and / or rituximab, with the aim to preserve kidney function and reduce risk to ESKD. Despite the current standard of care (which includes steroids, CNIs), there is persistent unmet need as up to 40% of patients reach ESKD and there are no FDA-approved disease-modifying drugs. Given the severity of clinical symptoms (e.g., ESKD risk), autoimmune FSGS patients would benefit from novel, efficacious therapies.

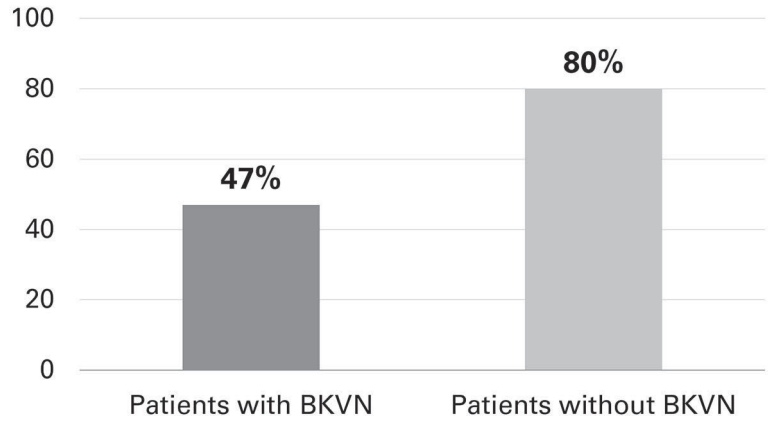
There are approximately 15,000 adult MCD patients and almost 10,000 pediatric MCD patients in the United States. Recently, anti-nephrin antibodies were identified in approximately 50% of pediatric MCD and adult MCD patients, indicating potential autoimmune involvement in disease pathology, which correlated to higher uACR and serum albumin levels. Patients are typically managed via steroids or other immunosuppressive therapies including cyclophosphamide, mycophenalate mofetil (MMF) and Levamisole. Additional treatments include diuretics for edema, ACE inhibitors or ARBs to reduce proteinuria, and dietary changes like a low-sodium diet. No FDA-approved therapies are currently available for MCD.

Given the autoimmune involvement in the disease pathology for at least some sub-populations of FSGS and MCD patients, potentially via B-cell mediated immune/inflammatory pathways, as demonstrated by response to rituximab in some patients, there is reason to believe that therapies that inhibit the proliferation and maturation of auto-reactive B-cells, such as atacicept, may be efficacious.

MAU868 in reactivated BK infection among kidney transplant recipients

We have exclusive worldwide rights, pursuant to the Novartis License, to MAU868, which is a potential treatment for reactivated BK infection in kidney transplant recipients. While up to 90% of healthy adults have been infected with BKV at some point in their lives, it remains latent in everyone except severely immunocompromised populations such as kidney transplant recipients. There are approximately 80,000 kidney transplants annually worldwide, with approximately 20,000 in the United States. Approximately 225,000 kidney allograft recipients are living in the United States. Waitlists to receive kidneys are long: approximately 3–5 years and 75,000 people long in the United States. Up to 12% of transplants per year are re-transplants, which further limits organ availability for new patients. BKV is a polyoma virus that is tropic to the kidney and bladder tissue and can reactivate with the immunosuppression required for kidney transplant. This reactivation can cause BKVN, a condition in which BK infection, typically first identified as BK viremia, triggers inflammation, which then progresses to renal fibrosis and tubular injury; as shown in Figure 13, BKVN is a leading cause of allograft loss, a devastating outcome for kidney transplant recipients.

Figure 13: Graft survival (%) in kidney transplant patients is worse with BKVN



Currently, there are no approved treatment options for BK viremia or BKVN. We shared full Cohort 1 and Cohort 2 results in 2022 from the Phase 2 trial conducted by Amplyx. Following feedback from the FDA on the Phase 2 clinical trial, we are evaluating strategies for continued development, including a potential next clinical trial. We believe that MAU868 has the potential to become standard of care for the treatment of BK viremia in order to prevent devastating consequences such as BKVN.

Pathophysiology of BKV in kidney transplant

BKV has a worldwide seroprevalence of up to 90%. Primary BK infection is typically acquired during childhood, after which the virus establishes lifelong infection in the kidney and bladder tissue. Most people do not experience any known adverse effects from either primary or persistent infection. Control of infection is dependent on CD4+ and CD8+ T cell immunity, which can be displaced by immunosuppressants. In the setting of kidney transplant and related immunosuppression, latent virus can be reactivated or new virus can be transmitted via the donor kidney. BKV reactivation is marked first by viruria—or detection of virus in the urine, and then viremia—detection of viral DNA in the blood, and most commonly occurs within the first year of transplant.

Viremia typically occurs in 15% of kidney transplant recipients, after which BKVN may occur. Approximately 3-4% of kidney transplant recipients develop BKVN.

BKVN disease burden and diagnosis

BKVN may lead to allograft injury and in some cases, allograft loss. 24–60% of all graft losses are due to BKV-associated disease. The average cost of a kidney transplant in the United States is over $440,000. Pre-transplant, recipients are typically on dialysis, for which the cost is approximately $90,000 per year; there is an approximate 450% increase in annual medical cost to treat transplant recipients who experience graft loss.

Most institutions monitor for BK in both the urine, through polymerase chain reaction (PCR) and urinalysis, and plasma, via PCR. It is common practice to screen kidney transplant recipients for BK viremia via PCR test monthly in the first six months post-transplant and then every three months until two years post-transplant, after which patients are typically screened annually. Also, at any sign of allograft dysfunction, physicians will test for BK viremia. Viral load levels >1000 copies/mL are considered positive for BK viremia, and levels >10,000 copies/mL are considered presumptive BKVN. Kidney allograft biopsy is considered the gold standard for diagnosing BKVN. Late diagnosis of BKV can lead to irreversible renal function decline and poor treatment outcomes.

Kidney transplant market opportunity

An estimated 80,000 kidney transplants are conducted globally each year, with approximately 20,000 in the United States, 20,000 in Europe, 1,500 in Japan, and 10,000 in China. Approximately 225,000 kidney allograft recipients are living in the United States. Waitlists to receive kidneys are long: 3–5 years and 75,000 people deep in the United States. Up to 12% of transplants per year are re-transplants, which further limits organ availability for new patients. Approximately 15% of kidney transplant recipients develop BK viremia. Patients can be risk stratified for BK viremia based on the degree of immunosuppression employed, which is related to the degree of human leukocyte antigen (HLA) match between the graft and recipient; the greater the mismatch, the more intense immunosuppression required, which increases the risk of BKV reactivation.

We estimate the market for a novel agent to treat reactivated BK infection in kidney transplant recipients to be a large commercial opportunity. We believe that MAU868 has the potential to become standard of care for the treatment of reactivated BK infection in order to prevent devastating consequences following kidney transplantation such as BKVN and graft loss.

Current standard of care for kidney transplant patients with BK viremia

Currently, there is no approved treatment specific to BKV. Upon detection of BK viremia, physicians' first line of defense is to reduce immunosuppression with the goal of restoring CD4+ and CD8+ T cell immunity without causing acute rejection. Initial modification will typically consist of lowering MMF by 50% followed by a reduction in tacrolimus by 50%. If no improvement is observed, use of MMF and tacrolimus will be stopped and dose of prednisone will be increased. Other agents such as intravenous immunoglobulin (IVIG), leflunomide, and cidofovir, are occasionally used—but all have limited data and both leflunomide and cidofovir have serious safety concerns. After development of BKVN, patients have limited options and may continue to receive antivirals or IVIG. Physicians are not satisfied with current treatment options for BKV and highlight that there is a significant unmet need for a viable therapy.

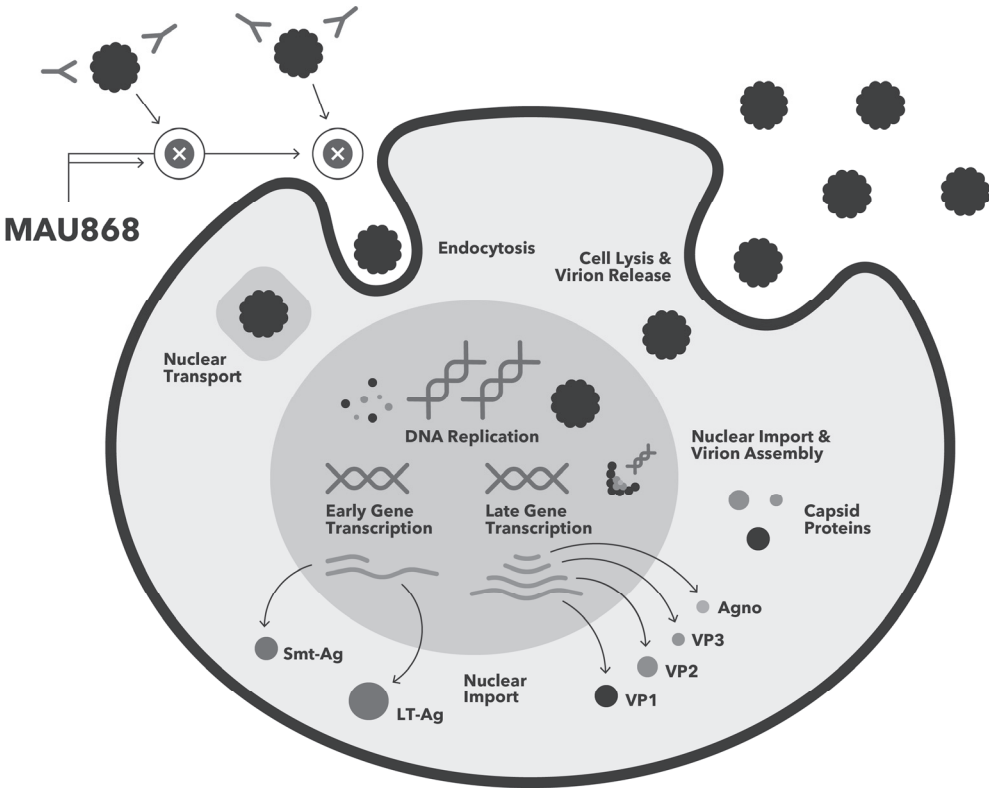
Emerging therapies in development

Despite the high level of unmet need in treating BK viremia and preventing devastating consequences, there is limited development in the space. Memo Therapeutics is also developing a BKV-neutralizing monoclonal antibody and is in Phase 2 clinical development.

Our solution: MAU868

MAU868 is a human monoclonal antibody (IgG1/l isotype subclass) directed against the major viral capsid protein of BKV, VP1, which is essential for binding to and infection of new cells, as shown in Figure 14. MAU868 neutralizes all four serotypes of BKV at sub-nanomolar concentrations and has a high barrier to resistance in vitro (resistant isolates of BKV were not selected in vitro at any of the concentrations of MAU868 investigated). MAU868 is being developed for the treatment of BKV disease in kidney transplant recipients (BKV nephropathy) and being considered for hematopoietic stem cell transplant (HSCT) recipients (BKV-associated hemorrhagic cystitis). MAU868 also has neutralizing activity in vitro against the closely related JC virus, the cause of progressive multifocal leukoencephalopathy.

Figure 14: MAU868 blocks BK virion binding



Clinical development of MAU868

Phase 1

A first-in-human, randomized, blinded, placebo-controlled, single ascending dose study to assess the safety, tolerability, and pharmacokinetics of MAU868 following IV or SC administration to healthy adult subjects was performed. Administration of up to 100 mg/kg MAU868 IV and 3 mg/kg MAU868 SC were well tolerated. No deaths or serious adverse events were reported, and there were no adverse events that led to the discontinuation of the drug or the study.

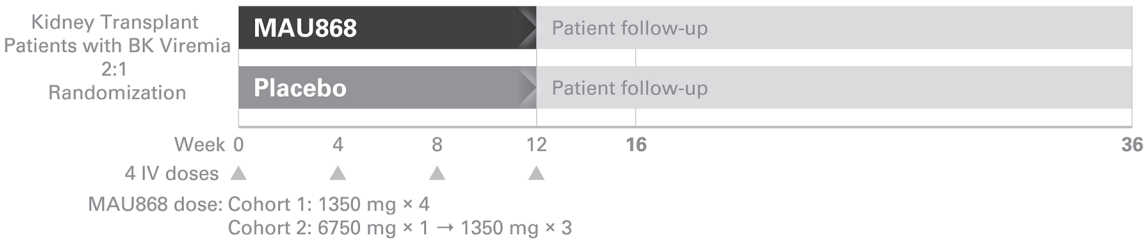
Phase 2

We completed a Phase 2 randomized, double-blind, placebo-controlled clinical trial designed to assess the safety, tolerability, and efficacy of MAU868 for the treatment of allograft-threatening BKV infection in kidney (or kidney-pancreas) transplant recipients in 2022. Two sequential cohorts enrolled a total of 28 participants with BK viremia. As shown in Figure 15, each cohort was designed to randomize approximately 12 participants (8 to MAU868 and 4 to placebo), for which Cohort 1 (1350 mg IV approximately every 28 days for a total of 4 doses) and Cohort 2 (6750 mg IV on Day 1, 1350 mg IV every 28 days for 3 additional doses) have completed dosing.

The primary objective of the clinical trial was to assess the safety and tolerability of MAU868, with secondary objectives to assess the impact of MAU868 on BKV related outcomes. MAU868 has been shown in an interim analysis of week 12 data from Cohorts 1 and 2 to be well-tolerated and showed a greater proportion of participants with decrease in BK plasma viral load versus placebo.

At the ASN 2022 conference, final results from the Phase 2 clinical trial of MAU868 versus placebo showed that MAU868 was well tolerated and demonstrated clinically meaningful reductions in BK antiviral activity through 36 weeks in kidney transplant patients with BK viremia.

Figure 15: MAU868 phase 2 clinical trial design



Future clinical trials

Following feedback from the FDA on the Phase 2 clinical trial, we are evaluating strategies for continued development, including a potential next clinical trial.

Exclusive license agreement with Ares Trading S.A.

On October 29, 2020, we entered into the Ares Agreement with Ares, an affiliate of Merck, pursuant to which Ares granted us an exclusive worldwide license to certain patents and related know-how to research, develop, manufacture, use and commercialize therapeutic products containing atacicept or any other compound that is covered by a claim of such licensed patents. Pursuant to the Ares Agreement, Ares also transferred inventory of licensed product to us for use in our clinical development of atacicept.

Per the Ares Agreement, we have obligations to use commercially reasonable efforts to develop at least one licensed product, to launch at least one licensed product in a major market country within a specified time frame after receiving marketing approval for such product and to maintain sufficient resources to manufacture and supply licensed products to meet the market demand in each country for which a licensed product has received marketing approval.

As consideration under the Ares Agreement, we paid Ares $25.0 million upon delivery and initiation of the transfer of specified information and supply of drug product and drug substance and $15.0 million upon achievement of the FDA's filing of the BLA for atacicept for IgAN which was paid in January 2026. We are required to pay Ares additional aggregate milestone payments, including $20.0 million upon regulatory approval for IgAN in the U.S., and other potential milestone payments of up to $141.5 million upon the achievement of regulatory filing and approval milestones for other geographic regions and indications, and aggregate milestone payments of up to $515.0 million upon the achievement of specified worldwide aggregate annual net sales milestones, beginning with $15.0 million if net sales reach $250.0 million and $50.0 million if net sales reach $500.0 million. Commencing on the first commercial sale of licensed products, we are obligated to pay tiered royalties of low double-digit to mid-teen percentages on annual net sales of the products covered by the license. Our obligation to pay royalties on a licensed product-by-licensed product and country-by-country basis will expire at the latest of (i) 15 years after the first commercial sale of such licensed product in such country; (ii) the expiration of the last valid claim of a licensed patent that covers such licensed product in, or its use, importation or manufacture with respect to, such country; and (iii) expiration of all applicable regulatory exclusivity periods in such country with respect to such licensed product. In the

event we sublicense our rights under the Ares Agreement, we are obligated to pay Ares a percentage ranging from the mid single-digit to the low double-digits of specified sublicensing income received.

The term of the Ares Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of our obligation to pay royalties to Ares with respect to such licensed product in such country. We have the right to terminate the Ares Agreement at will upon a specified notice period, provided that such termination is not within two years of the effective date of the Ares Agreement. Ares has the right to terminate the Ares Agreement in the event we challenge the validity of the licensed patents. Additionally, either party can terminate the Ares Agreement for the other party's uncured material breach or bankruptcy.

Asset purchase agreement with Amplyx and exclusive license with Novartis

On December 16, 2021, we entered into an asset purchase agreement (Amplyx Agreement) with Amplyx.

Pursuant to the terms of the Amplyx Agreement, we acquired all of Amplyx's right, title and interest in and to certain assets of Amplyx related to MAU868, a monoclonal antibody that was under development by Amplyx for the treatment of BKV infections (Purchased Assets). The Purchased Assets include an investigational new drug application filed with the U.S. Food and Drug Administration, patents, contracts, including the Novartis License, chemical and biological materials, and development and regulatory files, documentation, data, results and other electronic records related to MAU868. We also assumed certain liabilities of Amplyx arising out of the Purchased Assets. We and Amplyx have made customary representations and warranties and agreed to customary covenants in the Amplyx Agreement. Subject to certain limitations, each of we and Amplyx has also agreed to indemnify the other for breaches of representations and warranties and other specified matters.

As part of the consideration under the Amplyx Agreement, we are obligated to make certain milestone payments to Amplyx in an aggregate amount of up to $7.0 million based on certain regulatory milestones. Further, we are required to pay Amplyx low single digit percentage royalties based on net sales on a country-by-country and product-by-product basis.

MAU868 is subject to the Novartis License, which was assigned to us by Amplyx. Pursuant to the terms of the Novartis License, we obtained a worldwide, exclusive license from Novartis to develop, manufacture and commercialize MAU868, subject to certain retained rights for research and development by Novartis, provided that Novartis may not develop or sell products incorporating monoclonal antibody targeting BKV and treating BKV disease within a certain period. We will be solely responsible for all research, development, regulatory, manufacturing and commercialization activities of MAU868. Pursuant to the Novartis License, we are obligated to make certain milestone payments to Novartis in an aggregate amount of up to $62.0 million based on certain clinical development, regulatory and sales milestones. Further, we are required to pay Novartis mid- to high-single digit percentage royalties based on net sales on a country-by-country and product-by-product basis. Unless terminated earlier, the Novartis License will remain in effect with respect to each MAU868 product until the expiration of the royalty term for such product. We may terminate the Novartis License for convenience with 60 days' prior written notice. We or Novartis may terminate the Novartis License for the other party's uncured material breach. Novartis may terminate the Novartis License for our insolvency. Upon termination, any license granted by Novartis to us will terminate.

Exclusive License Agreement with Stanford

On January 13, 2025, we entered into an exclusive license agreement with Stanford to acquire global rights to VT-109, a novel, next-generation dual BAFF/APRIL inhibitor. This agreement enables us to develop and market VT-109 in return for an upfront license issue fee, annual license maintenance fees, development, regulatory, and commercial milestones, and earned royalties on net sales. In the event we sublicense our rights under the Stanford Agreement, we are obligated to pay Stanford a percentage of specified sublicensing income received.

Intellectual property

Our success depends in part upon our ability to protect our core technology and intellectual property. To protect our intellectual property rights, we rely on patents, trademarks, copyrights and trade secret laws, confidentiality procedures, and employee disclosure and invention assignment agreements. Our intellectual property is critical to our business and we strive to protect it through a variety of approaches, including by obtaining and maintaining patent protection in the United States and internationally for our product candidate, and other inventions that are important to our business. For our product candidates, we generally intend to pursue patent protection covering compositions of matter, including new formulations, methods of making and methods of use. As we continue the development of our product candidates, we intend to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through claims covering additional methods of use.

As of December 31, 2025, we have licensed, including pursuant to sublicenses, from Ares, an affiliate of Merck, a patent portfolio related to atacicept that contains four issued U.S. patents (8,513,393, 8,637,021, 8,852,591, and 8,956,611), as well as certain foreign counterparts of a subset of these patents in foreign countries, including Australia, Brazil, Canada, China, Hong Kong, Israel, India, Japan, Mexico, Singapore, South Korea, South Africa, and countries within the European Patent Convention and the Eurasian Patent Organization. The issued patents include claims covering methods of purifying atacicept, formulations and various methods of

treatment, and are expected to expire between 2027 and 2029, without considering any patent term extension. We have also licensed pending applications directed to treatment of IgAN with atacicept. These applications are pending in Australia, Brazil, Canada, China, the Eurasian Patent Organization, European Patent Office, Hong Kong, Indonesia, Israel, Japan, South Korea, Mexico, Malaysia, New Zealand, Philippines, Singapore, Thailand, Taiwan, the United States, and South Africa. Any issued patents would be expected to expire in 2041, without considering any patent term extension.

As of December 31, 2025, we have filed a patent cooperation treaty (PCT) application which gives us the opportunity to gain patent rights in multiple countries directed to treatment of autoimmune glomerulopathies other than IgAN with atacicept, including pMN, FSGS, and MCD. In addition, we have filed additional applications in Taiwan and Argentina directed to treatment of autoimmune glomerulopathies other than IgAN with atacicept, including pMN, FSGS, and MCD. Any issued patents would be expected to expire in 2045, without considering any patent term extension. We also own pending U.S. provisional applications directed to treating severe IgAN patient populations with atacicept, as well as treating IgAN with monthly dosing of atacicept. Any issued patents would be expected to expire in 2046, without considering any patent term extension.

Because atacicept is a biologic, marketing approval would also provide 12 years of market exclusivity from the approval date of a BLA in the United States. We are currently seeking orphan drug designation for atacicept in IgAN from the FDA, which, if secured, would provide seven and ten years, in the United States, respectively, of regulatory exclusivity protection from the approval date. We have received orphan drug designation for atacicept in the EU and Japan.

As of December 31, 2025, our patent portfolio licensed from Novartis and covering MAU868 includes three issued U.S. patents with claims covering the composition of matter of MAU868, and methods of neutralizing BKV or JC virus as well as methods of treating or reducing the likelihood of BKV or JC virus associated disorders. Corresponding foreign counterparts are granted in countries within the European Patent Convention, Australia, China, Japan, India, Israel, Mexico, Macau and Taiwan, and pending in Canada. Any issued patents in this family are expected to expire in 2036, without considering patent term extension. The 20-year expiration date for patents in this family is in 2036. In addition, we have applications co-owned with, and licensed from, Novartis directed to dosing regimens for MAU868, and includes applications pending in the U.S. as well as in Australia, Brazil, Canada, China, Eurasian Patent Organization, European Patent Office, Hong Kong, Indonesia, Israel, Japan, Korea, Mexico, Malaysia, New Zealand, Singapore, Thailand, Taiwan, and South Africa. Any issued patents would be expected to expire in 2041, without considering patent term extension.

As of December 31, 2025, we have licensed from Stanford a patent portfolio related to a soluble B-cell maturation antigen (sBCMA) variant FC-fusion proteins useful for treating diseases including IgAN, pending in the U.S., Australia, Canada, China, European Patent Convention, Hong Kong, India, Japan, South Korea, Singapore, Taiwan, and United Arab Emirates. Any issued patents in this patent portfolio would be expected to expire in 2041, without considering any patent term extension.

As of December 31, 2025, we own a pending United States provisional application directed to sBCMA variant FC-fusion proteins useful for treating diseases including IgAN. Any issued patents claiming priority to this provisional application would be expected to expire in 2046, without considering any patent term extension.

In addition to patents, we may rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors, and non-solicitation, confidentiality, and invention assignment agreements with our employees and consultants. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties, such agreements will not be breached, or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. For more information, see "Risk factors—Risks related to our intellectual property."

Furthermore, we seek trademark protection in the United States and internationally where available and when we deem appropriate.

Use of generative artificial intelligence in the workplace

In July 2025, we adopted a generative artificial intelligence (GenAI) policy to provide all employees and contractors with guidelines for the responsible use of GenAI tools and mitigate the risk of misuse, unethical outcomes, potential biases, inaccuracy, data leaks and information security breaches.

Under this policy, GenAI tools may only be used on pre-authorized equipment, and requests for the use of new GenAI tools will be evaluated on a case-by-case basis considering factors such as confidentiality, data sensitivity, ethical and legal implications, and potential business impact. We will review and update this policy periodically to respond to any changes in applicable laws, emerging risks, and strategic business requirements.

Manufacturing and supply

We manage a number of external contract manufacturing organizations (CMOs) to develop and manufacture our product candidates.

Atacicept is a native human TACI-Fc fusion protein that impacts the B cell pathway, which has well characterized implications in immunologic diseases. The human IgG1-Fc was modified to reduce the Fc binding to the C1q component of complement and the interaction with Fc receptors.

Atacicept is designed to be manufactured in accordance with current Good Manufacturing Practices (cGMPs) using a process similar to that used routinely for production of monoclonal antibodies.

The atacicept drug product is available as a ready-to-use injection solution in a pre-filled syringe (PFS) at strengths of 25 mg/mL, 75 mg/mL, or 150 mg/mL of trial drug. Each atacicept PFS is designed to deliver a 1 mL solution of drug product. All formulation components are pharmacopeia grade.

The Ares Agreement includes the transfer of all existing inventory of atacicept drug substance and drug product, for our use in planned and future clinical trials.

We acquired approximately 35,000 PFS of atacicept and approximately 25,000 PFS of placebo, as part of the Ares Agreement. This drug product will be utilized for our ongoing clinical trials, as needed.

The atacicept manufacturing supply chain is fully established using CMOs and is operational to supply products for clinical and, if approved, commercial use. An atacicept PFS/autoinjector combination product is in development for clinical use and commercial use, if approved.

Raw materials and supplies required to produce our products candidates are available in some instances from one supplier and in other instances from multiple suppliers. In those cases where raw materials are only available through one supplier, such supplier may be either a sole source (the only recognized supply source available to us) or a single source (the only approved supply source for us among other sources). Although to date we have not experienced any significant delays in obtaining any raw materials from our suppliers, we cannot provide assurance that we will not face shortages from one or more of them in the future. Please see the risk factor, "We contract with third parties for the manufacture of our product candidates for our ongoing clinical trials, and expect to continue to do so for additional clinical trials of our product candidates and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates necessary for their development or commercialization, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts." described in "Risk Factors" in Part I, Item 1A of this Annual Report.

MAU868 is an IgG1 monoclonal antibody that binds to BKV protein VP1. It is designed to be manufactured according to cGMP using a high expression Chinese hamster ovary (CHO) cell and a standard antibody manufacturing process that is completely free from animal or human derived raw materials. The MAU868 manufacturing supply chain is fully established using contract manufacturing organizations with contracts that are assignable to Vera Therapeutics.

The fully formulated MAU868 drug product is provided as a 3 mL fill in a 6 mL vial which can be combined with multiple vials to prepare infusions at different dosage strengths for use in clinical trials. The drug product formulation is composed of MAU868 as the active substance, a buffering agent, and both a sugar and a surfactant as stabilizing agents.

VT-109 is an engineered Fc-fusion protein containing BCMA variant. This molecule is in early-stage process development.

Commercialization plans

Our commercialization planning efforts are currently focused primarily on launch readiness for atacicept.

We estimate the market opportunity for novel therapeutics in IgAN to be approximately 160,000 patients in the United States, 136,000 patients in Europe and 130,000 in Japan, at estimated peak year of sales, based on our assumptions, secondary research, and primary market research with physicians and payors. In order to capitalize on this opportunity, we are developing a specialty commercial infrastructure focused on IgAN, engaging treating physicians, including nephrologists, educating and engaging patients, and ensuring market access for patients.

Through the Ares Agreement, we were granted worldwide rights to the development and commercialization of atacicept in all indications. We intend to commercialize atacicept ourselves in the United States and other key markets, if approved. Within certain ex-U.S. markets, we may consider strategic collaborations to facilitate commercialization.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. This is also true for the development and commercialization of treatments for immunologic diseases. Though we believe that our focus, experienced team, scientific knowledge, and intellectual property provide us with

competitive advantages, we face competition from a number of sources, including large and small biopharmaceutical companies, universities, and other research institutions.

Many of our competitors have significantly greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA approval for superior products. Many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or any future product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidates or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Atacicept in IgAN

Despite the high morbidity associated with IgAN, current standard-of-care treatment relies largely on supportive care therapies, including renin-angiotensin system inhibitors (RASi) and SGLT2i, as well as immunosuppressive treatments such as corticosteroids. Supportive treatments fail to target the origin of pathophysiology in IgAN, putting patients at risk of progressive kidney damage and leading to high rates of kidney failure that result in dialysis or transplant and increased risk of early death.

Growing evidence suggests stringent treatment goals for IgAN including the fundamental treatment goal of minimizing eGFR loss to <1 mL/min/year, and highlights prevention or reduction of IgA immune complex formation via reduction in Gd-IgA1 as a first-line treatment goal. Most patients are not achieving recommended proteinuria and eGFR goals, leaving them at a substantial lifetime risk of ESKD.

As treatment guidelines have evolved, there is increasing emphasis on the use of disease-modifying therapies that address the immunologic drivers of disease simultaneously with supportive care.

Atacicept is expected to be indicated to reduce proteinuria in patients living with IgAN who are at risk of disease progression. In ORIGIN 3, all patients were previously treated with a RAAS inhibitor and 56% of patients were also treated with SGLT2i. At approval, atacicept will compete with corticosteroids, targeted budesonide, complement inhibitors in addition to other b-cell modulators like sibeprenlimab.

Among emerging therapies, we consider our most direct competitors with respect to atacicept in IgAN to be approved products: the reformulated steroid from Asahi Kasei Corp., the anti-APRIL monoclonal antibody from Otsuka Pharmaceuticals, both the complement inhibitor and selective ETA receptor antagonist from Novartis, and the endothelin and angiotensin II receptor antagonist from Travere Therapeutics, Inc.; programs in Phase 3 clinical development: Roche/Ionis, Vertex, AstraZeneca, Biogen, Takeda, and Novartis; and the following companies with programs in Phase 2 of clinical development: Arrowhead Pharmaceuticals, NovelMed, and Eladon Pharmaceuticals.

Atacicept in pMN, FSGS, and MCD

There are no FDA-approved therapies for pMN. Companies with pMN trials in Phases 2 or 3 include Vertex, Roche, BeOne Medicines, Biogen, Climb Bio, and Walden Biosciences. There are currently no FDA-approved therapies for FSGS. Travere's FILSPARI received an extended FDA review of the sNDA in FSGS, with a PDUFA target action date of April 13, 2026. Companies with FSGS trials in Phases 2 or 3 include the following: Sanofi, Eli Lilly, Astellas, Walden Biosciences, Boehringer Ingelheim, Novartis, and Vertex. There are no FDA-approved therapies for MCD. Companies with MCD trials in Ph2/Ph3 include Sanofi, Travere Therapeutics, and Walden Biosciences.

MAU868

There are currently no anti-BKV therapies approved, either in the kidney transplant or HSCT setting. The standard of care in both settings is to reduce immunosuppression as a first line, and potentially to offer IVIG in kidney transplant recipients or antivirals with limited clinical evidence, including leflunomide and cidofovir, in either setting. There are few industry-sponsored programs in

development for these indications; we consider our most direct competitor to be Memo Therapeutics AG's AntiBKV, a neutralizing monoclonal antibody in a Phase 2/3 clinical trial.

VT-109

The current landscape of B cell modulators primarily includes monoclonal antibodies, or Fc-fusion proteins containing TACI or TACI variants, including atacicept. VT-109 is a novel BAFF/APRIL dual-inhibitor B cell maturation antigen (BCMA) molecule which, if successfully developed, approved, and commercialized, may compete with the existing approaches to treat B cell mediated autoimmune diseases, many of which are described in the preceding paragraphs on IgAN. We consider the most advanced direct competitor to VT-109 to be the BCMA Fc-fusion protein from Aurinia Pharmaceuticals Inc., which is currently in Phase 1 clinical development.

Government regulation

Government authorities in the United States at the federal, state and local level and in other countries and jurisdictions, including the EU, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, such as our investigational medicines and any future investigational medicines. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

Regulatory approval in the United States

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug and Cosmetic Act (FDCA), and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post- approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Biological products used for the prevention, treatment or cure of a disease or condition of a human being are subject to regulation under the FDCA, except the section of the FDCA that governs the approval of a New Drug Application (NDA). Biological products are approved, or licensed, for marketing under provisions of the Public Health Service Act (PHSA) via a BLA. The application process and requirements for approval of BLAs for originator biological products are similar to those for NDAs for new chemical entities, and biologics are associated with similar approval risks and costs as drugs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending NDAs or BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Biological products must be approved by the FDA pursuant to a BLA before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical laboratory and animal studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice (GLP) requirements;
- submission to the FDA of an Investigational New Drug Application (IND), which must become effective before human clinical trials may begin;
- approval of the protocol and related documents by an institutional review board (IRB) or independent ethics committee representing each clinical trial site before each clinical trial may be commenced;
- performance of adequate and well controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practices (GCP) requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- preparation of and submission to the FDA of a BLA for marketing approval that includes sufficient evidence of establishing the safety, purity, and potency of the proposed biological product for its intended indication, including from results of nonclinical testing and clinical trials;
- payment of any user fees for FDA review of the BLA;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the biologic, or components thereof, will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- satisfactory completion of any potential FDA audits of the clinical trial sites that generated the data in support of the BLA to assure compliance with GCPs and integrity of the clinical data;

- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA;
- satisfactory completion of an FDA advisory committee review, if applicable; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications of use in the United States.

Preclinical studies

Before testing any biological product candidates in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies.

Prior to beginning the first clinical trial with a product candidate in the United States, an IND must be submitted to the FDA and the FDA must allow the IND to proceed. An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA allowance that such investigational product may be administered to humans in connection with such trial. Such authorization must be secured prior to interstate shipment and administration. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND sponsor must also submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, to the FDA as part of an IND. Some long-term preclinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCPs, an international standard, codified in FDA regulations, meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated in the trial. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

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 (DSMB). This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study.

There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website. Information related to the product, patient population, phase of investigation, clinical trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Disclosure of the results of these clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. 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. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the clinical trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3:

- Phase 1 clinical trials generally involve a small number of healthy volunteers, or in some cases, patients with a specified disease or condition. The primary purpose of these clinical trials is to assess the metabolism, pharmacokinetics, pharmacologic action, side effect tolerability, safety of the product candidate, and, if possible, obtain early evidence of effectiveness.
- Phase 2 clinical trials generally involve administration of a product candidate to a limited patient population with a specified disease or condition to identify possible short-term side effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for the targeted disease or condition and to determine dosage tolerance and appropriate dosage.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to provide substantial evidence of efficacy for the product in its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

These Phases may overlap or be combined. In some cases, FDA may require, or firms may voluntarily pursue, post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including non-compliance with regulatory requirements or a finding that the 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 drug or biologic has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the investigational medicines do not undergo unacceptable deterioration over their shelf life.

FDA review processes

Following completion of the clinical trials, the results of preclinical studies and clinical trials are submitted to the FDA as part of a BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity and potency of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic or drug may be marketed in the United States.

The cost of preparing and submitting a BLA is substantial. Under the PDUFA, each BLA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. 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. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved BLA is also subject to an annual program fee.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review to determine if it is substantially complete before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, for its intended use, and whether the product is being manufactured in accordance with cGMP to ensure its continued safety, purity and potency.

Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the

submission. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process can be extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether such facilities comply with cGMP requirements and to ensure readiness for commercial manufacturing . The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

The FDA also may audit data from clinical trials to ensure compliance with GCP requirements and the integrity of the data supporting safety and efficacy. Additionally, the FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it generally follows such recommendations when making decisions on approval.

After the FDA evaluates a BLA, it will issue either an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter generally outlines the deficiencies in the BLA and may require additional clinical data, additional pivotal clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing in order for FDA to reconsider the application. 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 or request an opportunity for a hearing. The FDA has committed to reviewing such resubmissions in two or six months, depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the resubmitted BLA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, including to subpopulations of patients, which could restrict the commercial value of the product. Furthermore, as a condition of BLA approval, the FDA may require a REMS to help ensure that the benefits of the biologic outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals and elements to assure a product's safe use (ETASU). An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation on its own does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Orphan drug exclusivity may be lost if the FDA later determines that the request for designation was materially defective. Further, competitors may receive approval of either a different product for the same indication or the same product for a different indication. In the latter case, because healthcare professionals are free to prescribe products for off-label uses, the competitor's product could be used for the orphan indication despite another product's orphan exclusivity.

Expedited development and review programs

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational biologic. For example, fast track designation may be granted for product candidates that are intended to treat a serious or life-threatening disease or condition, where preclinical or clinical data demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to both the product candidate and the specific indication for which it is being studied. The sponsor of a new biologic candidate can request the FDA to designate the candidate for a specific indication for fast track status

concurrent with, or after, the submission of the IND for the candidate. The FDA must determine if the biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's BLA before the application is complete. This "rolling review" is available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval.

Breakthrough therapy designation may be granted for product candidates that are intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition if preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new biologic candidate may request that the FDA designate the candidate for a specific indication as a breakthrough therapy concurrent with, or after, the submission of the IND for the biologic candidate. The FDA must determine if the biological product qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to product candidates designated as breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team and taking other steps to design the clinical trials in an efficient manner. The designation also includes all of the fast track program features, including the potential for rolling review of an application, if the relevant criteria are met.

Priority review may be granted to applications for products candidates that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review. Under priority review, the FDA's goal is to review an application for an original biologic within six months after the filing date, compared to ten months for a standard review. Priority review designation does not change the standard for approval or the quality of evidence necessary to support approval.

In addition, depending on the design of the applicable clinical trials, a product candidate may be eligible for accelerated approval. Specifically, product candidates that are intended to treat a serious or life-threatening condition and that generally provide a meaningful therapeutic advantage to patients over existing treatments may be approved on the basis of either 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. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Use of the accelerated approval pathway entails submission of a BLA with the surrogate or intermediate clinical endpoint data while continuing to conduct the trial(s) to completion and is usually contingent on a sponsor's agreement to complete and/or conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

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 the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval, but may expedite the development or approval process.

Additional controls for biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. 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 may also 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 conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Combination products

A combination product is a product comprised of two or more regulated components, e.g., drug and medical device, that are physically combined and produced as a single entity, packaged together in a single package, or packaged separately but intended to be labeled for use together. Atacicept in a prefilled autoinjector would be such a combination of therapeutic and delivery device.

FDA is divided into various branches, or Centers, by product type. Different Centers typically review drug, biologic, or device applications. In order to review an application for a combination product, FDA must decide which Center should be responsible for the review. FDA regulations require that FDA determine the combination product's primary mode of action (PMOA), which is the single mode of a combination product that provides the most important therapeutic action of the combination product. The Center that regulates that portion of the product that generates the PMOA becomes the lead evaluator. If there are two independent modes of action, neither of which is subordinate to the other, FDA makes a determination as to which Center to assign the product based on consistency with other combination products raising similar types of safety and effectiveness questions or to the Center with the most expertise in evaluating the most significant safety and effectiveness questions raised by the combination product. When evaluating an application, a lead Center may consult other Centers but still retain complete reviewing authority, or it may collaborate with another Center, by which the Center assigns review of a specific section of the application to another Center, delegating its review authority for that section. Typically, FDA requires a single marketing application submitted to the Center selected to be the lead evaluator, although the agency has the discretion to require separate applications to more than one Center. We believe that our prefilled autoinjector would have a biologic PMOA.

Pediatric information

Under the Pediatric Research Equity Act (PREA), BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA generally does not apply to any biological product for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act (BPCA) provides a six-month extension of any exclusivity—patent or non-patent—for a biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of the biologic in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Post-approval requirements

Once a BLA is approved, a product may be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Biologics may be marketed only for the approved indications and in a manner consistent with the provisions of the approved labeling. Although physicians may prescribe products for off-label uses as the FDA and other regulatory authorities do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Companies may only share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling.

Adverse event reporting and submission of periodic safety summary reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing and surveillance to monitor the effects of an approved product, including requirements for REMS, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects a biologic product's manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with required regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning or other enforcement-related letters or holds on ongoing or planned clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product approvals or licenses;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

U.S. marketing exclusivity

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency.

Regulatory approval in the European Union

To market any product in the EU, we would need to comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products.

The process regarding approval of medicinal products in the EU follows roughly the same lines as in the United States and likewise generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU GLP requirements;
- submission of a single clinical trial application (CTA) through the Clinical Trials Information System (CTIS) to the relevant national authorities of the member states of the EU (EU Member States) in which a clinical trial is planned to be conducted, which must be approved by such national authorities and the subject of a positive opinion from at least one independent ethics committee before the trial may begin in each country where the clinical trial is planned;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;

- submission to the relevant competent authorities of a marketing authorization application which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- satisfactory completion of an inspection by the relevant competent national authorities of EU Member States of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced EU Good Manufacturing Practice (GMP);
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the marketing authorization application; and
- review and approval by the relevant competent authority of the marketing authorization application before any commercial marketing, sale or shipment of the product.

Whether or not we obtain FDA approval for a product, we must obtain approval of the product by the EU regulatory authorities before we can commence clinical trials or marketing of the product in the EU. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The approval process varies from country to country, can involve additional testing beyond that required by FDA, and may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, promotion, and reimbursement vary greatly from country to country.

Non-clinical studies

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls. Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements. The results of the non-clinical studies, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

Clinical trials

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, guidelines on GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU Member States, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation No. 536/2014 (CTR), which was adopted in April 2014, entered into application on January 31, 2022, repealing and replacing the former Clinical Trials Directive 2001/20 (CTD).

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the CTR, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the “EU portal,” the CTIS; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference EU Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned EU Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and ethics committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory. Once the CTA is approved, clinical study development may proceed.

The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with GMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In the EU, medicinal products can only be commercialized after a related marketing authorization has been granted. To obtain a marketing authorization for a product in the EU, an applicant must submit a marketing authorization application, either under a centralized procedure administered by the EMA, or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid throughout the European Economic Area, which is comprised of the 27 EU Member States plus Iceland, Liechtenstein and Norway. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products), and (iv) products with a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized authorization procedure, the EMA's Committee for Medicinal Products for Human Use (CHMP) conducts the initial assessment of a product. The CHMP is composed of experts nominated by each EU Member State, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the CHMP acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP is required to issue an opinion within 210 days of receipt of a valid application, excluding clock stops. The CHMP's opinion is sent to the European Commission, which uses the opinion as the basis for its decision whether or not to grant a marketing authorization within 67 days of receipt.

In order to grant the marketing authorization, the EMA or the competent authorities of the EU Member States make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. After a medicine has been authorized and launched, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review.

Alternative authorization pathways, accelerated assessment and PRIME

In the EU, in accordance with Article 14(7) of Regulation (EC) 726/2004, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional marketing authorization for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional marketing authorization is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional marketing authorization can be converted into a traditional marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the marketing authorization will cease to be renewed.

A marketing authorization may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional marketing authorization, a marketing authorization granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard marketing authorization. However, unlike the conditional marketing authorization, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the marketing authorization "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the marketing authorization will be withdrawn if the risk-benefit ratio is no longer favorable.

Accelerated assessment may be granted by the CHMP in exceptional cases, when a marketing authorization application is submitted in respect of a medicinal product for human use targeting an unmet medical need which is expected to be of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In these circumstances, the applicant may request an accelerated assessment procedure pursuant to Article 14(9) of Regulation (EC) 726/2004, which must be substantiated. If the CHMP accepts the request for accelerated assessment, the time limit of 210 days for the CHMP's opinion is reduced to 150 days excluding clock stops. The CHMP may, however, revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIority MEdicines scheme (PRIME), which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Validity of marketing authorizations

A marketing authorization has, in principle, an initial validity of five years. The market authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original market authorization was granted. To support the application, the market authorization holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period for the marketing authorization. Once subsequently definitively renewed, the market authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized procedure marketing authorization) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Pediatric development

In the EU, Regulation (EC) No 1901/2006 provides that all marketing authorization applications for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan (PIP), agreed with the EMA's Pediatric Committee (PDCO). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which market authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate (SPC), if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Manufacturing regulation in the EU

In addition to a marketing authorization, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including GMP standards. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU Member States. Marketing authorization holders and/or manufacturing and import authorization, or marketing authorization holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

Data and market exclusivity

The EU provides opportunities for data and market exclusivity related to marketing authorizations. Upon receiving amarketing authorization, innovative medicinal products are generally entitled to receive eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic or biosimilar application for eight years from the date of authorization of the innovative product. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed

from the initial marketing authorization of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of eleven 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 EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Orphan medicinal products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. In the EU, Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that (i) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects not more than five in 10,000 persons in the EU when the application is made, or, (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in its development; and (iii) there exists no satisfactory authorized method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or even, if such method exists, the product will be of significant benefit to those affected by that condition.

Regulation (EC) No. 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for designation as an orphan product can be made any time prior to the submission of an marketing authorization application. A marketing authorization for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought.

Orphan medicinal product designation entitles an applicant to incentives such as fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon a grant of marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10-year period if (i) the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-authorization requirements

Similar to the United States, both market authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of a market authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for the establishment and maintenance of that system, and oversees the safety profiles or medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (PSURs).

All new marketing authorization applications must include a risk management plan (RMP) describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk- minimization measures or post-

authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics (SmPC), which may require approval by the competent national authorities in connection with a marketing authorization. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Combination products

The EU regulates medical devices and medicinal products separately, and through different legislative instruments. Products that are a combination of a medicinal product and a medical device may be regulated as either a medicinal product, a medical device or, subject to certain requirements, on the basis of both sets of rules. The applicable requirements governing placing a drug-device combination on the EU market will vary depending on the type of drug-device combination product and on which of the components of the combination has the primary mode of action.

Drug-device combination products intended to administer a medicinal product where the medicinal product and the device form a single integral product that is not reusable and for which the action of the medicinal product is principal to that of the medical device are regulated as medicinal products. The EMA or the EU Member State national competent authority will assess the product in accordance with the rules for medicinal products described above but the device part must comply with the EU Medical Devices Regulation (MDR) (including the general safety and performance requirements (GSPR) provided in Annex I). As part of the marketing authorization application, the applicant must also submit, where available, the results of the assessment of the conformity of the medical device part of the product with the MDR contained in the manufacturer's EU Declaration of Conformity of the device or the relevant Certificate of Conformity issued by a notified body. If the marketing authorization application does not include the results of the conformity assessment, and where the conformity assessment of the device, if used separately, requires the involvement of a notified body, the competent authorities must require the applicant to provide a notified body opinion on the conformity of the device with the relevant GSPRs

Drug-device combination products that form a single integral product that is not reusable and for which the action of the medicinal products is ancillary to that of the medical device are governed by the regulatory framework applicable to medical devices in accordance with the MDR. However, the quality and safety of the medicinal product , including the benefit or risk of its incorporation must be provided from one of the national competent authorities or from the EMA before a notified body can issue a EU certificate..

By contrast, drug-device combination products which do not form a single integral product will be regulated separately. This may include, for example a drug-device combination product where a medical device and a medicinal product are co-packaged and the medical device is intended solely to be used for the administration of the co-packaged medicinal product. In these circumstances, the medicinal product will be governed by the regulatory framework applicable to medicinal products and the medical device will be governed by the MDR. However, the characteristics of a medical device used for the administration of a medicinal product may impact the quality, safety and efficacy profile of the medicinal product. As a result, as part of the marketing authorization application submitted to the competent authorities for the medicinal product, the applicant may need to provide additional information regarding the characteristics of the co-packaged medical device that may impact on the quality, safety and/or efficacy of the medicinal product. Similar requirements may apply where the products are not co-packaged but the medicinal product information makes an explicit reference to a specific medical device.

The requirements regarding quality documentation for medicinal products when used with a medical device, including single integral products, co-packaged and referenced products, are outlined in the EMA guideline of July 22, 2021, which became applicable as of January 1, 2022.

Regulatory Framework in the United Kingdom

The United Kingdom's (UK) withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency (MHRA) is now the UK's standalone regulator for medicinal products and medical devices. The UK is now a third country to the EU.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. On April 28, 2025, the UK adopted an amendment to the UK clinical trials regulations intended to support a more streamlined and flexible regulation of clinical trials, removing unnecessary administrative burdens on trial sponsors, while protecting the interests of trial participants. It also intends to bring the UK regulatory framework for clinical trials, which is still based on the CTD, into closer

alignment with the CTR. The amendment will become applicable on April 28, 2026, following a one-year transition period. In addition, in October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure. In order to obtain a UK market authorization to commercialize products in the UK, an applicant must be established in the United Kingdom and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK. Applications are governed by the Human Medicines Regulations (SI 2012/1916) and are made electronically through the MHRA Submissions Portal. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, a 150-day assessment (subject to clock-stops) and a rolling review procedure. The rolling-review procedure permits the separate or joint submission of quality, non-clinical, and clinical data to the MHRA which can be reviewed on a rolling basis. After an application under the rolling-review procedure has been validated, the decision should be received within 100 days (subject to clock-stops).

In addition, since January 1, 2024, the MHRA may rely on the International Recognition Procedure (IRP) when reviewing certain types of marketing authorization applications. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g., the regulators in Australia, Canada, Switzerland, Singapore, Japan, the U.S. and the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a market authorization in the United Kingdom. Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60 day period and the approval from the trusted regulatory partner selected has been granted within the previous 2 years or if there are such major objections identified or such approval hasn't been granted within the previous 2 years within 110 days. Applicants can submit initial marketing authorization applications to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland remained within the scope of EU authorizations in relation to centrally authorized medicinal products untilJanuary 1, 2025. However, on January 1, 2025, an arrangement as part of the so-called "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes and EU labeling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in the UK, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in the UK.

European and United Kingdom data collection and processing

The collection, receipt, storage, generation, transfer, access, protection, securing, disposal, transmittal, sharing, use, disclosure and other processing (commonly referred to as processing) of health-related and other personal data about clinical trials participants and other individuals in Europe is governed by the European Union's General Data Protection Regulation (EU GDPR), and in the UK is governed by the European Union (Withdrawal) Act 2018 and the UK Data Protection Act 2018 (UK GDPR). The EU GDPR and UK GDPR require companies to, among other things, give detailed disclosures about how they are processing personal data; ensure any consents relied on to process personal data (including special categories of personal data, such as health information) meet the strict EU GDPR requirements; contractually impose data protection measures on vendors entrusted with personal data; maintain adequate data security measures; notify regulators and affected individuals of certain data breaches; meet extensive privacy governance and documentation requirements; honor individuals' data protection rights, including their rights to access, correct and delete their personal data; and refrain from transferring personal data from Europe or the UK to most other countries unless specific safeguards can be implemented. Companies that violate the EU GDPR or UK GDPR can face private litigation, prohibitions on data processing and heavy fines. Complying with the EU GDPR and UK GDPR may be costly and require us to limit our activities in Europe. If our efforts to comply are not successful, we may face litigation, reputational harm, significant penalties and other liabilities.

Marketing

Much like the Anti-Kickback Statute prohibition in the United States, as described below, the provision of benefits or advantages to physicians and other health care professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in many EU Member States which have adopted specific anti-gift statutes that further limit commercial practices for medicinal products, in particular vis-à-vis healthcare professionals and organizations. Payments made to physicians and other health care professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with health care professionals may require prior notification or approval by the health care professional's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the EU Member States.

Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU Member States have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on pharmaceutical companies. Certain countries also mandate implementation of commercial compliance programs or require disclosure of marketing expenditures and pricing information.

Violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, disgorgement, additional reporting obligations and oversight if a manufacturer becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and imprisonment.

International regulation

In addition to regulations in the United States and Europe, a variety of foreign regulations govern clinical trials, commercial sales and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA or European Commission approval.

Other healthcare laws and regulations and legislative reform

Healthcare laws and regulations

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our operations, including any arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws that may affect the business or financial arrangements and relationships through which we conduct research and would market, sell and distribute our products. The healthcare laws that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, 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. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, Affordable Care Act), to a stricter standard such that 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. Further, the Affordable Care Act codified case law 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 civil False Claims Act.
- Federal civil and criminal false claims laws, such as the False Claims Act, which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, 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 False Claims Act. As a result of a

modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims.

- The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their implementing regulations, which impose privacy, security and data breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates and subcontractors that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.
- Federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- The federal transparency requirements under the Physician Payments Sunshine Act, created under the Affordable Care Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members.
- State and foreign laws that are analogous to each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers.
- State and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare professionals; state and foreign laws that require the reporting of marketing expenditures or drug pricing, including information pertaining to and justifying price increases; state and local laws that require the registration of pharmaceutical sales representatives; state and foreign laws that prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals; state and foreign laws that require the posting of information relating to clinical trials and their outcomes; and other federal, state and foreign laws that govern the privacy and security of health information or personal data in certain circumstances, including state health information privacy and data breach notification laws which govern the processing of health-related and other personal data, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

If our operations are found to be in violation of any of these laws or any other current or future healthcare laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, if any of the physicians or other healthcare professionals or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Legislative reform

We operate in a highly regulated industry, and new laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, related to healthcare availability, the method of delivery and payment for healthcare products and services could negatively affect our business, financial condition and prospects. There is significant interest in promoting healthcare reforms, and it is likely that federal and state legislatures within the United States and the governments of other countries will continue to consider changes to existing healthcare legislation.

For example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. The Affordable Care Act, among other things, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry.

There have been executive, judicial and congressional challenges and amendments to certain aspects of the Affordable Care Act. For example, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law, which among other things, extended enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminated the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how other healthcare reform measures of the current administration will impact our business.

In addition, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. In 2011, the U.S. Congress enacted the Budget Control Act, which included provisions intended to reduce the federal deficit. The Budget Control Act, among other things, resulted in reductions in Medicare payments to providers beginning in 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect through 2032, absent additional congressional action. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. If government spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA, to continue to function at current levels, which may impact the ability of relevant agencies to timely review and approve research and development, manufacturing and marketing activities, which may delay our ability to develop, market and sell any product candidates we may develop. In addition, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our anticipated product revenues.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for drug products. For example, the IRA, among other things, (i) directs the U.S. Department of Health and Human Services (HHS) to negotiate the price of certain high-expenditure, single-source biologics covered under Medicare that have been on the market for at least 11 years, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law (Medicare Drug Price Negotiation Program), and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions began to take effect progressively in fiscal year 2023. CMS published the agreed-upon price for the initial ten drugs, which will first be effective in 2026, and the subsequent 15 drugs, which will first be effective in 2027. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program, although it is currently subject to legal challenges.

The One Big Beautiful Bill Act, enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how these proposals will be implemented, the policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our product candidates, if approved. On the one hand, significant tariffs have been threatened to be imposed on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, although proposed regulations have not yet been published. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a

product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug pricing reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

It is difficult to predict the future legislative landscape in healthcare and the effect on our business, results of operations, financial condition and prospects. However, we expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration.

Environmental, health and safety laws and regulations

We and our third-party contractors are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In particular, our product candidates use PBDs, which are highly potent cytotoxins that require special handling by our and our contractors' staff. In the event of contamination or injury, or failure to comply with environmental, health and safety laws and regulations, we could be held liable for any resulting damages, fines and penalties associated with such liability could exceed our assets and resources. Environmental, health and safety laws and regulations are becoming increasingly more stringent. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations.

Pharmaceutical coverage, pricing and reimbursement

The availability and extent of coverage and adequate reimbursement by governmental and private third-party payors are essential for most patients to be able to afford expensive medical treatments. In both domestic and foreign markets, sales of our product candidates will depend substantially on the extent to which the costs of our product candidates will be covered by third- party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors decide which products will be covered and establish reimbursement levels for those products.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage approval and reimbursement for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement at a satisfactory level. If coverage and adequate reimbursement of our future products, if any, are unavailable or limited in scope or amount, such as may result where alternative or generic treatments are available, we may be unable to achieve or sustain profitability. Adverse coverage and reimbursement limitations may hinder our ability to recoup our investment in our product candidates, even if such product candidates obtain regulatory approval.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. There is no uniform policy for coverage and reimbursement in the United States and, as a result, coverage and reimbursement can differ significantly from payor to payor. In the United States, CMS determines whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often, but not always, follow the CMS's decisions regarding coverage and reimbursement. It is difficult to predict what third-party payors will decide with respect to coverage and reimbursement for fundamentally novel products

such as ours, as there is no body of established practices and precedents for these new products. Further, one payor's determination to provide coverage and adequate reimbursement for a product does not assure that other payors will also provide coverage and adequate reimbursement for that product. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates. There can be no assurance that our product candidates will be considered medically necessary or cost-effective. Therefore, it is possible that any of our product candidates, even if approved, may not be covered by third-party payors or the reimbursement limit may be so restrictive that we cannot commercialize the product candidates profitably.

Reimbursement authorities in Europe may be more restrictive than payors in the United States. In the EU, pricing and reimbursement schemes vary widely from country to country. In the EU, governments influence the price of 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. For example, some countries provide that products may be marketed only after an agreement on reimbursement price has been reached. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. In addition, the EU provides options for the EU Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product, may adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for product but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions.

In addition, some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment (HTA) process is conducted to assess 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 individual countries. 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 EU Member States.

In 2011, Directive 2011/24/EU was adopted at the EU level. This directive establishes a voluntary network of national authorities or bodies responsible for HTA in the individual EU Member States. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, in December 2021, Regulation No. 2021/2282 on HTA (HTA Regulation), was adopted. The HTA Regulation has applied from January 12, 2025 although it will enter into force iteratively and initially apply to new active substances to treat cancer and to all advanced therapy medicinal products, it will then be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Selected high-risk medical devices will also be assessed under the HTA Regulation as of 2026. The HTA Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. It will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU Member States, can further reduce prices. Furthermore, many EU Member States have increased the amount of discounts required on pharmaceutical products, and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many EU Member States. The downward pressure on healthcare costs in general, and prescription products in particular, has become increasingly intense. As a result, there are increasingly higher barriers to entry for new products.

Furthermore, the containment of healthcare costs has become a priority of foreign and domestic governments as well as private third-party payors. The prices of drugs have been a focus in this effort. Governments and private third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. We also expect to experience pricing pressures due to the trend towards managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. These and other cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower-than-anticipated product revenues. In addition, the publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if coverage and adequate reimbursement of our products is unavailable or limited in scope or amount, our revenues and the potential profitability of our product candidates in those countries would be negatively affected.

Employees and human capital resources

As of December 31, 2025, we had a total of 249 full-time employees. We employ physicians, professionals in research and development, clinical, regulatory, manufacturing, commercial, finance, legal and other functions that are important to our business. We

are not a party to any collective bargaining agreements. We use temporary workers such as consultants and advisors in certain instances when we think it is in the best interests of our business.

Attracting, developing, and retaining highly qualified individuals are key to our success. To do so, we believe we offer competitive compensation packages—inclusive of base salary, bonus, and equity, and benefits. We also sought to establish a values-based culture enhanced by principles that set us apart: our empathy for patients and other stakeholders, our owner's mindset, our prioritization of clarity, our cross-functional collaboration, and our sense of urgency. These values enhance the working environment for our current employees and attract our desired candidates.

Facilities

We occupy 40,232 square feet of office space as our corporate headquarters at 2000 Sierra Point Parkway in Brisbane, California, under lease though March 2029.

Company information

We were incorporated as a Delaware corporation in May 2016. Our principal executive offices are located at 2000 Sierra Point Parkway, Suite 1200, Brisbane, California 94005. Our corporate website address is www.veratx.com. We post links on our website to the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the U.S. Securities and Exchange Commission (SEC): annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. All such filings are available through our website free of charge. The SEC also maintains an internet site at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Information contained on or accessible through our website is not a part of this Annual Report, and the inclusion of our website address in this report is an inactive textual reference only.

Legal proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the risks described below could harm our business, financial condition, results of operations, growth prospects, and/or stock price or 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 consider all of the risk factors described when evaluating our business.

Risks related to our financial position and need for additional capital

We have completed a limited number of clinical trials for our lead product candidate, atacicept, and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.

We are a late clinical-stage biotechnology company and we have no products approved for commercial sale, have not generated any revenue from product sales and have incurred losses since inception. To date, we have devoted substantially all of our resources to our research and development efforts, pre-clinical studies and clinical trials, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult to accurately predict our future success or viability than it would be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by late-stage biotechnology companies in rapidly evolving fields. We may face difficulty transitioning from a company with a clinical development focus to a company capable of supporting commercial operations. If we do not adequately address these risks and difficulties or successfully make such a transition, our business, financial condition, results of operations and prospects will be significantly harmed.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs of our product candidates or future commercialization efforts.

Developing treatments for immunological and rare diseases, including conducting nonclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses will increase in connection with our ongoing activities, particularly as we continue to conduct clinical trials of, and seek marketing approval for, our product candidates. We anticipate incurring significant costs associated with the development of our product candidates. Our expenses could increase beyond expectations if we are required by the FDA, or any comparable foreign regulatory authority, to perform clinical trials or nonclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. In addition, if we obtain marketing approval for product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. We cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. We also will continue to incur costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of December 31, 2025, we had $714.6 million in cash, cash equivalents and marketable securities. We expect that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operations and capital expenditure requirements beyond the next 12 months from the date of this Annual Report. Our estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic nature of our business and the macroeconomic and geopolitical environment generally. We anticipate that our expenses will increase substantially if, and as, we:

- initiate or continue nonclinical studies and clinical trials for our product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;

- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets, and know-how;
- acquire, develop or in-license other product candidates and technologies and further expand our clinical product pipeline;
- attract, develop and retain additional clinical, scientific, quality control, commercial, and manufacturing management and administrative personnel; and
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

Advancing the development of our product candidates will require a significant amount of capital. Our working capital and available credit will not be sufficient to fund all of the activities that are necessary to complete the development of our product candidates through approval and commercial launch.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Adequate additional financing may not be available to us on acceptable terms, or at all. Adverse geopolitical and macroeconomic developments, such as potential disruptions in access to bank deposits and lending commitments due to bank failures, ongoing military conflicts, related sanctions, actual and anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, could affect our ability to access capital as and when needed. Our failure to raise capital as and when needed, or on acceptable terms, would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

We have incurred net losses since inception and have never generated revenue from product sales. We expect to continue to incur net losses at least until we have one or more approved products that achieve commercial success.

We have incurred net losses in each reporting period since the commencement of our operations and have not generated any revenue from product sales to date. We had net losses of $299.6 million, $152.1 million and $96.0 million for the fiscal years ended December 31, 2025, 2024, and 2023, respectively. We had an accumulated deficit of $760.9 million as of December 31, 2025. Our losses have resulted principally from expenses incurred in research and development and from general and administrative costs and other expenses that we have incurred while building our business infrastructure. Our product candidates are in clinical and pre-clinical development. Even if one or more product candidates is commercialized, we expect that it will be several years, if ever, before revenue from product sales will result in net income. Even if we succeed in receiving marketing approval for and commercializing our product candidates in one or more indications, we expect that we will continue to incur substantial research and development and other expenses as we continue the clinical development programs for our product candidates in other indications.

We expect to continue to incur increased expenses and operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval for our product candidates. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be an indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital. In any particular period, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We have incurred losses and negative cash flows from operations. As a development stage company, we expect to incur significant and increasing losses at least until regulatory approval is granted for our product candidates. Regulatory approval is not guaranteed and may never be obtained. As a result, there is a possibility that the company may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with our collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize our product candidates. Our ability to generate revenue from product sales depends heavily on our and our potential future collaborators' success in:

- completing clinical development of product candidates and programs and identifying and developing new product candidates;
- seeking and obtaining marketing approvals for any product candidates that we develop;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a sales force, marketing, medical affairs and distribution infrastructure or, alternatively, collaborating with a commercialization partner;

- achieving adequate access and reimbursement by government and third-party payors for product candidates that we develop;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for product candidates that we develop, if approved;
- obtaining market acceptance of product candidates that we develop as viable treatment options;
- addressing any competing technological and market developments;
- maintaining our rights under our existing license agreements and any similar agreements we may enter into in the future;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference, infringement or other intellectual property-related claims, if any; and
- attracting, developing and retaining qualified personnel.

Even if any product candidate that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing such approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities to perform clinical trials or nonclinical studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not be able to reach or sustain profitability, and may need to obtain additional funding to continue operations.

The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In June 2025, we entered into a Loan and Security Agreement (2025 Loan Agreement) with a loan syndicate involving Oxford Finance LLC, Oxford Finance Credit Fund II LP, Oxford Finance Credit Fund III LP, and Oxford Finance Credit Fund IV LP (collectively, Oxford) providing for borrowing capacity of up to $500.0 million. As of December 31, 2025, our outstanding debt balance under the 2025 Loan Agreement was $75.0 million. Our overall leverage and certain obligations and affirmative and negative covenants contained in the related documentation could adversely affect our financial health and business and future operations by limiting our ability to, among other things, satisfy our obligations under the 2025 Loan Agreement, refinance our debt on terms acceptable to us or at all, plan for and adjust to changing business, industry and market conditions, use our available cash flow to fund future acquisitions and make dividend payments, and obtain additional financing for working capital, to fund growth or for general corporate purposes, even when necessary to maintain adequate liquidity.

If we default under the 2025 Loan Agreement, Oxford may accelerate all of our repayment obligations and exercise all of their rights and remedies under the 2025 Loan Agreement and applicable law, potentially requiring us to renegotiate our agreement on terms less favorable to us. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Oxford could declare a default upon the occurrence of customary events of default, including events that they interpret as a material adverse change as delineated in the 2025 Loan Agreement, payment defaults or breaches of certain affirmative or negative covenants, thereby requiring us to repay the loan immediately. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. Additionally, if we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Risks related to the discovery, development and commercialization of our product candidates

We are substantially dependent on the success of our product candidates. If we are unable to complete development of, obtain regulatory approval for and commercialize our product candidates in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

Our future success is heavily dependent on our ability to timely complete clinical trials, obtain marketing approval for and successfully commercialize our product candidates. We expect that a substantial portion of our efforts and expenses over the next several years will continue to be devoted to the development of our product candidates.

We plan to invest significant efforts and financial resources in the research and development of our product candidates, which will require additional clinical development, evaluation of clinical, nonclinical and manufacturing activities, marketing approval from regulatory authorities, and significant marketing efforts before we can generate any revenues from product sales. We are not permitted

to market or promote our product candidates before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. We cannot assure you that our planned clinical development programs for our product candidates will be completed in a timely manner, or at all, or that we will be able to obtain approval for our product candidates from the FDA or comparable foreign regulatory authorities. If we are unable to complete development of, obtain regulatory approval for and commercialize our product candidates in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business, financial condition, results of operations and prospects will be significantly harmed.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of nonclinical studies and early clinical trials may not be predictive of the results of subsequent clinical trials. We have a limited operating history and have limited experience in conducting large scale clinical trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials. For example, atacicept has been the subject of clinical trials by prior sponsors, including a Phase 2 trial in systemic lupus erythematosus (SLE), that missed its primary endpoint in the overall study population. In the future, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or any potential future collaborator may decide to conduct additional clinical trials or nonclinical studies. Any future delays or abandonment could harm our business, financial condition, results of operations and prospects. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications.

Our future clinical trials may not be successful. If any product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business, financial condition, results of operations and prospects may be significantly harmed. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the dropout rate among clinical trial participants. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether our clinical trials will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. If we are unable to bring our product candidates to market, our ability to create long-term shareholder value will be limited.

In addition, we rely in part on nonclinical, clinical and quality data generated by CROs and other third parties in connection with our planned regulatory submissions. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, our development programs may be significantly delayed, and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase.

Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in nonclinical studies and clinical trials nonetheless failed to obtain FDA or comparable foreign regulatory authority approval. We cannot guarantee that the FDA or foreign regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit an application seeking approval of our product candidates. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured, the terms of such approval may limit the scope and use, which may also limit commercial potential. Furthermore, the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA or comparable foreign regulatory authorities delaying, limiting or denying approval of a product candidate.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of participants, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory authorizations to commence a clinical trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards (IRBs) or positive ethics committee opinions;
- IRBs refusing to approve or ethics committees issuing negative opinions, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocols;
- clinical sites deviating from trial protocol or dropping out of a trial;
- study conduct issues, which could confound the clinical endpoints and/or data;
- manufacturing sufficient quantities of clinical trial material to supply the clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- delays in enrollment due to low prevalence or incidence rates of subjects with the applicable disease;
- delays in enrollment due to a shift in our prioritization and dedication of resources towards other product candidates or indications;
- subjects choosing an alternative treatment or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- regulatory authorities imposing a clinical hold;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- shutdowns, either temporarily or permanently, of any facility manufacturing our product candidates or any of their components, including by order from the FDA or comparable foreign regulatory authorities due to violations of current good manufacturing practice (cGMP) or similar foreign requirements, regulations or other applicable requirements;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices (GCP) or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled participants in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

If we experience delays in the completion of, or termination of, any clinical trial, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down development and approval processes and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval.

Any delays in our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial

viability of such product candidates could be significantly reduced. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with IgAN, the availability of competitive products, and significant competition for recruiting participants in clinical trials.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of participants to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of participants to complete any of our trials. Although we have engaged certain third-party investigators to assist with participant enrollment, there can be no assurance that we will be able to maintain our relationships with such third parties or that such third parties will be successful in helping us identify patients.

Factors that may generally affect participant enrollment include:

- the size and nature of the patient population;
- the number and location of clinical sites we enroll;
- competition with other companies for clinical sites or patients;
- the drug background and clinical experience (e.g., safety profile, risk/benefit assessment, mechanism of action, known proof of concept);
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain participant consents;
- risk that enrolled participants will drop out before completion;
- a shift in our prioritization and dedication of resources towards other product candidates or indications; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

In addition, if any significant adverse events or other side effects are observed in any of our future clinical trials or other sponsor development programs of similar mechanism of action that may result in a drug class effect, it may make it more difficult for us to recruit patients to our clinical trials and participants may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Our inability to enroll or retain a sufficient number of participants for our clinical trials would result in significant delays, which would increase our costs and have an adverse effect on our company.

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.

We have limited financial and human resources, which has in the past and may in the future cause us to make prioritization and resource allocation decisions. 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 research and 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 may develop our product candidates in combination with other therapies, which exposes us to additional risks.

We may develop our product candidates in combination with one or more currently approved therapies. Even if a product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke or modify approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell such product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If

the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market our product candidates.

The EU regulates medical devices and medicinal products separately, through different legislative instruments, and the applicable requirements will vary depending on the type of drug-device combination product. For instance, drug-delivery products intended to administer a medicinal product where the medicinal product and the device form a single integral product are regulated as medicinal products in the EU. In such a case, the marketing authorization application must include – where available – the results of the assessment of the conformity of the device part with the EU Medical Devices Regulation contained in the manufacturer's EU declaration of conformity of the device or the relevant certificate issued by a notified body. If the marketing authorization application does not include the results of the conformity assessment and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required, the European Medicine Agency or the EU member state competent authority must require the applicant to provide a notified body opinion on the conformity of the device. By contrast, in case of drug-delivery products intended to administer a medicinal product where the device and the medicinal product do not form a single integral product (but are e.g. co-packaged), the medicinal product is regulated in accordance with the rules for medicinal products described above while the device part is regulated as a medical device and will have to comply with all the requirements set forth by the EU Medical Devices Regulation.

The incidence and prevalence for target patient populations of our product candidates in specific indications are based on estimates and third-party sources. If the market opportunities for our product candidates, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our drug development strategy, including acquiring or in-licensing product candidates and determining indications on which to focus in nonclinical or clinical trials. These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, acceptance of our drugs by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to. If the market opportunities for our product candidates, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve and sustain profitability might be materially and adversely affected.

Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more participant 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 preliminary or top-line data from our nonclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary 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. Top-line data 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, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our clinical trials. Interim data 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 participant data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory authorities, 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 our particular program, the approvability or commercialization of our 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 material or otherwise appropriate information to include in our disclosure.

If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could significantly harm our business, financial condition, results of operations and prospects.

We face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. The current standard-of-care for IgAN consists of treatment with off-label use of RAAS inhibitors, including ACE inhibitors and ARBs, to control blood pressure, or steroids with or without other immunosuppressive agents to non-specifically reduce inflammation. SGLT2 inhibitors, including AstraZeneca's Farxiga, which is approved for chronic kidney disease, is becoming the standard-of-care in some geographies including the United States. Among emerging therapies, we consider our most direct competitors with respect to atacicept in IgAN to be approved products: the reformulated steroid from Asahi Kasei Corp., the anti-APRIL monoclonal antibody from Otsuka Pharmaceuticals, both the complement inhibitor and selective ETA receptor antagonist from Novartis, and the endothelin and angiotensin II receptor antagonist from Travere Therapeutics, Inc.; programs in Phase 3 clinical development: Roche/Ionis, Vertex, AstraZeneca, Biogen, Takeda, and Novartis; and the following companies with programs in Phase 2 of clinical development: Arrowhead Pharmaceuticals, NovelMed, and Eladon Pharmaceuticals.

There are no FDA-approved therapies for pMN. Companies with pMN trials in Phases 2 or 3 include Vertex, Roche, BeOne Medicines, Biogen, Climb Bio, and Walden Biosciences. There are currently no FDA-approved therapies for FSGS. Travere's FILSPARI received an extended FDA review of the sNDA in FSGS, with a PDUFA target action date of April 13, 2026. Companies with FSGS trials in Phases 2 or 3 include the following: Sanofi, Eli Lilly, Astellas, Walden Biosciences, Boehringer Ingelheim, Novartis, and Vertex. There are no FDA-approved therapies for MCD. Companies with MCD trials in Ph2/Ph3 include Sanofi, Travere Therapeutics, and Walden Biosciences.

In the kidney transplant or hematopoietic stem cell transplant setting, there are currently no anti-BK Virus (anti-BKV) therapies approved. The standard of care in both settings is to reduce immunosuppression as a first line, and potentially to offer intravenous immune globulin (IVIG) in kidney transplant recipients or antivirals with limited clinical evidence, including leflunomide and cidofovir, in either setting. There are few industry sponsored programs in development for these indications; we consider our most direct competitor to be Memo Therapeutics AG's Anti-BKV, a neutralizing monoclonal antibody in a Phase 2/3 clinical trial.

The current landscape of B cell modulators primarily includes monoclonal antibodies, or Fc-fusion proteins containing TACI or TACI variants, including atacicept. VT-109 is a novel BAFF/APRIL dual-inhibitor B cell maturation antigen (BCMA) molecule which, if successfully developed, approved, and commercialized, may compete with the existing approaches to treat B cell mediated autoimmune diseases, many of which are described in the preceding paragraphs on IgAN. We consider the most advanced direct competitor to VT-109 to be the BCMA Fc-fusion protein from Aurinia Pharmaceuticals Inc., which is currently in Phase 1 clinical development.

Many of our competitors have significantly greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA or comparable approval for superior products. Many of our competitors have established and in-use distribution channels for the commercialization of their products, whereas we have no such proven channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or any future product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidates or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and participant registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Changes in methods of manufacturing or formulation of our product candidates may result in additional costs or delays.

As our product candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, and manufacturing sites are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. 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 commercialize our product candidates, if approved, and generate revenue.

Risks related to regulatory approval and other legal compliance matters

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business, financial condition, results of operations and prospects will be significantly harmed.

The time required to obtain approval by the FDA and comparable foreign authorities typically takes many years following the commencement of clinical trials. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Any product candidate we may develop could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or comparable foreign regulatory authorities may determine that our product candidates are not safe, pure, and/or potent (or effective), only moderately effective, or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval, potentially resulting in a restrictive label and limiting commercial use;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials may not be sufficient to support the submission of a Biologics License Application (BLA), or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that the risk-benefit ratio for our proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- disruptions at the FDA and other government and regulatory agencies caused by funding shortages, furloughs or other reasons could result in delays in reviewing regulatory submissions or extensions of time necessary for new drugs to be reviewed and/or approved.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

In addition, even if we obtain approval of our product candidates for one indication, regulatory authorities may not approve such product candidates for other indications, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy (REMS). Certain regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or may approve them with a label that does not include the labeling claims necessary or desirable for successful commercialization of our product candidates. In addition, if we are unable to obtain regulatory approval, or if regulatory approval results in a limited label, our business, financial condition, results of operation and prospects will be significantly harmed.

Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our product candidates would depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products, such as TARPEYO®, FILSPARI®, FABHALTA®, VANRAFIA®, and VOYXACT®;
- the clinical indications for which the product candidate is approved;
- restrictions on use, such as boxed warnings or contraindications in labeling, or a REMS or comparable foreign restriction, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- our pricing and the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- the availability of our product candidates for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- inclusion or exclusion of our product candidates from treatment guidelines established by various physician groups;
- unfavorable publicity relating to our product candidates or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and accessible to patients. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare professionals, government agencies, regulatory authorities or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from such product candidate and may not be able to achieve or sustain profitability.

Our business entails a significant risk of product liability and product liability claims could significantly harm our business, financial condition, results of operations and prospects.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in obtaining regulatory approval of a product, such claims could result in an FDA or other regulatory authority investigation of the safety and effectiveness of our product, our manufacturing processes and facilities or our marketing programs. FDA or other regulatory authority investigations could potentially lead to a recall of our product or more serious enforcement action, limitations on the approved indications for which it may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels at a future date. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities caused by product liability claims, which could significantly harm our business, financial condition, results of operations and prospects.

Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with the use of our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to

interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. For example, Merck previously conducted APRIL-LN, a Phase 2/3 clinical trial aimed to evaluate the efficacy and safety of atacicept in patients with active lupus nephritis (LN), receiving newly initiated mycophenlate mofetil (MMF) and corticosteroids (CS). Two weeks before the initiation of atacicept, significant decreases in immunoglobulin G (IgG) levels began unexpectedly with initiation of MMF and high-dose CS, and persisted upon initiation of atacicept, which led to trial termination. Such drug-related side effects could affect participant recruitment or the ability of enrolled participants to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

If product candidates we develop are associated with undesirable side effects or have unexpected characteristics in nonclinical studies or clinical trials when used alone or in combination with other approved products or investigational drugs, we may need to interrupt, delay or abandon their development or limit 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. Treatment-related side effects could also affect participant recruitment or the ability of enrolled subjects to complete a trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may significantly harm our business, financial condition, results of operations and prospects.

Participants in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our nonclinical studies or previous clinical trials. Our product candidates may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory authorities. In addition, if our product candidates are used in combination with other therapies, such product candidates may exacerbate adverse events associated with the therapy and it may not be possible to determine whether such adverse events were caused by our product candidate or the agent with which it was combined. The inclusion of patients with advanced disease in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting participants to the clinical trials, participants may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB or ethics committee may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could significantly harm our business, financial condition, results of operations and prospects.

Further, toxicities associated with our products not seen during clinical testing may also develop after any approval, if obtained, and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on nonclinical studies or early-stage clinical trials.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or other foreign regulatory authority grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the marketing approval of the product candidate in their countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our product is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if any product candidate we develop receives regulatory approval, it could be subject to significant post-marketing regulatory requirements and will be subject to continued regulatory oversight.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the marketed product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or applicable foreign regulatory authorities approve any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning letters;
- civil and criminal penalties;
- injunctions;
- suspension, variation or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not be able to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If these actions impose constraints on FDA's or foreign regulatory authorities' ability to engage in oversight and implementation activities in the normal course, it may significantly harm our business, financial condition, results of operations and prospects.

We may seek but fail to obtain orphan drug designations from the FDA or other regulatory authorities for our product candidates, and even where we have obtained such designations, we may be unable to receive or maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

We may seek orphan drug designation for some or all of our product candidates. Under the Orphan Drug Act, the FDA may designate a drug product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States but where there is no reasonable expectation to recover the costs of developing and marketing a treatment drug in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and application fee waivers. However, orphan drug designation neither shortens the development time nor regulatory review time of a product candidate nor gives the candidate any advantage in the regulatory review or approval process.

If a product receives the first FDA approval for the disease or condition for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same disease or condition for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for a disease or condition broader than the orphan designated disease or condition and may be lost if the FDA later determines that the request for designation was materially defective. Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan disease or condition due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care.

We received orphan medicinal product designation for atacicept in the EU in October 2024. In the EU, a medicinal product may receive orphan designation under Article 3 of Regulation (EC) 141/2000 if its sponsor can establish that (i) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition and (ii) either (1) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (2) the product, without the benefits derived from orphan status, would be unlikely to generate sufficient returns in the EU to justify the necessary investment in its development. Moreover, in order to obtain orphan designation in the EU it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU or, if such a method exists, the product will be of significant benefit to those affected by the condition. The application for orphan designation must be submitted before the application for marketing authorization. Orphan medicinal product designation entitles an applicant to financial incentives such as fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Moreover, upon grant of a marketing authorization and assuming the requirements for orphan designation are also met at the time the marketing authorization is granted, orphan medicinal product are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. This market exclusivity period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify continued market exclusivity. In addition, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten year period of market exclusivity on an individual basis in very select cases, such as with consent from the marketing authorization holder, if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities of the authorized product or if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

We also received orphan drug designation for atacicept in Japan in September 2025. In Japan, drugs can be designated as orphan drugs if they are (1) intended for use in less than 50,000 patients in Japan or, if the usage is for a designated intractable disease, the number of patients is less than approximately one-thousandth of the population; (2) there is a high medical need due to the seriousness of the disease for which there are no sufficient alternative drugs or treatments or high efficacy or safety is expected with the new drug compared with existing products; and (3) the development plan is appropriate and there is reasonable possibility of development success. The benefits of orphan drug designation in Japan include subsidies to reduce the financial burden of product development, guidance and consultation from governmental agencies on development activities with a priority consultation system, tax credits for development costs, eligibility for priority review, and following approval, extension of the exclusivity period for up to ten years as well as premium pricing.

If we do not receive or maintain orphan drug designation for our product candidates, it could limit our ability to realize revenues.

Even though MAU868 has Fast Track designation from FDA for the prevention of BK viremia in renal transplant and hematopoietic stem cell transplant, it may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that MAU868 will receive marketing approval.

If a drug or biologic is intended for the treatment of a serious or life-threatening condition or disease, whether alone or in combination with other drugs or biologics, and nonclinical or clinical data demonstrate the potential to address an unmet medical need for such condition or disease, the product candidate may qualify for FDA Fast Track designation, for which sponsors must apply. The FDA has broad discretion whether or not to grant this designation. Fast Track designation allows for more frequent communication

with the FDA and the potential for rolling review of a marketing application. Although we have received Fast Track designation for the investigation of MAU868 for the prevention of BK viremia in renal transplant and hematopoietic stem cell transplant recipients, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional nonclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA or comparable foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or comparable foreign regulatory authorities may seek to withdraw any accelerated approval.

Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. For example, endpoints assessing changes in 24-hour urine protein-to-creatinine ratio (UPCR) have been accepted by FDA as surrogate primary endpoints for clinical trials of drugs targeting patients with IgAN, while assessments of estimated glomerular filtration rate (eGFR) slope have been viewed by regulators as the more conventional endpoint assessing clinical benefit in IgAN patients. We are currently seeking accelerated approval for atacicept based on the UPCR endpoint results observed in our ORIGIN 3 trial while continuing the trial to collect eGFR data to demonstrate improvement in kidney function.

An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to complete ongoing trials and/or conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit and to report regularly to the FDA on progress of such trials. Additionally, unless and until converted to full approval at the time of satisfying the conditions of any accelerated approval letter, the sponsor must submit any promotional materials for the accelerated approval drug to FDA at least 30 days prior to use. Third-party payors may refuse to provide coverage or reimbursement for the drug until the confirmatory studies are complete. Additionally, if such post-approval studies fail to confirm the drug's clinical benefit, or if the product sponsor fails to complete any confirmatory studies in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis.

Prior to seeking accelerated approval for any of our other product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all. The FDA or comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited review or approval for our product candidates would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may seek EMA PRIME (PRIority MEdicines) designation or other designations, schemes or tools for one or more of our product candidates. In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, some which provide incentives similar to the Breakthrough Therapy designation in the United States. For instance, in the EU, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a "standard" marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

Furthermore, marketing authorizations may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to the introduction of specific procedures. This may arise when the intended indications are very rare and, in

the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This type of marketing authorization is close to a conditional marketing authorization as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a marketing authorization. However, unlike a conditional marketing authorization, the applicant does not have to provide the missing data and will never have to. Although a marketing authorization "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the marketing authorization may be withdrawn where the risk-benefit ratio is no longer favorable.

The competent regulatory authorities in the EU have broad discretion whether to grant such an accelerated assessment, conditional marketing authorization or marketing authorization under exceptional circumstances, and, even if such assessment or authorization is granted, we may not experience a faster development process, review or authorization compared to conventional procedures. Moreover, the removal or threat of removal of such marketing authorizations may create uncertainty or delay in the clinical development of our product candidates and threaten the commercialization prospects of our products and product candidates, if approved. Such an occurrence could materially impact our business, financial condition and results of operations.

A Breakthrough Therapy Designation from the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive FDA approval.

We have obtained Breakthrough Therapy Designation from the FDA for atacicept for the treatment of IgAN, and we may seek additional Breakthrough Therapy Designations for our product candidates where we believe the clinical data support such designation. A "Breakthrough Therapy" is defined as a drug or biologic 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, where preliminary clinical evidence indicates that the drug or biologic 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, increased interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as Breakthrough Therapies also receive the same benefits associated with Fast Track designation, including eligibility for rolling review of a submitted BLA.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process or review and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification and rescind the designation.

Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations, or policy changes could hinder their ability to hire, retain or deploy key leadership and other personnel, and prevent new or modified products from being developed, reviewed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also prolong the time necessary for new biologics or modifications to approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities. If a prolonged government shutdown occurs, or if changes in policy, funding shortages or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our planned regulatory submissions, which could have a material adverse effect on our business.

Biosimilars to our product candidates may provide competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act), signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (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. 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.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk 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. 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 will depend on a number of marketplace and regulatory factors that are still developing.

In the EU, upon receiving a marketing authorization, innovative medicinal products are generally entitled to receive eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial marketing authorization of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of eleven 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 chemical/biological entity, and products may not qualify for data exclusivity. In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

If any approved products are subject to biosimilar competition sooner than we expect, we will face significant pricing pressure and our commercial opportunity will be limited.

The successful commercialization of any product candidate we develop will depend in part on the extent to which governmental authorities, private health insurers, and other third-party payors provide coverage and adequate reimbursement. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if any and if approved, could limit our ability to market those products and decrease our ability to generate revenue.

We intend to seek approval to market our product candidates in the United States, the EU, Japan, and certain foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, in the United States, the EU, and other jurisdictions, market acceptance and sales of an approved product candidate will depend significantly on the availability of adequate coverage and reimbursement from third-party payors.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford treatments. If we obtain marketing approval of a product candidate, sales of such product will depend substantially, both in the United States and internationally, on the extent to which the costs of the product will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only at inadequate levels, we may not be able to successfully commercialize any product candidates we develop. Even if coverage is provided, the approved reimbursement amount may not be sufficient to allow us to establish or maintain pricing to support an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS), determines which new products will be covered and reimbursed under Medicare. Private third-party

payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our product to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Governmental payors, as well as other third-party payors, including pharmacy benefit managers, have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and/or biosimilars. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our product. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, whether the level of reimbursement will be adequate.

Outside the United States, pharmaceutical sales are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as those we are developing or may develop in the future. In many countries, particularly the countries of the EU, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical study that compares the cost-effectiveness of our product candidates or any future product candidates we may develop to other available therapies. The Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU 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 EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No. 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 began to apply on January 12, 2025 through a phased implementation. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for any product that we commercialize may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates that we commercialize from third-party payors, the adoption of those products and potential sales revenue would be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for a product for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to commercialize our product candidates and may adversely affect the prices we may obtain and may have a negative impact on our business and results of operations.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that

may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not be able to achieve or sustain profitability.

For example, the Affordable Care Act substantially changed healthcare financing, access, and delivery by both governmental and private insurers. The Affordable Care Act 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. Under currently applicable U.S. law, certain products not usually self-administered, including injectable drugs, may be eligible for coverage under Medicare Part B. As a condition of receiving Medicare Part B reimbursement, manufacturers are required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program, which requires manufacturers to extend discounts to participating entities. These programs may be subject to change as a result of future health reform measures and may reduce the profitability of any successfully commercialized product candidate.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted in 2010. 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 will remain in effect until 2032, unless additional congressional action is taken. Additionally, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, effective January 1, 2024. These laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations. In addition, Congress is considering additional health reform measures.

Moreover, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Most significantly, the Inflation Reduction Act of 2022 (IRA) was signed into law in August 2022. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap (with resulting prices for the initial ten drugs first effective in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), redesigns the Medicare Part D benefit (starting in 2025), and replaces the Part D coverage gap discount program with a new discounting program (which began on January 1, 2025). CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the subsequent 15 drugs, which will first be effective in 2027. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program, although the program is currently subject to legal challenges. HHS has issued and will continue to issue guidance implementing the IRA. While the impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the proposals will be implemented, the policies may have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for any product candidate we commercialize. On the one hand, significant tariffs have been threatened to be imposed on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, although proposed regulations have not yet been published. Such regulatory proposals or executive actions could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry. If most favored nation pricing was ever to be codified by legislation, it could have a significant financial impact on our company.

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, marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. One state has utilized a so-called prescription drug affordability board to impose an upper payment limit in the state, while another state has enacted legislation that bans price increases that outpace inflation. Other enacted state laws affect the distribution of pharmaceuticals. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects.

Additional health reform measures may continue and affect our business in unknown ways, including proposed policies to reduce regulations and expenditures across government agencies, which could create additional uncertainty for our business. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

We expect that the Affordable Care Act, the IRA, as well as other healthcare reform measures that may be adopted in the future, particularly under the Trump administration, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. 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, achieve and sustain profitability or commercialize our product candidates.

The terms of future potential marketing approvals for our product candidates and ongoing regulation regarding promotional activities and post-market obligations may limit how we manufacture and market products that are approved, and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

FDA and comparable foreign regulations and guidance may be revised or reinterpreted by the competent authorities in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen 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 approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation (CTR), which was adopted in 2014 and repeals the EU Clinical Trials Directive (CTD), became applicable on January 31, 2022. While the CTD required a separate clinical trial application (CTA), to be submitted in each EU Member State in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial is approved, clinical study development may proceed. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials (and related applications) are fully subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans. In light of the entry into application of the CTR on January 31, 2022, we were required to transition clinical trials for which we have obtained regulatory approvals in accordance with the CTD to the regulatory framework of the CTR. Transition of clinical trials governed by the CTD to the CTR was required for clinical trials which had at least one site active in the EU on January 30, 2025. A timely transitioning application was filed with the competent authorities of EU Member States through the Clinical Trials Information Systems in order to continue the clinical trial past January 30, 2025.

Furthermore, on April 28, 2025, the UK adopted an amendment to the UK clinical trials regulations intended to support a more streamlined and flexible regulation of clinical trials, removing unnecessary administrative burdens on trial sponsors, whilst protecting the interests of trial participants. It also intends to bring the UK regulatory framework for clinical trials, which is still based on the CTD, into closer alignment with the CTR. The amendment will become applicable on April 28, 2026 following a one-year transition period.

In addition, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. On April 26, 2023, the European Commission published a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. The European Parliament and the Council of the EU adopted their respective positions on April 10, 2024 and June 4, 2025. Subsequent inter-institutional trilogue negotiations are expected to last until at least the end of 2025/early 2026 and a common position on the text was agreed upon on December 11, 2025, in the context of subsequent inter-institutional trilogue negotiations. The proposed revisions remain to be adopted, and are not expected to become applicable before 2028.

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 approvals for any other products would harm our business, financial condition, and results of operations.

Our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal, state and foreign healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare professionals and third-party payors play a primary role in the recommendation and prescription of our product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our product for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their implementing regulations, also imposes obligations, including mandatory contractual terms, upon certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered 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 annually report to CMS information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state and foreign laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures. Some state and foreign laws require biotechnology companies to report information on the pricing of certain drug products. Some state and local laws require the registration of pharmaceutical sales representatives.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians and other healthcare professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. Outside the United States, interactions between pharmaceutical

companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Infringement of related laws could result in substantial fines and imprisonment.

Payments made to physicians and other healthcare professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians and other healthcare professionals may require prior notification or approval by the physician's or other health care professional's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. 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 civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare professionals or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class actions) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business information, trade secrets, intellectual property, information we collect about trial participants in connection with clinical trials in the U.S. and abroad, and sensitive third-party information (collectively, sensitive information). Our data processing activities subject us to numerous obligations relating to data privacy and security, such as various state, federal, and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual obligations and other obligations relating to data privacy and security.

Outside the United States, our operations may be subject to an increasing number of laws, regulations and industry standards governing data privacy and security. For example, the EU's General Data Protection Regulation (EU GDPR) and the UK's Data Protection Act 2018 (UK GDPR) (collectively, GDPR), Canada's Personal Information Protection and Electronic Documents Act (PIPEDA), Australia's Privacy Act, India's Information Technology Act, China's Personal Information Protection Law (PIPL) and South Korea's Personal Information Protection Act impose strict requirements for processing of personal data, including clinical trials participants and other individuals. For instance, companies that violate the GDPR can face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests, temporary or definitive prohibitions on data processing and other corrective actions, fines of up to the greater of 20 million Euros under the EU GDPR / 17.5 million pounds under the UK GDPR, or 4% of their worldwide annual revenue, whichever is higher. Furthermore, China's PIPL imposes a set of specific obligations on covered businesses in connection with their processing and transfer of personal data and imposes fines of up to RMB 50 million or 5% of the prior year's total annual revenue of the violator.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework). These mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant

adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as the EEA and/or UK) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of the EEA for allegedly violating the EU GDPR's cross-border data transfer limitations. Additionally, companies that transfer personal data out of the EEA and/or UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Regulators in the United States are also increasingly scrutinizing certain personal data transfers and have imposed, and may in the future impose, certain personal data transfer or localization requirements.

In the United States federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g. Section 5 of the Federal Trade Commission Act), other similar laws (e.g. wiretapping laws). For example, HIPAA, as amended by HITECH, imposes, among other things, specific requirements relating to the privacy, security, and transmission and breach reporting of individually identifiable health information.

Additionally, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act (collectively, the CCPA), requires covered businesses that process the personal data of California residents to, among other things: to (i) provide specific disclosures to California residents in privacy notices; (ii) honor requests of such individuals to exercise certain privacy rights; and (iii) enter into specific contractual provisions with service providers that process California resident personal data on the business's behalf. The CCPA also provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws have been enacted or are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While certain of these laws exempt or may exempt data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We also publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. Regulators are increasingly scrutinizing these statements, and if these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our information processing practices and policies, divert resources from other initiatives and projects, including increased costs related to insurance, cybersecurity and information technology, and could restrict the way products and services involving data are offered, all of which could significantly harm our business, financial condition, results of operations and prospects.

We may at times fail (or be perceived to have failed) in our effort to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third-party partners (such as contract research organizations and clinical trial sites) may fail (or be perceived to have failed) to comply with such obligations, which could negatively impact our business operations. If we or our third-party partners fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class actions) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process sensitive information or to operate in certain jurisdictions; limited ability to develop or commercialize our

products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could significantly harm our business, financial condition, results of operations or prospects.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. 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. We also could incur significant costs associated with civil or criminal fines and penalties.

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 maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing the provision of 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, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials 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 or contractors, 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, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

In addition, our product and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our product, or our failure to obtain any required import or export authorization for our product, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our product may create delays in the introduction of our product in international markets or, in some cases, prevent the export of our product to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or product targeted by such regulations, could result in decreased use of our product by, or in our decreased ability to export our product to existing or potential customers with international operations. Any decreased use of our product or limitation on our ability to export or sell access to our product would likely significantly harm our business, financial condition, results of operations and prospects.

We are subject to various laws relating to foreign investment and the export of certain technologies, and our failure to comply with these laws or adequately monitor the compliance of our suppliers and others we do business with could subject us to substantial

fines, penalties and even injunctions, the imposition of which on us could have a material adverse effect on the success of our business.

We are subject to U.S. laws that regulate foreign investments in U.S. businesses and access by foreign persons to technology developed and produced in the United States. These laws include Section 721 of the Defense Production Act of 1950, as amended by the Foreign Investment Risk Review Modernization Act of 2018, and the regulations at 31 C.F.R. Parts 800 and 801, as amended, administered by the Committee on Foreign Investment in the United States; and the Export Control Reform Act of 2018, which is being implemented in part through Commerce Department rulemakings to impose new export control restrictions on "emerging and foundational technologies" yet to be fully identified. Application of these laws, including as they are implemented through regulations being developed, may negatively impact our business in various ways, including by restricting our access to capital and markets; limiting the collaborations we may pursue; regulating the export of our products, services, and technology from the United States and abroad; increasing our costs and the time necessary to obtain required authorizations and to ensure compliance; and threatening monetary fines and other penalties if we do not.

Risks related to employee matters, managing our growth and other risks related to our business

Unfavorable geopolitical and global economic conditions, including tariffs and trade tensions, could adversely affect our business, financial condition and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy, the global financial markets, and adverse geopolitical and macroeconomic developments. U.S. and global market and economic conditions have been, and continue to be, volatile due to many factors, including tariffs and trade tensions, supply chain challenges, ongoing military conflicts, related sanctions, changes in U.S.-China relations, elevated inflation rates and the responses by central banking authorities to control such inflation, among others. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, bank failures, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our manufacturers and our suppliers operate.

In addition, a severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have been significantly elevated compared to recent historical levels, and continued high rates of inflation may result, directly or indirectly, in increases in our operating costs (including our labor costs) and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

In response to the invasion of Ukraine by Russia, the United States, United Kingdom and EU, along with others, imposed significant new sanctions and export controls against Russia, Russian banks and certain Russian individuals and may implement additional sanctions or take further punitive actions in the future. The full economic and social impact of the sanctions imposed on Russia (as well as possible future punitive measures that may be implemented), as well as the counter-measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia, which could conceivably expand into the surrounding region, remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, supply chain continuity and reduced access to liquidity in both Europe and globally, and has introduced significant uncertainty into global markets. As a result, our business and results of operations, including conduct of any global clinical trials with sites in eastern Europe and western Asia, may be adversely affected by the ongoing conflict between Ukraine and Russia and related sanctions, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict.

Tensions between the United States and China have increased over the past few years as a result of disputes in areas including trade policy, intellectual property, cybersecurity and data privacy, as well as due to geopolitical conflicts such as the war between Ukraine and Russia. We conduct manufacturing and clinical development activities in China. Any unfavorable government policies on cross-border relations or international trade, changes to law, executive orders, tariffs, treaties or trade agreements, or deterioration in U.S.-China relations or international trade may adversely affect the import or export of our drug candidates and materials required for manufacturing or otherwise delay our product development activities, which could in turn have a material adverse effect on our business, financial condition and results of operations.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees and key consultants.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams, including certain key consultants.

Furthermore, although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for all of our executives or employees. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and growth prospects.

The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which is adversely impacting, and may continue to adversely impact, our business.

Current or future tariffs may result in increased research and development expenses, including with respect to increased costs associated with active pharmaceutical ingredients, raw materials, laboratory equipment and research materials and components. In addition, such tariffs may increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

Trade disputes, tariffs, restrictions and other political tensions between the U.S. and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, results of operations and financial condition. In addition, trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this Annual Report.

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market such product candidates, if approved.

In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of our product candidates, if approved, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any product candidate that may receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

As an organization, we have never commercialized a product candidate, and we are currently building marketing, sales force, market access, and distribution capabilities. To achieve commercial success for a product candidate, which we may license to others, we will rely on the assistance and guidance of those collaborators. For any product candidates for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our current or any future product candidate we may develop, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or educating adequate numbers of physicians on the benefits of our current or any future product candidates we may develop and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of any of our product candidates, if approved. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our current or any future product candidate we may develop, we may not generate revenues from such product candidate or be able to achieve or sustain profitability.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2025, we had 249 full-time employees, including 144 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we continue to operate as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and other comparable foreign regulatory authorities' review processes for our product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

In addition, we are conducting multiple clinical trials of atacicept. Given the small size of our organization, we may encounter difficulties managing multiple clinical trials at the same time, which could negatively affect our ability to manage growth of our organization. Our future financial performance and our ability to successfully develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

Our headquarters is located in Brisbane, California, in a region which in the past has experienced severe earthquakes and fires. If earthquakes, fires, other natural disasters, terrorism or similar unforeseen events beyond our control prevent us from using all or a significant portion of our office facilities, it may be difficult or, in certain cases, impossible for us to continue our business for a period of time. We do not have a comprehensive internal disaster recovery or business continuity plan in place and any third-party service provider plans are limited in nature. We may incur substantial expenses as a result of the absence or limited nature of our plans, which could have a material adverse effect on our business. Furthermore, parties integral to our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect

our supply chain, it could have an adverse effect on our development plans and ability to conduct our clinical trials, and future commercialization plans.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Inflation Reduction Act of 2022 includes provisions that will affect the U.S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. Future guidance from the Internal Revenue Service and other tax authorities with respect to new or existing tax legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to such legislation or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under tax legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense. We continue to examine the impact tax legislation may have on our business. We urge investors to consult with their legal and tax advisers regarding the implications of past and potential future changes in U.S. tax laws on an investment in our common stock.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred losses during our history, we expect to continue to incur significant losses for the foreseeable future, and we may never achieve profitability. As of December 31, 2025, we had federal and state net operating loss (NOL) carryforwards of $389.9 million and $42.3 million, respectively, of which $10.2 million of federal NOL carryforwards and $37.0 million of state NOL carryforwards will begin expiring in the years 2032 and 2036, respectively, if not utilized. We also have $379.6 million of federal NOL carryforwards as of December 31, 2025 that do not expire. Our NOL carryforwards are subject to review and possible adjustment by the U.S. and state tax authorities. NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. NOLs arising in tax years beginning after December 31, 2017, and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss, and NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of current year taxable income. At the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently enacted legislation that, with certain exceptions, suspends the ability to use California net operating losses to offset California income and limits the ability to use California business tax credits to offset California taxes, for taxable years beginning after 2023 and before 2027. It is generally uncertain if and to what extent various states will conform to federal tax laws.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in our ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership. Our ability to utilize those NOLs could be limited by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have an adverse effect on our cash flows and results of operations.

A variety of risks associated with marketing our current or any future product candidate we may develop internationally could significantly harm our business, financial condition, results of operations and prospects.

We plan to seek regulatory approval of our current or any future product candidates we may develop outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

These and other risks associated with our international operations may significantly harm our business, financial condition, results of operations and prospects.

Risks related to our intellectual property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our and our current or future licensors', licensees' or collaborators' ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our product candidates and technologies related to their various uses. We generally seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad related to our proprietary technologies, and their manufacture and uses that are important to our business, as well as inventions and improvements that are important to the development and implementation of our business. Our owned and in-licensed patents and patent applications in both the United States and certain foreign jurisdictions relate to our product candidates. There can be no assurance that the claims of our owned or in-licensed patents, or any patent application that issues as a patent, will exclude others from making, using or selling our product candidates or any future product candidates or products that are substantially similar to our product candidates or any future product candidates. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. We may seek to protect our proprietary position by acquiring or in-licensing additional relevant issued patents or pending applications from third parties. If we or our potential licensors, licensees or collaborators are unable to obtain or maintain patent protection with respect to our product candidates, proprietary technologies and their uses, our business, financial condition, results of operations and prospects could be significantly harmed.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our owned or in-licensed patent applications or our current or future licensors', licensees' or collaborators' patent applications will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Moreover, in the future, some of our owned or in-licensed patents and patent applications may be co-owned with third parties. If we are unable to obtain exclusive licenses to any such co-owners' interest in such patents or patent applications, then such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. Thus, the degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could significantly harm our business, financial condition, results of operations and prospects.

We cannot be certain that the claims in our U.S. pending patent applications and corresponding international applications will be considered patentable by the United States Patent and Trademark Office (USPTO) courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patent(s) will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- patent applications must be filed in advance of certain events (e.g., third-party filings, certain sales or offers for sale, or other activities that might be legally deemed to be public disclosures) and we might not be aware of such events or otherwise might not succeed in filing applications before they occur;
- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection, for example, if patentable aspects are publicly disclosed, by us or a third party, such as by public use, sale or offer for sale, or publication.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Further, although we require our employees, commercial contractors, and certain consultants and investigators to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ, we cannot guarantee that we have entered into such agreements with each party, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach such agreements and claim ownership in intellectual property that we believe is owned or in-licensed by us. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Should any of the above events occur, it could significantly harm our business, financial condition, results of operations and prospects.

If we breach our license agreement with Ares, an affiliate of Merck related to atacicept, the license agreement with Novartis related to MAU868, or the license agreement with Stanford related to VT-109, we could lose the ability to continue the development and commercialization of atacicept, MAU868, or VT-109, respectively.

We are dependent on patents, know-how and proprietary technology licensed or sublicensed to us from Ares, Novartis, and Stanford. Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our and our licensor's proprietary technologies without infringing the proprietary rights of third parties. Ares, Novartis, or Stanford may have the right to terminate the applicable license agreement in full in the event we materially breach or default in the performance of any of the obligations under the applicable license agreement. A termination of any of our existing license agreements could result in the loss of significant rights and could harm our ability to commercialize our product candidates. Additionally, certain patents, know-how and proprietary technology of third parties, including certain composition of matter patents, are sublicensed to us and in the event the applicable license agreement terminates, expires or is in dispute, it could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Disputes may also arise between us and Ares, an affiliate of Merck, Novartis, Stanford, or any future potential licensors, regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

In addition, we acquired worldwide, exclusive rights to atacicept pursuant to the Ares Agreement, and worldwide, exclusive rights to develop, manufacture and commercialize MAU868 pursuant to the asset purchase agreement (Amplyx Agreement) with Amplyx Pharmaceuticals, Inc. (Amplyx), a wholly owned subsidiary of Pfizer, Inc., pursuant to which we acquired Amplyx's right, title and interest in the license agreement between Amplyx and Novartis related to MAU868. We also entered into an exclusive license agreement with Stanford for rights to VT-109. The Ares Agreement, Novartis License, and Stanford Agreement are complex, and certain provisions 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 increase what we believe to be our financial or other obligations under such agreement, either of which could have an adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangement on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have an adverse effect on our business, financial conditions, results of operations, and prospects.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

We may be required to make significant payments under our license agreements related to our product candidates.

As consideration for the license under the Ares Agreement, we paid Ares $25.0 million in 2020 upon delivery and initiation of the transfer of specified information and materials and $15.0 million in January 2026 upon achievement of the BLA filing. We are required to pay Ares additional aggregate milestone payments, including $20.0 million due upon regulatory approval for IgAN in the U.S., and up to $141.5 million upon the achievement of regulatory filing and approval milestones for other geographic regions and indications, and aggregate milestone payments of up to $515.0 million upon the achievement of specified worldwide aggregate net sales milestones, beginning with $15.0 million if net sales reach $250.0 million and $50.0 million if net sales reach $500.0 million. Commencing on the first commercial sale of licensed products, we are obligated to pay tiered royalties of low double-digit to mid-teen percentages on annual net sales of the products covered by the license. In the event we sublicense our rights under the Ares Agreement, we are obligated to pay Ares a percentage ranging from the mid-single-digit to the low double-digits of specified sublicensing income received.

Under the Amplyx Agreement, we are obligated to make certain milestone payments to Amplyx in an aggregate amount of up to $7.0 million based on the achievement of certain regulatory milestones. Further, we are required to pay Amplyx low single digit percentage royalties on net sales of MAU868 on a country-by-country and product-by-product basis. In addition, pursuant to the Novartis License, we are obligated to make certain milestone payments to Novartis in an aggregate amount of up to $62.0 million based on the achievement of certain clinical development, regulatory and sales milestones. Further, we are required to pay Novartis mid-to high-single digit percentage royalties based on net sales of MAU868 on a country-by-country and product-by-product basis.

Under the Stanford Agreement, we are obligated to make certain milestone payments to Stanford based on the achievement of certain development, regulatory, and commercial milestones. Further, we are required to pay Stanford royalties based on net sales of VT-109 worldwide. In the event we sublicense our rights under the Stanford Agreement, we are obligated to pay Stanford a percentage of specified sublicensing income received.

If milestone or other non-royalty obligations become due, we may not have sufficient funds available to meet our obligations, which will adversely affect our business operations and financial condition.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent positions of biotechnology companies generally are highly uncertain, involve complex legal and factual questions for which important legal principles remain unsolved and have been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our product candidates, or which effectively prevent others from commercializing competitive technologies and product candidates. In addition, the laws of foreign countries may not protect our rights

to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body.

Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Legal standards relating to valid and enforceable claim scope are unsettled in the United States and elsewhere and disputes challenging or re-defining scope are common in the biopharmaceutical industry. Even if patent applications we own or in-license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could significantly harm our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad.

The process by which patent applications are examined and considered for issuance as patents involves consideration by the relevant patent office of "prior art" relative to the invented technology. Different countries have different rules about what information or events can be considered "prior art," and different requirements regarding when a patent application must be filed relative to any particular piece of potential prior art. Moreover, legal decisions can re-interpret or change whether particular information or events are considered to be "prior art." Still further, in the United States, patent applicants are required to notify the USPTO of any material "prior art" of which they are aware for the patent examiner to consider in addition to independent searches that the patent examiner is required to do. Also, in the United States and certain other jurisdictions, third parties are entitled to submit prior art to patent offices for consideration during examination.

We may not be aware of certain relevant prior art, may fail to identify or timely cite certain prior art, or may not be able to convince a patent examiner that our patent(s) should issue in light of the art. Also, we cannot be certain that all relevant art will be or was identified during examination of a patent application so that, even if a patent issues, it may be susceptible to challenge that it is not valid over art that was not considered during its examination.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or other jurisdictions, or become involved in post-grant challenges such as opposition, derivation, revocation, reexamination, post-grant review (PGR) and inter partes review (IPR), or other similar proceedings, or in litigation, challenging our patent rights, including by challenging the validity or the claim of priority of our patents. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, including art of which we were unaware, and art which was not raised during prosecution of any of our patents or patent applications. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would significantly impact our business, financial condition, results of operations and prospects. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates or could embolden competitors to launch products or take other steps that could disadvantage us in the marketplace or draw us into additional expensive and time consuming disputes. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

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. For example:

- we may not be able to detect infringement of our issued patents;
- others may be able to develop products that are similar to our product candidates, but that are not covered by the claims of the patents that we may in-license in the future or own;
- our competitors may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our product candidates;

- we, or our current or future collaborators or license partners, might not have been the first to make the inventions covered by the issued patents or patent applications that we may in-license in the future or own;
- we, or our current or future collaborators or license partners, might be found not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we may in-license in the future or own will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents, for which we are not aware;
- issued patents that we hold rights to may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- issued patents may not have sufficient term or geographic scope to provide meaningful protection;
- our competitors might conduct research and development activities 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;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets, and a third party may subsequently file a patent covering such intellectual property.

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

Our commercial success depends significantly on our ability to operate without infringing, misappropriating or otherwise violating the patents and other proprietary rights of third parties. Claims by third parties that we infringe, misappropriate or otherwise violate their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement, misappropriation or other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. A finding by a court or administrative body that we infringe the claims of issued patents owned by third parties could preclude us from commercializing our product candidates.

Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation adversarial activity, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology industry, including patent infringement lawsuits, and proceedings, such as oppositions, reexaminations, IPR proceedings, PGR proceedings, and other third party submissions, before the USPTO and/or corresponding foreign patent offices. In addition, many companies in intellectual property-dependent industries, including the biotechnology industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous third-party U.S. and foreign issued patents and pending patent applications may exist in the fields in which we are developing our product candidates. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

It is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may be unable to develop, manufacture, market, sell and commercialize products or services or perform research and development or other activities covered by these patents. In the event that any of these patents were to issue and be asserted against us, we believe that we would have defenses against any such assertion, including that such patents are not valid. However, if such defenses to such assertion were unsuccessful, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents. We could also be required to obtain a license to such patents, which may not be available on commercially reasonable terms or at all. If we are unable to obtain such a license, we could be precluded from commercializing any product candidates that were ultimately held to infringe such patents.

As the biotechnology industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a

certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Still further, we cannot rely on our experience that third parties have not so far alleged that we infringe their patent rights, as provisions of U.S. patent laws provide a safe harbor from patent infringement for therapeutic products under clinical development.

Any claims of patent infringement, misappropriation or other violations asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing our product candidates;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Any patent-related legal action against us claiming damages or seeking to enjoin commercial activities relating to our products, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or a future strategic partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our processes for our product candidates to avoid infringement, if necessary.

An adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could significantly harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have an adverse effect on our ability to raise additional funds or otherwise significantly harm our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights from third parties that we identify as necessary for future product candidates we may develop through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights.

While we may have in-licensed patents that cover our product candidates, it is possible that third parties may have blocking patents that prevent us from marketing, manufacturing or commercializing our patented products and practicing our in-licensed patented technology.

We may be unsuccessful in acquiring or in-licensing compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for practicing inventions claimed by our patents, including the manufacture, sale and use of our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of 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. 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 have to abandon development of the relevant program or product candidate, which could significantly harm our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors or other third parties may infringe, misappropriate or otherwise violate our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement or other intellectual property claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we may in-license in the future or own is not valid, is unenforceable, and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our owned or in-licensed patents do not cover the technology in question. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at any of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would significantly harm our business, financial condition, results of operations and prospects.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. 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 not have sufficient financial or other resources to conduct such litigation or proceedings adequately. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

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

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could significantly harm our business, financial condition, results of operations and prospects.

Derivation proceedings may be necessary to determine inventorship, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine inventorship with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not

offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have an adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

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

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Further, the United States has enacted and implemented wide-ranging patent reform legislation and 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 decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future. For example, recent decisions raise questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in the future and whether patent expiration dates may be impacted. An inability to obtain, enforce, and defend patents covering our proprietary technologies (including those for our product candidates) would adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States and Europe. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications 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 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 subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

It is possible that we do not transfer or perfect ownership of all patents, patent applications or other intellectual property. This possibility includes the risk that we do not identify all inventors, or identify incorrect inventors, which may lead to claims disputing inventorship or ownership of our patents, patent applications or other intellectual property by former employees or other third parties. There is also a risk that we do not establish an unbroken chain of title from inventors to us. Errors in inventorship or ownership can sometimes also impact priority claims. If we were to lose ability to claim priority for certain patent filings, intervening art or other events may preclude us from issuing patents.

Litigation may be necessary 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 an

outcome could significantly harm our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. Various extensions may be available, but there can be no assurance that any such extensions will be obtained, and the life of a patent, and the protection it affords, is limited. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. There is a risk that we may take action that detracts from any accrued patent term adjustment. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our earliest in-licensed patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, financial condition, prospects and results of operations.

Any of the foregoing could significantly harm our business, financial condition, results of operations and prospects.

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

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the EU. 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 per approved drug product, and only those claims covering the approved drug product, 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 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 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 impacted and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

We will not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we will not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These infringing products may compete with our product candidates without any available recourse.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Because the legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceutical products, it could be difficult for us to stop the infringement, misappropriation or violation of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our intellectual property and other proprietary rights in foreign jurisdictions could result in substantial costs and divert our

efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly, could put our patent applications or the patent applications of our licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. 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.

The ongoing conflict in Ukraine and related sanctions could significantly devalue our Russian and Eurasian patents. Recent Russian decrees may significantly limit our ability to enforce Russian patents. We cannot predict when or how this situation will change.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we 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 significantly harmed.

In addition, recordation of licenses with respect to exclusively licensed patent rights outside of the United States is potentially costly and we might fail to record such rights timely. If we fail to timely record our patent rights, third parties may try to seek licenses from the patent owners, or we may not be able to recover full damages for patent infringement in jurisdictions where we have no such recordations, any of which could significantly harm our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment, and other requirements imposed by regulations and governmental 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 governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or patent applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, potential competitors might be able to enter the market with similar or identical products or technology, which could significantly harm our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business, financial condition, results of operations and prospects could be significantly harmed.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business, financial condition, results of operations and prospects may be significantly harmed. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could significantly harm our business, financial condition, results of operations and prospects.

In addition, any proprietary name we propose to use with our current or future products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the 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 proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

If we are unable to protect the confidentiality of our trade secrets, our business, financial condition, results of operations, prospects and competitive position would be significantly harmed.

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology or processes. Further, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, or claim ownership in intellectual property that we believe is owned or in-licensed by us. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, 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 from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. Any of the foregoing could significantly harm our business, financial condition, results of operations and prospects.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, lessees of shared multi-company property and other third parties. Many of our employees and consultants were previously employed at, may have previously provided or may be currently providing consulting services to, other biotechnology companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed 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 or patent applications. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates or technologies we may develop. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts and cause us to lose valuable intellectual property rights or personnel, which could significantly harm our business, financial condition, results of operations and prospects. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can. 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. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have an adverse effect on our ability to raise additional funds or otherwise significantly harm our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others.

We may enter into license agreements in the future with others to advance our research or allow commercialization of our product candidates. These and other licenses may not provide exclusive rights to use such 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 in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in our licenses.

If we fail to comply with our obligations under any such license agreements, including obligations to make various milestone payments and royalty payments and other obligations, the licensor may have the right to terminate the license. If these agreements are terminated, we could lose intellectual property rights that are important to our business, be liable for any damages to such licensors or be prevented from developing and commercializing our product candidates, and competitors could have the freedom to seek regulatory approval of, and to market, products identical to ours. Termination of these agreements or reduction or elimination of our

rights under these agreements may also result in our being required to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business, including the payment of all applicable fees for patents covering our product candidates. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected. Further, we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control the prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by the actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have an adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may need to obtain additional licenses from existing licensors and others to advance our research or allow commercialization of product candidates we develop. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could significantly harm our business, financial condition, results of operations and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

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.

Disputes may arise between us and our past, current or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are 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 significantly harm our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could significantly harm our business, financial condition and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could significantly harm our competitive position, business, financial condition and prospects.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

We may develop, acquire, or license intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as march-in rights). If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects.

Risks related to our dependence on third parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition, results of operations and prospects could be significantly harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our nonclinical studies and clinical trials and to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our nonclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for the conduct of clinical trials, as well as Good Laboratory Practices (GLPs), which include regulations and guidelines governing the conduct of certain nonclinical studies. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, GLPs, or similar requirements, the data generated in our studies and clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials or nonclinical studies before approving our marketing applications, if ever. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or nonclinical studies have complied with GCP or GLP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations or similar foreign requirements. Failure to comply and maintain adequate

documentation with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely, and our business, financial condition, results of operations and prospects could be significantly harmed.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. In addition, our CROs could fail to perform, we could terminate their agreements or they could go out of business. If our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding CROs involves substantial cost and requires management time and focus, and could delay development and commercialization of our product candidates. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays with CROs in the future or that these delays or challenges will not significantly harm our business, financial condition, results of operations and prospects.

Prior to obtaining the rights to MAU868 from Amplyx, third parties had been responsible for all development activities. Although we believe these historical development activities were conducted in accordance with applicable rules and regulations in material respects, we cannot assure you that we will not discover inaccuracies or noncompliance in prior development activities that have an adverse effect on the future development of MAU868. For example, a regulatory authority may choose to inspect an investigational site and/or vendor such as a CRO for a MAU868 study that was previously conducted by Amplyx. Findings from such inspections could have an impact on the review of any future marketing applications by the FDA or foreign regulatory authorities.

In connection with our acquisition of MAU868, we have assumed the responsibility for ongoing clinical studies with MAU868, including related expenses and manufacturing and regulatory activities, which were previously managed and funded by Amplyx. This includes responsibility for the Phase 2 clinical trial of MAU868 for the treatment of reactivated BK virus (BKV) infection in kidney transplant recipients previously conducted by Amplyx. Any adverse events or reactions experienced by subjects in the trial may be attributed to MAU868 and may limit our ability to obtain regulatory approval with labeling that we consider desirable, or at all.

We contract with third parties for the manufacture of our product candidates for our ongoing clinical trials, and expect to continue to do so for additional clinical trials of our product candidates and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates necessary for their development or commercialization, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for clinical trials under the guidance of members of our organization. Furthermore, raw materials for our product candidates are sourced, in some cases, from a single source supplier. If we were to experience an unexpected loss of supply of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of our product candidates, if we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;

- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;
- disruptions resulting from the effect of public health pandemics or epidemics; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We have limited control over the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations or similar foreign requirements for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar foreign requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates, or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. We, or our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP or similar foreign requirements. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations or similar foreign requirements. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or other drugs necessary for the development or commercialization of our product candidates and significantly harm our business, financial condition, results of operations and prospects.

Furthermore, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies is prohibitive, our development and commercialization efforts would be impaired, which would significantly harm our business, financial condition, results of operations and prospects.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or other drugs necessary for the development or commercialization of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our product for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide nonclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and significantly harm our business, financial condition, results of operations and prospects. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or

closure of product facilities due to possible contamination. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would significantly harm our business, financial condition, results of operations and prospects.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

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

In the future, we may partner with third-party collaborators for the development and commercialization of our product candidates. Our likely collaborators for any future collaboration arrangements would likely include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

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 revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates 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;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;

- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us 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 attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for 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; and
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

If we decide to establish collaborations in the future, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our current or any future product candidates we may develop will require substantial additional cash to fund expenses. We may continue to seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

If we seek collaborations in the future, we will face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a 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 or comparable foreign regulatory authorities, 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 drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidates. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

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. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into additional collaborations, we may not be able to negotiate 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 a 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 product revenue.

Risks related to ownership of our common stock

The price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock has been, and is likely to be, highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. For example, the closing price of our common stock from January 1, 2025 to January 31, 2026, has ranged from a low of $18.86 to a high of $55.67. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report, these factors include:

- the timing and results of nonclinical studies and clinical trials of our current or any future product candidates we may develop or those of our competitors;
- regulatory actions with respect to our product candidate or our competitors' products;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- developments associated with our license with Ares, an affiliate of Merck, including any termination or other change in our relationship with Ares or Merck;
- developments associated with our license with Novartis, including any termination or other change in our relationship with Novartis or Amplyx;
- developments associated with our license with Stanford, including any termination or other change in our relationship with Stanford;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- the public release of clinical trial data from companies perceived by investors to be comparable to us;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our securities by us, our insiders or our other stockholders; and
- general geopolitical, macroeconomic, industry and market conditions, including tariffs and trade tensions, supply chain challenges, ongoing military conflicts, related sanctions, changes in U.S.-China relations, elevated inflation rates and the responses by central banking authorities to control such inflation.

In addition, the trading prices for common stock of other biotechnology companies have been highly volatile as a result of factors unrelated to the specific company or its technology. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability

to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

If we experience material weaknesses in internal control over financial reporting in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404) requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting on an annual basis. Our independent registered public accounting firm is required to attest to our management report on internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002. The process of compiling the system, process, and controls documentation necessary to perform the evaluation required under Section 404 is costly and challenging. We have incurred additional professional fees and other expenses and expended significant management efforts to comply with Section 404. In particular, these expenses and efforts increased in connection with the requirement to furnish an attestation report on internal control over financial reporting by our independent registered public accounting firm in our Annual Report on Form 10-K for the year ended December 31, 2024. We expect that these increased levels of expenses and efforts associated with Sarbanes-Oxley compliance will continue.

We have in the past and may in the future identify material weaknesses in our internal control over financial reporting. If we identify any such material weaknesses, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock in the future or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

As of December 31, 2025, there were 71,267,429 shares of common stock outstanding.

Further, certain holders of our common stock have rights, subject to certain conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We also register all shares of common stock that we issue under our equity compensation plans. Such shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

In addition, we have in the past and may in the future issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

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

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. For example, since our initial public offering, we have completed a number of follow-on public offerings of our common stock. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we

may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.

We have never declared or paid any cash dividends on our equity securities. We currently anticipate that we will retain 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. In addition, the terms of the 2025 Loan Agreement restrict our ability to declare and pay dividends without the prior written consent of Oxford. Any return to stockholders will therefore be limited to any appreciation in the value of our common stock, which is not certain.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our amended and restated certificate of incorporations or amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (DGCL), which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in 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.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States are 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 (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware)

and any appellate court therefrom is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our bylaws (as each may be amended from time to time);
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder);
- any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants.

This choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying such offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may 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 the exclusive forum provision contained 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, financial condition, results of operations and prospects.

General risk factors

If our information technology systems, or those of any of our third-party partners (such as contract research organizations and clinical trial sites), or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; additional costs; loss of revenue or profits; and other adverse consequences.

In the ordinary course of business, we and our third-party partners (such as contract research organizations and clinical trial sites) process confidential information, including intellectual property, proprietary business information, preclinical and clinical trial data and personal data (such as sensitive information) (collectively, Confidential Information).

As a result, we and our third-party partners are vulnerable to a variety of evolving threats that could cause security incidents. Cyberattacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our Confidential Information and information technology systems, and those of our third-party partners. These threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors that are becoming increasingly sophisticated in using techniques and tools – including artificial intelligence – that circumvent security controls, evade detection and remove forensic evidence.

Some actors, including without limitation nation-state and nation-state-supported actors, now engage and are expected to continue to engage in cyberattacks for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and our third-party partners (such as contract research organizations and clinical trial sites) may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and our third-party partners are also subject to a variety of evolving threats, including but not limited to errors or malfeasance by personnel, malware (including as a result of advanced persistent threat intrusions), malicious code (such as viruses and worms), software vulnerabilities, hacking, denial or degradation of service attacks, misconfigurations, credential stuffing, social-engineering attacks (including deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), ransomware attacks, supply-chain attacks, software "bugs", server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications and electrical failures, earthquakes, fires, floods and other similar threats. Any integration of AI in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of Confidential Information and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has increased risks to our information technology systems and Confidential Information, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance upon third-party partners and technologies to operate critical business systems and to process Confidential Information could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party partners in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third-party partners to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. If our third-party partners experience or have experienced a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party partners fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of our third-party partners). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption from time to time that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our Confidential Information or our information technology systems, or those of the third-party partners. A security incident or other interruption could disrupt our ability (and that of our third-party partners (such as contract research organizations and clinical trial sites)) to provide our products or services. We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and Confidential Information. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal data or other proprietary or sensitive information or other similar disruptions. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators and investors, of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. Security incidents, or perceived security incidents, may result in material

adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing information (including personal data); substantial remediation costs; litigation (including class actions); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms.

There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our information technology systems and Confidential Information. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be certain that our insurance coverage will be adequate or sufficient to protect us from or mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available to us on economically reasonable terms, or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer Confidential Information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our Confidential Information could be leaked, disclosed or revealed as a result of or in connection with our employees', personnel's or third-party partners' use of generative AI technologies.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities.

The requirements of being a public company may strain our resources, result in more litigation and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Stock Market LLC and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes that have materially affected, or are likely to materially affect, our internal controls and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could

result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations and prospects may be harmed.

These rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in SEC filings required of a public company, our business and financial condition is more visible, which may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business, financial condition, results of operations and prospects.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation and shareholder derivative actions. We may be the target of these types of litigation and claims in the future. These claims and litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business, financial condition, results of operations and prospects.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us, our business or our market. If few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity

Risk management and strategy

We have developed, implemented and maintained a cybersecurity risk management program, designed to align with the National Institute of Standards and Technology Cybersecurity Framework 2.0 (NIST CSF 2.0), including various information security processes, designed to protect the confidentiality, integrity, and availability of our critical computer networks, third-party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and sensitive personal data, including that of our employees, consultants and clinical trial participants (Information Systems and Data).

Our cybersecurity risk management program is integrated into our overall risk management processes, and shares common methodologies, reporting channels and governance processes that apply across the risk management program to other legal, compliance, strategic, operational, and financial risk areas. For example, our Cybersecurity Risk Management Committee evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk. Depending on the environment and system, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data.

Key elements of our cybersecurity risk management program include but are not limited to the following:

- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents, and additional cybersecurity policies, including an information security program and acceptable use policy;

- risk assessments of certain environments and systems designed to help identify material risks from cybersecurity threats to our critical systems and information;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security processes;
- cybersecurity awareness training of our employees, including incident response personnel and senior management;
- a third-party risk management process for key service providers based on our assessment of their criticality to our operations and respective risk profile; and
- various other measures, including incident detection and response tools, encryption of certain data, network security for certain environments and systems, access controls for certain environments and systems, data segregation of certain data; physical security, asset management, third-party systems monitoring and cybersecurity insurance.

Additionally, we use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example professional services firms, such as legal counsel, cybersecurity consultants, forensic investigators, and cybersecurity software providers.

We use third-party service providers to perform a variety of functions throughout our business, such as software application providers, hosting companies, and contract research organizations. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider, including reviewing security questionnaires and imposing contractual obligations related to cybersecurity on the provider.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. We face risks from cybersecurity threats, including as a result of any prior cybersecurity incidents, that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. See our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report, including the section titled "*Risk Factors—General risk factors—If our information technology systems, or those of any of our third-party partners (such as contract research organizations and clinical trial sites), or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; additional costs; loss of revenue or profits; and other adverse consequences.*"

Cybersecurity Governance

Our board of directors considers cybersecurity risk as part of its general oversight function and has delegated to the audit committee oversight of cybersecurity risks, including oversight of management's implementation of our cybersecurity risk management program, such as oversight of mitigation of risks from cybersecurity threats. The Cybersecurity Risk Management Committee monitors and evaluates our threat environment and risk profile using various methods including, for example: manual and automated tools in certain environments and systems, subscribing to reports and services that identify certain cybersecurity threats, conducting scans of certain threat environments, evaluating certain cybersecurity threats reported to us, conducting internal and external audits of certain environments and systems, and performing third-party threat assessments.

The audit committee receives periodic reports from management concerning our cybersecurity threats and risks and the processes we have implemented to address them, including during audit committee meetings and other periodic updates. These reports are provided by members of our management team responsible for such reporting, including the Cybersecurity Risk Management Committee. In addition, management updates the audit committee, where it deems appropriate, regarding the cybersecurity incidents it considers to be significant.

The audit committee reports to the full board regarding its activities, including those related to cybersecurity. The full board also regularly receives briefings from management on our cyber risk management program. Board members receive presentations on cybersecurity topics from internal security staff or external experts as part of the board's continuing education on topics that impact public companies.

Our management team, including the Chief Operating Officer, Vice President of Information Technology, Senior Vice President of Legal, and the Head of Cybersecurity, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our management team's experience includes over 29 years of experience in cybersecurity and information technology matters for our Vice President of Information Technology, including multiple senior information technology leadership roles supervising cybersecurity teams and establishing cybersecurity risk assessment

programs in the biotech industry and 28 years of cybersecurity experience for our Head of Cybersecurity, including multiple senior cybersecurity roles.

The Chief Operating Officer is responsible for hiring appropriate personnel and third-party vendors, communicating key priorities to relevant personnel, and, in concert with members of the Cybersecurity Risk Management Committee, helping to integrate cybersecurity risk considerations into our overall risk management strategy. Our Chief Operating Officer, Vice President of Information Technology and Senior Vice President of Legal, in consultation with our third-party information technology team, is responsible for maintaining cybersecurity-related budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our incident response plan is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including the Cybersecurity Risk Management Committee. This group works with our incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response plan includes reporting to the audit committee of the board of directors for certain cybersecurity incidents.

Our management team takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include: briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in our information technology environment.

Item 2. Properties.

Our corporate headquarters are located in Brisbane, California. We occupy approximately 40,232 square feet of office space for our corporate headquarters under a lease that expires in March 2029. We believe our existing leased facility is in good condition and suitable for the conduct of our current business.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. We are not currently a party to any material legal proceedings. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock has traded on the Nasdaq Global Select Market under the symbol "VERA" since May 14, 2021. Prior to that, there was no public market for our stock. Our Class B common stock is not listed on any stock exchange nor traded on any public market.

Holders

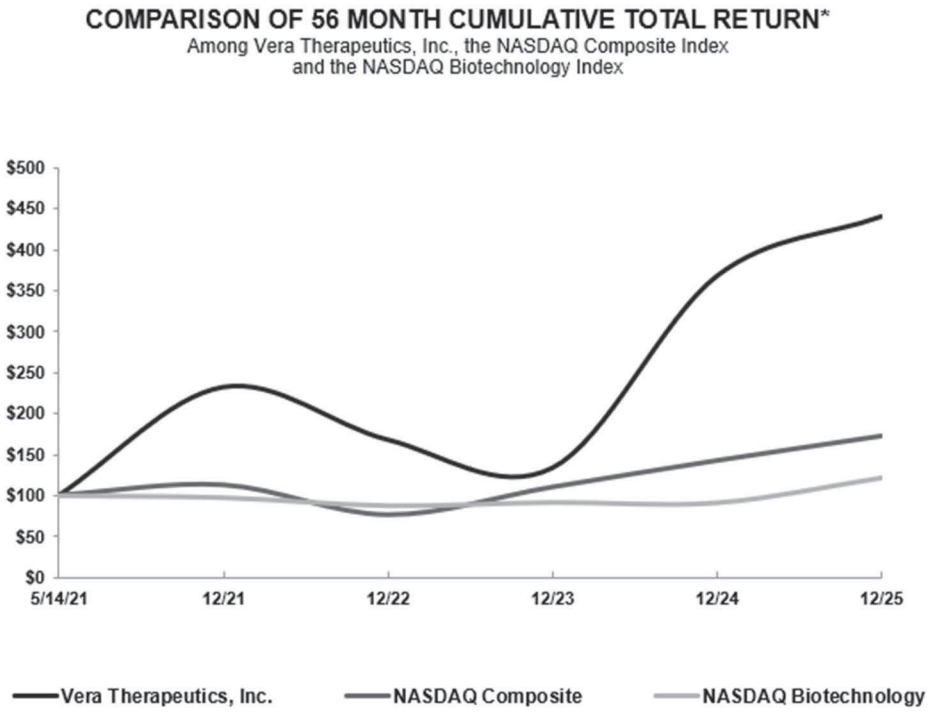
As of February 23, 2026, there were approximately 16 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our common or capital stock. We intend to retain any future earnings for the long-term growth of the business and do not expect to pay cash dividends in the foreseeable future. In addition, the terms of the Loan Agreement with Oxford restrict our ability to declare and pay dividends without the prior written consent of Oxford.

Stock Performance Graph

The following stock performance graph compares our cumulative total stock return with the cumulative total return for (i) the Nasdaq Composite Index, or IXIC, and (ii) the Nasdaq Biotechnology Index, or NBI, for the period from May 14, 2021 (the date when our shares began trading following our initial public offering) through December 31, 2025. The figures represented below assume an investment of $100 in our common stock at the closing price of $11.50 and in the Nasdaq Composite Index and the Nasdaq Biotechnology Index on May 14, 2021 and the reinvestment of dividends into shares of common stock. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of the possible future performance of our common stock. *The information under "Stock Performance Graph" is not deemed to be "soliciting material" or "filed" with the SEC or subject to Regulation 14A or 14C, or to the liabilities of Section 18 of the Exchange Act, and is not to be incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made before or after the date of this Annual Report and irrespective of any general incorporation language in those filings.*



	5/14/2021	12/31/2021	12/31/2022	12/31/2023	12/31/2024	12/31/2025
Vera Therapeutics, Inc. (VERA)	100.00	232.35	168.26	133.74	367.74	440.35
NASDAQ Composite Index (IXIC)	100.00	112.56	75.94	109.83	142.31	172.40
NASDAQ Biotechnology Index (NBI)	100.00	97.67	87.78	91.81	91.29	121.81

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Parties

None.

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 in conjunction with our financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. For a discussion of our financial condition and results of operations for 2024 as compared to 2023, except as set forth below, please refer to Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2024, which discussion is incorporated by reference herein.

In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, beliefs and expectations, and involve risks and uncertainties. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly in the sections titled "Special Note Regarding Forward-Looking Statements" and "Risk Factors."

Overview

We are a late clinical-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases. Our lead product candidate, atacicept, is currently being evaluated for the treatment of immunoglobulin A nephropathy (IgAN) and other autoimmune kidney diseases. Atacicept is a native human TACI-Fc fusion protein that binds both the B-cell activating factor (BAFF) and A proliferation-inducing ligand (APRIL) cytokines and is self-administered subcutaneously at home. We are conducting ORIGIN 3, the pivotal Phase 3 trial of atacicept 150 mg in IgAN. The trial met the primary efficacy endpoint of reduction in proteinuria as measured by 24-hour urine protein-to-creatinine ratio (UPCR) at week 36, where participants treated with atacicept achieved a 46% reduction from baseline in UPCR with a statistically significant and clinically meaningful 42% reduction in UPCR compared to placebo ($p<0.0001$). The incidence of adverse events was generally balanced between the atacicept and placebo groups, with fewer serious adverse events reported with atacicept than placebo, no safety signals indicating immunosuppression, and no deaths in either treatment group. In November 2025, we submitted a Biologics License Application (BLA) for atacicept for the treatment of adults with IgAN to the U.S. Food and Drug Administration (FDA) through the Accelerated Approval Program. On January 7, 2026, the FDA granted priority review to the application and assigned a Prescription Drug User Fee Act (PDUFA) target action date of July 7, 2026. If approved, atacicept would be the first B-cell modulator inhibiting both BAFF and APRIL for IgAN, offering patients an autoinjector for at-home self-administration.

The ORIGIN Phase 2b clinical trial evaluated the safety and efficacy of atacicept in 116 participants with IgAN and reported positive results at 24 weeks in January 2023, 36 weeks in June 2023, and 96 weeks in October 2024. The trial remained blinded through 36 weeks, after which all participants were eligible for the open label extension portion of the study and received atacicept 150 mg through 96 weeks. Atacicept met its primary endpoint at 24 weeks with a statistically significant reduction in UPCR. Through 36 weeks, participants treated with atacicept demonstrated reductions in galactose-deficient IgA1 (Gd-IgA1, the autoantigen produced by B cells in patients with IgAN), hematuria, and UPCR, with stable estimated glomerular filtration rate (eGFR). The improvements in Gd-IgA1, hematuria, UPCR and eGFR represent the quartet of findings consistent with IgAN disease modification. The 96-week open label extension results showed consistent and sustained reductions in Gd-IgA1, hematuria, and UPCR, with continued eGFR stabilization at a rate similar to the general population without kidney disease. Atacicept's safety profile appeared favorable, and comparable to placebo, across the ORIGIN program in IgAN.

We believe that atacicept has pipeline-in-a-molecule potential, with potential application in multiple diseases. Based on data from the ORIGIN Phase 2b trial, the FDA granted Breakthrough Therapy Designation to atacicept for the treatment of IgAN. We have also committed to providing long-term access to atacicept for ORIGIN participants through ORIGIN EXTEND, a long-term Phase 2 extension study that offers atacicept to participants who completed ORIGIN Phase 2b or 3 until, if approved, commercial availability in their country or region. We are evaluating atacicept in other autoimmune kidney diseases, including primary membranous nephropathy (pMN), focal segmental glomerulosclerosis (FSGS) and minimal change disease (MCD), in patients with anti-phospholipase A2 receptor (PLA2R) or anti-nephrin autoantibodies in the Phase 2 PIONEER clinical trial. Potential future indications include anti-neutrophil cytoplasmic antibody-associated vasculitis (AAV), lupus nephritis (LN), Sjogren's disease, systemic lupus erythematosus (SLE), systemic sclerosis, generalized myasthenia gravis, and idiopathic thrombocytopenic purpura.

We also hold worldwide, exclusive development and commercial rights to MAU868, a potentially first-in-class monoclonal antibody to treat reactivated BK virus (BKV) infections, for which we completed a Phase 2 clinical trial in 2022. In January 2025, we acquired worldwide, exclusive development and commercial rights to VT-109, a novel, next-generation dual BAFF/APRIL inhibitor that is in preclinical development. We believe that our current pipeline programs leverage the deep expertise of our team and have strong potential commercial synergies.

We do not have any product candidates approved for commercial sale, and we have not generated any revenue from product sales. Our ability to generate revenue sufficient to achieve profitability, if ever, will depend on the successful development and eventual commercialization of one or more of our product candidates, which we expect will take a number of years. We also do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for nonclinical and clinical testing, as well as for commercial manufacturing if any of our

product candidates obtain marketing approval. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

To date, we have funded our operations primarily through proceeds from the sale of shares of our common stock, redeemable convertible preferred stock, debt financing and convertible promissory notes. As of December 31, 2025, we had $714.6 million in cash, cash equivalents and marketable securities, compared to $640.9 million as of December 31, 2024.

We have incurred significant operating losses since the commencement of our operations. Our net losses were $299.6 million, $152.1 million, and $96.0 million for the years ended December 31, 2025, 2024, and 2023 respectively, and we expect to incur significant and increasing losses for the foreseeable future as we continue to advance our product candidates toward commercialization. Our net losses may fluctuate significantly from period to period, depending on the timing of expenditures on our research and development activities. As of December 31, 2025, we had an accumulated deficit of $760.9 million, compared to $461.3 million as of December 31, 2024. Our primary use of cash is to fund operating expenses, which consist of research and development and general and administrative expenditures. Cash used to fund operating expenses depends on the timing of when we pay these expenses, as reflected in the changes in our working capital balances.

We expect to continue to incur net operating losses for at least the next several years, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. We expect our expenses and capital requirements will increase significantly in connection with our ongoing activities as we:

- initiate or continue nonclinical studies and clinical trials for our product candidates; seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets, and know-how;
- acquire, develop or in-license other product candidates and technologies and further expand our clinical product pipeline;
- attract, develop and retain additional clinical, scientific, quality control, commercial, and manufacturing management and administrative personnel; and
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

We also expect to increase the size of our administrative function to support the growth of our business. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We will require substantial additional funding to develop our product candidates and support our continuing operations. Until such time that we can generate significant revenue from product sales or other sources, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which could include income from collaborations, strategic partnerships, or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to have to delay, reduce or eliminate our product development or future commercialization efforts. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts. We cannot provide assurance that we will ever be profitable or generate positive cash flow from operating activities.

Geopolitical and Macroeconomic Developments

Due to geopolitical and macroeconomic events, including bank failures, tariffs and trade tensions, supply chain challenges, ongoing military conflicts, related sanctions, changes in U.S.-China relations, elevated inflation rates and the responses by central banking authorities to control such inflation, the U.S. and global financial markets experienced volatility, which has led to disruptions to trade, commerce, pricing stability, credit availability and supply chain continuity globally. As a result of these factors and other

geopolitical and macroeconomic developments described in this Annual Report, our business and results of operations may be adversely affected.

Although we did not see a significant financial impact to our business operations as a result of recent geopolitical and macroeconomic developments during the year ended December 31, 2025, there may be potential impacts to our business in the future that are highly uncertain and difficult to predict such as disruptions or restrictions in our supply chain, disruption or restrictions on our employees' ability to travel, disruptions to or delays in ongoing non-clinical trials, clinical trials, third-party manufacturing supply and other operations, interruptions or delays in the operations of the FDA or other regulatory authorities, and continued elevated inflation and interest rates which may increase the cost of conducting business activities or cause changes in availability and cost of credit and impact our ability to raise capital and conduct business development activities. The ultimate impact of these geopolitical and macroeconomic developments, as well as any lasting effects on our business, is highly uncertain and subject to continued change, and we recognize that macroeconomic and geopolitical factors may continue to present unique challenges for us.

We believe that our existing cash, cash equivalents and marketable securities held as of December 31, 2025, will be sufficient to fund our planned operations and capital expenditure requirements for at least the next 12 months from the date of this Annual Report. However, should adverse geopolitical or macroeconomic events, such as those discussed above, any recession or depression associated with those events or other events described herein, continue for a prolonged period, our results of operations, financial condition, liquidity and cash flows could be materially impacted as a result of a lower likelihood of effectively and efficiently developing and successfully commercializing our product candidates.

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.

	Year Ended December 31,		CHANGE	
(dollars in thousands)	2025	2024	AMOUNT	%
Operating expenses:				
Research and development	$ 215,256	$ 126,172	$ 89,084	71%
General and administrative	100,217	40,998	59,219	144%
Total operating expenses	315,473	167,170	148,303	89%
Loss from operations	(315,473)	(167,170)	(148,303)	89%
Other income (expense):				
Interest income	24,479	20,714	3,765	18%
Interest expense	(7,531)	(7,626)	95	(1)%
Other income, net	(1,089)	1,935	(3,024)	(156)%
Total other income	15,859	15,023	836	6%
Loss before provision for income taxes	$ (299,614)	$ (152,147)	$ (147,467)	97%

Research and Development Expenses

Research and development expenses represent a substantial portion of our operating expenses. Our research and development expenses consist primarily of direct and indirect expenses incurred in connection with the research and development of our product candidates. Direct expenses include costs incurred under agreements with third parties, including contract research organizations, contract drug manufacturing organizations and consultants directly related to our research and development of product candidates, and license and milestone fees incurred as a result of our contractual obligations for our development candidates. Indirect expenses include employee compensation and other personnel-related expenses, including stock-based compensation, facilities and depreciation related to buildings and equipment used by research and development personnel and activities and other expenses.

Research and development expenses are recorded as expense in the period in which the related activities occurred, and payments we make prior to the receipt of goods or services to be used in research and development efforts are deferred as prepaid expenses until the goods or services are received and used. We accrue expenses for contract research and development as the related services are performed by monitoring the status of specified activities and billings received from our external service providers. These expenses are accrued based on estimates and are adjusted as actual expenses become known. The cost incurred in obtaining technology licenses, including initial and subsequent milestone payments incurred under our licensing agreements, are recorded as expense in the period in which they are incurred, as the licensed technology, method or process has no alternative future uses other than for our research and development activities. Where contingent milestone payments are due to third parties under license or other agreements, the milestone

payment obligations are recognized as expense when achievement of the contingent milestone is probable, which is generally upon achievement of the milestone.

The following table summarizes our research and development expenses incurred during the respective periods.

	Year Ended December 31,		CHANGE	
(dollars in thousands)	2025	2024	AMOUNT	%
Direct research and development expenses				
Contract drug manufacturing	$ 74,193	$ 50,753	$ 23,440	46%
Clinical trial expenses	46,743	32,279	14,464	45%
Consulting and professional services	26,692	11,339	15,353	135%
Indirect research and development expenses				
Employee compensation and related benefits	62,013	29,048	32,965	113%
Facilities and other	5,615	2,753	2,862	104%
Research and development expenses	$ 215,256	$ 126,172	$ 89,084	71%

Research and development expenses increased by $89.1 million, or 71%, to $215.3 million in the year ended December 31, 2025, from $126.2 million in the year ended December 31, 2024, due to an increase of $23.4 million in contract drug manufacturing costs for clinical and potential commercial use, an increase of $14.5 million in clinical trial expenses due to greater numbers of active sites and completion of enrollment in ORIGIN 3 and expenses incurred for the PIONEER, monthly dose range finding and ORIGIN EXTEND trials, an increase of $15.4 million in consulting and professional services, including a $9.4 million increase in medical affairs and commercial planning expenses as we prepare for potential regulatory approval and commercialization of atacicept, an increase of $33.0 million for employee compensation and related benefit expenses, including a $8.7 million increase in stock-based compensation expense, due to growth in research and development headcount, and an increase of $2.9 million in facilities and other, including a $1.9 million increase in travel expenses to support research and development activities, including travel associated with medical conferences.

We expect our research and development expenses to increase in future periods as we seek regulatory approval of atacicept in IgAN in the U.S. and other markets, conduct additional clinical trials of atacicept, and if we expand development of atacicept in other indications or product configurations, or other product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and personnel-related expenses, including stock-based compensation, for our personnel in executive management, legal, finance, human resources, and other administrative functions. General and administrative expenses also include professional fees paid for accounting, auditing, legal, tax and consulting services, and other general overhead costs to support our operations. General and administrative expenses are recorded as expense in the period in which they are incurred, and payments we make prior to the receipt of goods or services to be used for general and administrative purposes are deferred as prepaid expenses until the goods or services are received and used.

The following table summarizes our general and administrative expenses incurred during the respective periods.

	Year Ended December 31,		CHANGE	
(dollars in thousands)	2025	2024	AMOUNT	%
Employee compensation and related benefits	$ 50,119	$ 19,796	$ 30,323	153%
Rent and facilities	3,111	2,651	460	17%
Legal and accounting services	8,147	4,802	3,345	70%
Consultants, including non-employee director compensation	5,461	3,564	1,897	53%
Commercial planning and medical affairs	19,387	3,248	16,139	497%
Other	13,992	6,937	7,055	102%
General and administrative expenses	$ 100,217	$ 40,998	$ 59,219	144%

General and administrative expenses increased by $59.2 million, or 144%, to $100.2 million in the year ended December 31, 2025, from $41.0 million in the year ended December 31, 2024, due to an increase of $30.3 million in employee compensation and related benefits expenses, including stock-based compensation, as a result of increased general and administrative employee headcount, an increase of $16.1 million in commercial and medical affairs expenses related to market research, market access and health economics activities related to commercialization planning of atacicept, an increase of $3.3 million in legal, accounting, and audit fees, an increase of $1.9 million in consulting expenses, including non-employee director stock-based compensation, an increase of $2.5 million in software expenses, an increase of $1.8 million in corporate communications expenses, and an increase of $1.7 million in business travel expenses.

Other Income, Net

(dollars in thousands)	Year Ended December 31, 2025	2024	CHANGE AMOUNT	%
Other income (expense):				
Interest income	$ 24,479	$ 20,714	$ 3,765	18%
Interest expense	(7,531)	(7,626)	95	(1)%
Other (expense) income, net	(1,089)	1,935	(3,024)	(156)%
Total other income, net	$ 15,859	$ 15,023	$ 836	6%

Total other income, net, increased by $0.8 million, or 6%, to $15.9 million in the year ended December 31, 2025, from $15.0 million in the year ended December 31, 2024, primarily due to an increase of $3.8 million in interest income from an increase in the average balance of marketable securities held during the year ended December 31, 2025 as compared to the year ended December 31, 2024, partially offset by an increase in other expense from $0.8 million in third-party legal and consulting fees and $1.0 million in amortization of deferred debt issuance costs for unfunded loan commitments, both relating to the refinancing of the Oxford credit facility in June 2025, an increase of $0.5 million in foreign exchange loss and a $0.5 million decrease in sublease income due to the expiration of a sublease concurrent with the expiration of the master lease in September 2025.

Liquidity and Capital Resources

To date, we have funded our operations primarily through proceeds from the sale of shares of our common stock, redeemable convertible preferred stock, debt financing and convertible notes. From our inception through December 31, 2025, we have raised aggregate net cash proceeds of approximately $1.3 billion from the issuance and sale of redeemable convertible preferred stock, convertible notes and common stock, and proceeds from our current and former loan agreements. Since the date of our incorporation, we have not generated any revenue from product sales and have incurred substantial operating losses and negative cash flows from operations.

In February 2024, we completed a follow-on public offering and issued 9,274,194 shares of common stock for net proceeds of approximately $269.6 million, after deducting underwriting fees and offering-related expenses. In October 2024, we completed a follow-on public offering and issued 7,142,858 shares of common stock, and in November 2024 we issued an additional 1,071,428 shares of common stock pursuant to the underwriters' full exercise of the 30-day option to purchase additional shares. We received aggregate net proceeds of approximately $323.6 million, after deducting underwriting fees and offering-related expenses. In December 2025, we completed a follow-on public offering and issued 7,058,824 shares of common stock for net proceeds of approximately $281.3 million, after deducting underwriting fees and offering-related expenses.

In June 2025, we entered into an agreement to refinance our existing debt by replacing the existing $50.0 million in notes payable with $75.0 million in new notes payable. We received aggregate net proceeds of approximately $23.3 million, after deducting debt issuance costs.

In August 2025, we entered into a Sales Agreement (Sales Agreement) with TD Securities (USA) LLC (TD Cowen). Under the Sales Agreement, we may offer and sell, from time to time, through TD Cowen as our sales agent and/or principal, shares of our common stock, having an aggregate offering amount of up to $200 million (Shares). We are not obligated to sell any Shares under this agreement. We will pay TD Cowen a commission of up to 3.0% of the gross sales proceeds of any Shares sold through TD Cowen under the Sales Agreement. As of December 31, 2025, no sales had been made under the Sales Agreement.

We use our cash to fund operations, primarily to fund our research and development efforts, clinical trials, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. Cash used to fund operating expenses is affected by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid assets.

We anticipate that we will continue to incur net losses for the foreseeable future as we continue research and development activities of our product candidates, hire additional staff, including clinical, commercial, operational, administrative and management personnel, and incur additional expenses associated with operating as a public company. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our clinical development activities and our product candidate portfolio and prepare for anticipated commercialization of atacicept. We expect that our research and development and general and administrative costs will increase substantially in connection with conducting additional clinical trials for our research programs and product candidates, contracting with third parties to support nonclinical studies and clinical trials, expanding our intellectual property portfolio, scaling up external commercial manufacturing capacity, building a sales, marketing and distribution infrastructure to commercialize any approved product candidates, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources.

As of December 31, 2025, we had cash, cash equivalents and marketable securities of $714.6 million, as compared to $640.9 million as of December 31, 2024. We believe, based on our current operating plan, that our cash, cash equivalents and marketable securities as of December 31, 2025 will be sufficient to fund our planned operations and capital expenditure requirements for at least the next 12 months from the date of this Annual Report.

Cash Flows

The following table summarizes our cash flows for the periods indicated.

	Year Ended December 31,	
(dollars in thousands)	**2025**	**2024**
Net cash used in operating activities	$ (241,104)	$ (134,679)
Net cash provided by (used in) investing activities	194,286	(425,029)
Net cash provided by financing activities	308,897	606,673
Net increase in cash and cash equivalents	$ 262,079	$ 46,965

Operating Activities

For the year ended December 31, 2025, we used $241.1 million of cash in operating activities, attributable to a net loss of $299.6 million, partially offset by non-cash charges of $34.7 million, a decrease in our net operating assets and liabilities of $23.0 million, and license fee payments of $0.8 million. Non-cash charges primarily consisted of $37.9 million of stock-based compensation, non-cash interest income of $7.0 million related to amortization of discount on purchases of marketable securities, and a $1.4 million reduction in the carrying amount of operating lease right-of-use assets, partially offset by $1.9 million net in accretion and amortization of loan exit fees and costs. The change in our net operating assets and liabilities was primarily due to an increase of $13.9 million in accounts payable, an increase of $14.4 million in accrued and other current liabilities, a decrease of $3.9 million in prepaid expenses and other assets, and a decrease of $1.5 million in operating lease liabilities.

For the year ended December 31, 2024, we used $134.7 million of cash in operating activities, attributable to a net loss of $152.1 million, partially offset by non-cash charges of $14.8 million and a decrease in our net operating assets and liabilities of $2.7 million. Non-cash charges primarily consisted of $20.8 million of stock-based compensation, non-cash interest income of $9.0 million related to amortization of discount on purchases of marketable securities, and a $2.1 million reduction in the carrying amount of operating lease right-of-use assets. The change in our net operating assets and liabilities was primarily due to an increase of $7.2 million in accrued and other current liabilities, a decrease of $3.5 million in accounts payable, and a decrease of $2.4 million in operating lease liabilities.

The increase in cash used in operating activities from the year ended December 31, 2024 to the year ended December 31, 2025 was primarily attributable to increased research and development, and general and administrative expenses.

Investing Activities

For the year ended December 31, 2025, our investing activities provided $194.3 million of cash, primarily resulting from the maturity of short-term marketable securities, less purchases of short-term marketable securities during the year.

For the year ended December 31, 2024, our investing activities used $425.0 million of cash, primarily resulting from the purchase of short-term marketable securities, less sales and maturities of short-term marketable securities during the year.

Financing Activities

For the year ended December 31, 2025, our financing activities provided $308.9 million of cash resulting from $300.0 million gross proceeds received from our December 2025 follow-on offering, $23.3 million in net proceeds from borrowings from the initial funding under the 2025 Loan Agreement in June 2025, after repayment of borrowings under the 2021 Loan Agreement, and $7.0 million proceeds from exercise of stock options and issuance of shares under our employee stock purchase plan, less $18.4 million offering costs related to our follow-on offerings including underwriting fees.

For the year ended December 31, 2024, our financing activities provided $606.7 million of cash resulting from $632.5 million gross proceeds received from our February and October 2024 follow-on offerings and $13.4 million proceeds from exercise of stock options and issuance of shares under our employee stock purchase plan, less $39.3 million offering costs related to our follow-on offerings including underwriting fees.

Material Cash Requirements

Our material cash requirements in the short- and long-term consist of the following operational expenditures, a portion of which contain contractual or other obligations.

Our primary uses of cash and operating expenses relate to contract drug manufacturing, clinical trial expenses, commercial launch planning, and paying employees and consultants to support our operations. Our research and development expenses in 2025 were $215.3 million and we expect to increase our investment in research and development expenses in 2026. Our general and administrative expenses were $100.2 million in 2025 and we expect to increase our general and administrative expenses to support our anticipated commercial launch of atacicept in 2026. On a long-term basis, we manage future cash requirements relative to our long-term business plans.

We also enter into agreements in the normal course of business with various third parties for preclinical, clinical and other services. These contracts are generally cancellable without material penalty upon written notice.

Operating costs also relate to our building leases for our office. Our operating lease obligations reflect those for our corporate headquarters office space in Brisbane, California. In August 2024, we entered into a non-cancellable operating lease for 40,232 square feet of office space in Brisbane, California, that has served as our corporate headquarters since November 2024. The term of this lease is 54 months.

Our future minimum lease payments as of December 31, 2025 were $3.0 million. Refer to Note 5 in the Notes to Financial Statements in Item 8 for further detail of our lease obligations.

2021 Loan Agreement

On December 17, 2021, we entered into the 2021 Loan Agreement. The 2021 Loan Agreement provided for term loans (collectively, the Loan) in an aggregate maximum principal amount of $50.0 million, of which $5.0 million was funded on December 17, 2021, $20.0 million was funded on November 4, 2022, and the remaining $25.0 million was funded in December 2023.

In March 2023, we opted to extend the final maturity date of the Loan from December 2026 to December 2027, based on positive Phase 2b clinical trial data of atacicept in IgAN, as provided in the 2021 Loan Agreement. We were required to make monthly interest-only payments for 60 months followed by full amortization through maturity.

In June 2025, the Company refinanced its debt under the 2021 Loan Agreement by entering into a new non-revolving loan and security agreement, the proceeds of which were partially used to prepay the outstanding principal balance of the 2021 Loan Agreement in full. As a result, the Company no longer has any contractual obligations and commitments under the 2021 Loan Agreement, which were previously described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the Annual Report.

2025 Loan Agreement

On June 2, 2025, we entered into the 2025 Loan Agreement. The 2025 Loan Agreement provides for term loans (collectively, 2025 Loan) in an aggregate maximum principal amount of $500.0 million, of which $75.0 million was funded on June 4, 2025.

The 2025 Loan Agreement is scheduled to mature in June 2030, but the maturity date can be extended based on achievement of a revenue-based interest-only extension milestone as of the end of the initial interest-only period in August 2029. If the Company achieves this interest-only extension milestone, the maturity date and the end of the interest-only period will be extended to June 2031 and August 2030, respectively. We are required to make monthly interest-only payments for 49 months (or 61 months upon achievement of the revenue-based interest-only extension milestone mentioned above) followed by full amortization through maturity.

The 2025 Loan incurs interest at a floating per annum rate (based on the actual number of days elapsed divided by a year of 360 days) equal to the sum of (a) the greater of (i) the 1-Month CME Term Secured Overnight Financing Rate (SOFR) and (ii) 3.75%, plus (b) 4.95%.

We are permitted to prepay the 2025 Loan in full or in part at any time upon 10 business days’ written notice to Oxford, subject to payment of the applicable Prepayment Fee (as defined below). Upon the earlier of the maturity date, acceleration of the 2025 Loan or prepayment of the 2025 Loan, we are required to make a final payment equal to 5.0% of the aggregate principal amount of the 2025 Loan (Final Fee). Any prepayments of the 2025 Loan must be accompanied by (a) accrued and unpaid interest thereon, (b) the Final Fee and (c) prepayment fee of (i) 2.0% of the portion of the 2025 Loan being prepaid if the repayment is on or before June 4, 2027 or (ii) 1.0% of the portion of the 2025 Loan being prepaid if the repayment is after June 4, 2027 through June 4, 2028. There is no Prepayment Fee for any prepayments occurring after June 4, 2028.

Our obligations under the 2025 Loan Agreement are secured by a security interest in substantially all of our assets, other than our intellectual property, which is subject to a negative pledge. The 2025 Loan Agreement contains two financial related covenants. Also included in the 2025 Loan Agreement are customary representations and covenants that, subject to exceptions, restrict our ability to, among other things: declare dividends or redeem or repurchase equity interests; incur additional liens; make loans and investments; incur additional indebtedness; engage in mergers, acquisitions, and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that are not related to our existing business.

Upon the occurrence of an event of default, a default interest rate of an additional 4.0% may be applied to the outstanding loan

balances, and Oxford may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the 2025 Loan Agreement. Events of default under the 2025 Loan Agreement include customary events of default, including, but not limited to: (i) non-payment; (ii) failure to perform any obligation under the 2025 Loan Agreement and related documents; (iii) the occurrence of a material adverse change; (iv) bankruptcy and other insolvency events; (v) cross-defaults; and (vi) judgment defaults.

Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these 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 financial statements, as well as expenses incurred during the reporting periods. Our estimates are based on our historical experience and on 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 that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

While our significant accounting policies are described in the notes to our financial statements, we believe that the following critical accounting policies and estimates are most important to understanding and evaluating our reported financial results.

Research and development contract costs, and related prepaid and accrued balances

We enter into various research and development and other agreements with commercial firms, researchers and others for provision of goods and services from time to time. These agreements are generally cancellable, and the related costs are recorded as incurred.

We estimate clinical trial expenses based on the services performed pursuant to contracts with clinical research organizations that conduct and manage clinical trials on our behalf. We also estimate manufacturing costs based on services performed pursuant to contracts with contract manufacturing organizations that develop and manufacture product on our behalf. In accruing service fees, we estimate the period over which services will be performed. These estimates are based on our communications with the third-party service providers and on information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies significantly from the estimate, we adjust the accrual accordingly to reflect the best information available at the time. When evaluating the adequacy of the accrued liabilities, we analyze progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Judgments and estimates are made in determining the prepaid and accrued balances at the end of the reporting period. Actual results may differ from our estimates. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

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

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. As of December 31, 2024 and December 31, 2025, we had cash, cash equivalents, and marketable securities of $640.9 million and $714.6 million, respectively, consisting primarily of money market funds, U.S. government bonds, and corporate debt securities.

Our primary exposure to market risk is interest rate sensitivity in our fixed income portfolio, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investment portfolio, an immediate 100 basis point change in interest rates as of December 31, 2024 and December 31, 2025 would not have a material effect on the fair market value of our cash, cash equivalents, and marketable securities. We have the ability to hold our investments until maturity, and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investment portfolio.

We are also exposed to interest rate risk in connection to our borrowings under our 2025 Loan Agreement with Oxford. As of December 31, 2025, we had $75.0 million of outstanding borrowings under the 2025 Loan Agreement. Pursuant to the 2025 Loan Agreement, outstanding indebtedness under the term loan bears interest at a per annum rate equal to the sum of (a) the greater of (i) the 1-Month CME Term SOFR (Term SOFR) and (ii) 3.75%, plus (b) 4.95%. We currently do not engage in any interest rate hedging activity, and we have no intention to do so in the foreseeable future. Based on the current interest rate of the term loan and the scheduled payments thereunder, we do not believe a 1.0% increase in the Term SOFR would have a material impact on our financial condition or results of operations. For more information regarding the 2025 Loan Agreement, see Note 6, Notes Payable, to our audited financial statements.

Financial Institution Risk

Substantially all of our cash is held with a single financial institution. Due to its size, this financial institution represents a minimal credit risk. Cash amounts held at financial institutions are insured by the Federal Deposit Insurance Corporation up to $250,000 per depositor, per financial institution.

Foreign Currency Exchange Risk

We are also exposed to market risk related to changes in foreign currency exchange rates, including recent changes resulting from monetary policies set by the U.S. and international central banks, inflationary pressures, and geopolitical developments, or instability or volatility in the global markets. From time to time, we contract with vendors that are located in Asia and Europe and whose balances due are denominated in foreign currencies. We are subject to fluctuations in foreign exchange rates in connection with these agreements. The volatility of exchange rates depends on many factors that we cannot forecast with reliable accuracy. We do not currently hedge our foreign currency exchange rate risk. As of December 31, 2025 and 2024, we held limited funds and future obligations denominated in foreign currencies. As such, a 10.0% increase or decrease in current exchange rates would not have a material effect on our financial results.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor, pricing of contracts for clinical trial and manufacturing costs, and indirectly, interest rates. We do not believe that inflation has had a material effect on our business, financial condition, or results of operations during the periods presented.

Item 8. Financial Statements and Supplementary Data.

VERA THERAPEUTICS, INC.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors
Vera Therapeutics, Inc.:

Opinions on the Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying balance sheets of Vera Therapeutics, Inc. (the Company) as of December 31, 2025 and 2024, the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2025, and the related notes (collectively, the financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In our opinion, the financial statements referred to above 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 each of the years in the three-year period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025 based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Basis for Opinions

The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's financial statements and an opinion on the Company's internal control over financial reporting 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 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 financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the financial statements included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control Over Financial Reporting

A company's 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for the debt refinancing

As discussed in Note 6 to the consolidated financial statements, on June 2, 2025, the Company entered into a new non-revolving loan and security agreement with a loan syndicate (debt refinancing agreement). The new agreement has a total borrowing capacity of up to $500.0 million, the proceeds of which were partially used to prepay the outstanding principal balance on the 2021 Loan Agreement (the debt refinancing). The Company evaluated the accounting treatment for the loan syndicate on a creditor-by-creditor basis. With respect to the continuing creditors, the Company accounted for this transaction as a loan modification, and with respect to the new lender, the Company accounted for this transaction as an issuance of debt.

We identified the evaluation of the accounting for the debt refinancing as a critical audit matter. Complex auditor judgment was required to evaluate the terms and provisions of the debt refinancing agreement in order to assess the appropriateness of the Company's application of the accounting guidance. Additionally, the audit effort associated with the evaluation of the Company's accounting for the debt refinancing required the involvement of professionals with specialized skills and knowledge.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of an control related to the Company's evaluation of the appropriate accounting guidance and technical accounting assessment for non-routine transactions. We read the debt refinancing agreement to understand the relevant terms and conditions of the transaction. We inspected the Company's accounting analysis for the transaction. We involved professionals with specialized skills and knowledge, who assisted in identifying and evaluating the key terms and provisions of the debt refinancing agreement and evaluating the Company's application of the relevant accounting literature in accounting for the debt refinancing.

/s/ KPMG LLP

We have served as the Company's auditor since 2018.

San Francisco, California
February 26, 2026

VERA THERAPEUTICS, INC.
Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 354,725	$ 92,646
Marketable securities	359,864	548,206
Prepaid expenses and other assets, current	14,294	10,366
Total current assets	728,883	651,218
Property and equipment, net	1,374	960
Operating lease right-of-use assets	1,923	3,372
Prepaid expenses and other assets, noncurrent	2,553	131
Total assets	$ 734,733	$ 655,681
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 21,898	$ 7,665
Operating lease liabilities	549	1,483
Accrued expenses and other liabilities	31,008	16,223
Total current liabilities	53,455	25,371
Long-term debt	74,838	50,687
Operating lease liabilities, noncurrent	1,919	2,468
Total liabilities	130,212	78,526
Stockholders' equity		
Class A common stock, $0.001 par value; 500,000,000 shares authorized as of December 31, 2025 and December 31, 2024; 71,267,429 and 63,559,858 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	71	64
Additional paid-in capital	1,364,529	1,037,948
Accumulated other comprehensive income	786	393
Accumulated deficit	(760,865)	(461,250)
Total stockholders' equity	604,521	577,155
Total liabilities and stockholders' equity	$ 734,733	$ 655,681

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

VERA THERAPEUTICS, INC.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2025	2024	2023
Operating expenses:			
Research and development	$ 215,256	$ 126,172	$ 78,225
General and administrative	100,217	40,998	23,787
Total operating expenses	315,473	167,170	102,012
Loss from operations	(315,473)	(167,170)	(102,012)
Other income (expense):			
Interest income	24,479	20,714	7,979
Interest expense	(7,531)	(7,626)	(3,786)
Other (expense) income, net	(1,089)	1,935	1,830
Total other income, net	15,859	15,023	6,023
Loss before provision for income taxes	(299,614)	(152,147)	(95,989)
Provision for income taxes	(1)	(1)	(1)
Net loss	$ (299,615)	$ (152,148)	$ (95,990)
Other comprehensive loss:			
Change in fair value on marketable securities	393	142	251
Comprehensive loss	$ (299,222)	$ (152,006)	$ (95,739)
Net loss per share attributable to common stockholders, basic and diluted	$ (4.66)	$ (2.75)	$ (2.25)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	64,233,814	55,326,680	42,707,072

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

VERA THERAPEUTICS, INC.
Statements of Stockholders' Equity
(in thousands, except share amounts)

	Class A Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances as of December 31, 2022	**27,800,861**	**$ 28**	**$ 290,216**	**$ (224)**	**$ (213,112)**	**$ 76,908**
Issuance of common stock from underwritten follow-on offering, net of offering costs	16,428,572	16	107,727	—	—	107,743
Issuance of common stock pursuant to exercise of options	111,927	—	781	—	—	781
Issuance of common stock upon vesting of restricted stock units	66,321	—	—	—	—	—
Issuance of common stock pursuant to employee stock purchase plan	44,480	—	275	—	—	275
Stock-based compensation	—	—	11,493	—	—	11,493
Unrealized gain on marketable securities	—	—	—	475	—	475
Net loss	—	—	—	—	(95,990)	(95,990)
Balances as of December 31, 2023	**44,452,161**	**$ 44**	**$ 410,492**	**$ 251**	**$ (309,102)**	**$ 101,685**
Issuance of common stock from underwritten follow-on offering, net of offering costs	17,488,480	18	593,219	—	—	593,237
Issuance of common stock pursuant to exercise of options	1,486,314	2	12,866	—	—	12,868
Issuance of common stock upon vesting of restricted stock units	108,409	—	—	—	—	—
Issuance of common stock pursuant to employee stock purchase plan	28,944	—	545	—	—	545
Proceeds from short swing settlement	—	—	37	—	—	37
Repurchase of common stock	(4,450)	—	(13)	—	—	(13)
Stock-based compensation	—	—	20,802	—	—	20,802
Unrealized gain on marketable securities	—	—	—	142	—	142
Net loss	—	—	—	—	(152,148)	(152,148)
Balances as of December 31, 2024	**63,559,858**	**$ 64**	**$ 1,037,948**	**$ 393**	**$ (461,250)**	**$ 577,155**
Issuance of common stock from underwritten follow-on offering, net of offering costs	7,058,824	7	281,174	—	—	281,181
Issuance of common stock pursuant to exercise of options	429,571	—	5,664	—	—	5,664
Issuance of common stock upon vesting of restricted stock units	157,838	—	—	—	—	—
Issuance of common stock pursuant to employee stock purchase plan	61,338	—	1,317	—	—	1,317
Proceeds from short swing settlement	—	—	500	—	—	500
Stock-based compensation	—	—	37,926	—	—	37,926
Unrealized gain on marketable securities	—	—	—	393	—	393
Net loss	—	—	—	—	(299,615)	(299,615)
Balances as of December 31, 2025	**71,267,429**	**$ 71**	**$ 1,364,529**	**$ 786**	**$ (760,865)**	**$ 604,521**

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

VERA THERAPEUTICS, INC.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2025	2024	2023
Cash flows from operating activities			
Net loss	$ (299,615)	$ (152,148)	$ (95,990)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	468	105	21
Accretion of discount and amortization of premium on debt securities, net	(6,981)	(8,972)	(4,433)
Accretion of loan exit fee and amortization of loan costs, net	1,857	810	326
Reduction in the carrying amount of operating lease right-of-use assets	1,449	2,064	2,224
Stock-based compensation	37,926	20,802	11,493
Payment of VT-109 license fee	800	—	—
Changes in operating assets and liabilities:			
Prepaid expense and other current assets	(3,928)	981	173
Other assets	51	351	(262)
Accounts payable	13,910	(3,453)	(873)
Accrued and other current liabilities	14,442	7,188	(2,215)
Operating lease liabilities	(1,483)	(2,407)	(2,645)
Net cash used in operating activities	(241,104)	(134,679)	(92,181)
Cash flows from investing activities			
Payment of VT-109 license fee	(800)	—	—
Purchase of property and equipment	(630)	(972)	(63)
Purchase of marketable securities	(310,446)	(703,015)	(224,930)
Proceeds from maturities of marketable securities	506,162	274,958	176,019
Proceeds from sale of marketable securities	—	4,000	9,543
Net cash provided by (used in) investing activities	194,286	(425,029)	(39,431)
Cash flows from financing activities			
Proceeds from exercise of stock options and employee stock purchase plan	6,981	13,413	1,056
Proceeds from refinancing under loan and security agreement, net	23,338	—	—
Payment of deferred issuance costs related to unfunded loan commitments	(3,517)	—	
Proceeds from short swing settlement	500	37	—
Proceeds from borrowings, net of costs	—	—	24,741
Repurchase of common stock	—	(13)	—
Proceeds from issuance of common stock in follow-on offerings	300,000	632,500	115,000
Payment of issuance costs and underwriting fees related to follow-on offerings	(18,405)	(39,264)	(7,256)
Net cash provided by financing activities	308,897	606,673	133,541
Net increase in cash and cash equivalents	262,079	46,965	1,929
Cash and cash equivalents, beginning of year	92,646	45,681	43,752
Cash and cash equivalents, end of year	$ 354,725	$ 92,646	$ 45,681
Supplemental disclosure of cash flow information			
Cash paid for interest expense	$ 6,720	$ 6,652	$ 3,352
Purchases of property and equipment included in accounts payable	$ 252	$ —	$ —
Follow-on offering costs included in accounts payable	$ 71	$ —	$ —
Follow-on offering costs included in accrued and other liabilities	$ 343	$ —	$ —

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

1. ORGANIZATION AND DESCRIPTION OF THE BUSINESS

Description of Business

Vera Therapeutics, Inc. (the Company) is a clinical stage biotechnology company focused on developing and commercializing treatments for patients with serious immunological diseases. The Company was incorporated in May 2016 in Delaware. The Company's headquarters are in Brisbane, California. The Company operates in one segment, Therapeutics, focused on developing and commercializing transformative treatments for patients with serious immunological diseases.

Liquidity

Since inception, the Company devoted substantially all of its resources to its research and development efforts, pre-clinical studies and clinical trials, building a sales, marketing and distribution infrastructure to support anticipated commercial launch activities, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. The Company has incurred recurring net operating losses and has not generated positive cash flows from operations since its inception and had an accumulated deficit of $760.9 million as of December 31, 2025. The Company had cash, cash equivalents and marketable securities of $714.6 million as of December 31, 2025. The Company has funded its operations primarily through the issuance of common stock, redeemable convertible preferred stock, debt financing and convertible notes. Management expects to continue to incur losses and negative cash flows from operations for at least the next several years.

Management believes that the Company's cash, cash equivalents and marketable securities as of December 31, 2025 will be sufficient to fund its planned operations and capital expenditure requirements for at least the next 12 months subsequent to the issuance date of these financial statements. The Company intends to raise additional capital through public or private equity offerings, debt financing, or other capital sources, which may include strategic collaborations or other arrangements with third parties in order to achieve its long-term business objectives. If the Company fails to obtain necessary capital when needed on acceptable terms, or at all, it could force the Company to delay, limit, reduce or terminate its product development programs, commercialization efforts or other operations.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP) and applicable rules and regulations of the Securities and Exchange Commission (SEC) regarding financial reporting. The U.S. dollar is the Company's functional and reporting currency.

Use of Estimates

The preparation of the Company's financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Management estimates that affect the reported amounts of assets and liabilities include the accrual of research and development expenses, valuation of equity awards for stock-based compensation, determination of incremental borrowing rate for operating leases, the valuation allowance for deferred tax assets, and fair value of marketable securities. The Company evaluates and adjusts its estimates and assumptions on an ongoing basis using historical experience and other factors. Actual results could differ from those estimates.

Concentrations of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company maintains bank deposits in federally insured financial institutions and these deposits may exceed federally insured limits. The Company is exposed to credit risk in the event of default by the financial institution holding its cash, cash equivalents, and marketable securities to the extent recorded in the balance sheet. The Company has not experienced any losses to date related to these concentrations.

The Company's future results of operations involve a number of other risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's current and

potential future product candidates, uncertainty of market acceptance of the Company's product candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals or sole-source suppliers. The Company relies on one supply chain for each of its product candidates. If any of the single source suppliers in any of the supply chains fails to satisfy the Company's requirements on a timely basis, it could suffer delays in its clinical development programs and activities, which could adversely affect operating results.

The Company's product candidates require approvals from the U.S. Food and Drug Administration and comparable foreign regulatory authorities prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed, or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash on deposit with financial institutions and highly liquid investments, primarily money market funds, with maturities of 90 days or less from the date of purchase.

Marketable Securities

The Company holds investments in marketable securities, consisting of U.S. government bonds, U.S. government agency securities, and investment grade corporate debt securities. Marketable debt securities with stated maturities of three months or less from the date of purchase are classified as cash equivalents and those with stated maturities of greater than three months as marketable securities on the balance sheet. The Company determines the appropriate classification of marketable debt securities at the time of purchase. The Company has the ability, if necessary, to liquidate its investments to meet its liquidity needs in the next 12 months, without significant penalty. Accordingly, those investments with contractual maturities greater than one year from the date of purchase are classified as current assets on the accompanying balance sheets. All marketable debt securities are classified as available-for-sale and are reported at estimated fair value, with unrealized gains and losses recorded in accumulated other comprehensive income within stockholders' equity. Interest, amortization and accretion of purchase premiums and discounts on marketable debt securities are included in other (expense) income, net, in the statements of operations and comprehensive loss.

The cost of available-for-sale marketable securities sold is based on the specific identification method. Realized gains and losses on the sale of available-for-sale marketable securities are recorded in other (expense) income, net in the statements of operations and comprehensive loss.

The Company periodically reviews marketable debt securities for impairment. For debt securities in an unrealized loss position, the Company determines whether a credit loss exists. The credit loss is estimated by considering available information relevant to the collectability of the security and information about past events, current conditions, and reasonable and supportable forecasts. Any decline in fair value due to a credit loss is recorded in other (expense) income, net in the statements of operations and comprehensive loss. Unrealized losses due to factors other than the credit loss are recognized in accumulated other comprehensive income (loss). In addition, if the Company has the intent to sell a debt security or it is more likely than not that the Company will be required to sell the security before recovery of the entire cost basis, an impairment charge equal to the difference between fair value and the cost basis is recorded in other (expense) income, net in the statements of operations and comprehensive loss. No impairment loss was recognized for the fiscal years ended December 31, 2025 and 2024.

The amortized or accreted cost basis of the marketable securities approximates its fair value.

Leases

The Company leases office space under operating leases and determines if the arrangement is a lease at inception. These lease agreements generally contain lease and non-lease components. Non-lease components primarily include fixed payments for maintenance, utilities, and management fees. The fixed costs of the lease components and associated non-lease components are combined and accounted together as a single lease component which is recognized as an increase to the operating lease right-of-use (ROU) assets and operating lease liabilities. For leases with a lease term of 12 months or less, ROU assets and lease liabilities are not recognized on the balance sheets.

Certain lease agreements may also contain variable payments, such as common area maintenance, real estate taxes, and insurance, which are expensed as incurred and not included in the lease ROU assets and lease liabilities. Operating lease cost (excluding variable lease costs) is recognized on a straight-line basis over the lease term.

ROU assets and lease liabilities are recognized at the present value of future lease payments at the lease commencement date. As the rate implicit in the Company's leases is not readily determinable, the Company uses an incremental borrowing rate based on information available at commencement date in determining the present value of future lease payments. The incremental borrowing rate is the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

Operating lease ROU assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make the contractual lease payments over the lease term. The current portion of operating lease liabilities is included in current liabilities, and the long-term portion is included in operating lease liabilities, noncurrent.

Foreign Currency Translations

Transactions denominated in foreign currencies are initially measured in U.S. dollars using the exchange rate on the date of the transaction. Foreign currency denominated monetary assets and liabilities are subsequently re-measured at the end of each reporting period using the exchange rate at that date, with the corresponding foreign currency transaction gain or loss recorded in the statements of operations and statements of cash flows. Nonmonetary assets and liabilities are not subsequently re-measured.

Fair Value Measurements

Fair value is defined as the exchange price to sell an asset or transfer a liability (exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Fair value should be based on the assumptions market participants would use when pricing the asset or liability. The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability as of the measurement date.

Fair value measurements are classified and disclosed in one of the following three categories:

Level 1 – Quoted unadjusted prices for identical instruments in active markets.

Level 2 – Quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-derived valuations in which all significant inputs and value drivers are observable in active markets.

Level 3 – Model derived valuations in which one or more significant inputs or significant value drivers are unobservable, including assumptions developed by the Company.

Fair value accounting is applied to all financial assets and liabilities that are recognized or disclosed in the financial statements on a recurring basis. The Company's financial instruments consist of cash and cash equivalents, marketable securities, prepaid expenses and other current assets, accounts payable and accrued expenses and long-term debt. Cash and marketable securities are reported at their respective fair values on the Company's balance sheets. The carrying amount of long-term debt approximates fair value due to its variable interest rate. The remaining financial instruments are reported on the Company's balance sheets at cost, which approximates their fair value due to their short-term nature.

Money market funds are highly liquid investments that are actively traded. The pricing information for the Company's money market funds is readily available and can be independently validated as of the measurement date. This approach results in the classification of these instruments as Level 1 within the fair value hierarchy.

There were no transfers of financial assets or liabilities between Levels 1, 2, or 3 for any of the periods presented.

Comprehensive Loss

Comprehensive loss consists of two components: net loss and other comprehensive income. Other comprehensive income refers to unrealized gains and losses that are recorded as an element of stockholders' equity and are excluded from net loss. For the years ended December 31, 2025, 2024, and 2023, other comprehensive income consists of unrealized gains and losses on marketable securities.

Research and Development Costs

Research and development costs are expensed as incurred and consist primarily of employees' salaries and related benefits, including stock-based compensation for employees engaged in research and development efforts, allocated overhead including rent, depreciation, information technology and utilities, contracted services, license fees, and external expenses to conduct and support the Company's operations that are directly attributable to the Company's research and development efforts. Payments made to third parties under these arrangements in advance of the performance of the related services by the third parties are recorded as prepaid expenses until the services are rendered.

Costs incurred in obtaining technology licenses including upfront and milestone payments incurred under the Company's licensing agreements are recorded as expense in the period in which they are incurred, provided that the licensed technology, method or process has no alternative future uses other than for the Company's research and development activities. Where contingent milestone payments are due to third parties under license or other agreements, the milestone payment obligations are recognized as expense when achievement of the contingent milestone is probable, which is generally upon achievement of the milestone.

The Company enters into various research and development and other agreements with commercial firms, researchers, and others for provisions of goods and services from time to time. These agreements are generally cancellable, and the related costs are recorded as

research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Judgments and estimates are made to determine the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

Stock-Based Compensation

The Company recognizes compensation expense based on estimated fair values for all stock-based payment awards made to the Company's employees, nonemployee directors and consultants that are expected to vest. The valuation of stock option awards is determined at the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the Company to make assumptions and judgments about the inputs used in the calculations, such as the fair value of the common stock, expected term, expected volatility of the Company's common stock, risk-free interest rate and expected dividend yield. The valuation of restricted stock awards is measured by the fair value of the Company's Class A common stock on the date of the grant.

For all stock options granted, the Company calculated the expected term using the simplified method (derived from the average midpoint between the weighted average vesting period and the contractual term of the award), as the Company has limited historical information to develop expectations about future exercise patterns and post-vesting employment termination behavior. The estimate of expected volatility is based on comparative companies' volatility. The risk-free rate is based on the yield available on United States Treasury zero-coupon issues corresponding to the expected term of the award. The Company records forfeitures when they occur. The Company determines the fair value of its Class A common stock using the market closing price on the date of grant.

The Company records compensation expense for service-based awards on a straight-line basis over the requisite service period, which is generally the vesting period of the award. The amount of stock-based compensation expense recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect tax rates expected to be in effect for the years in which the differences are expected to be reversed. A valuation allowance is provided if it is more likely than not that some or all of the deferred tax assets will not be realized.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, adjusted for outstanding shares that are subject to repurchase.

Diluted net loss per share is computed by giving effect to all potentially dilutive securities outstanding for the period using the treasury stock method or the if-converted method based on the nature of such securities. For periods in which the Company reports net losses, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, because potentially dilutive shares are not assumed to have been issued if their effect is anti-dilutive.

Recently Adopted Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board (FASB) issued ASU 2023-09, Improvements to Income Tax Disclosures (Topic 740). The ASU is intended to enhance the transparency and decision usefulness of income tax disclosures in response to investor requests. The amendments in ASU 2023-09 address these requests primarily through changes to the effective tax rate reconciliation, disaggregation of income taxes paid, and certain additional income tax-related disclosures. The guidance is effective for annual reporting periods beginning after December 15, 2024, with early adoption permitted. The Company adopted this standard effective January 1, 2025 using a retrospective approach, and it did not have a material impact on the Company's financial statements or related disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

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. This update will improve disclosures about a public business entity's expenses and address requests from investors for more detailed information about the types of expenses (including purchases of inventory, employee compensation, depreciation, amortization, and depletion) in commonly presented expense captions (such as cost of sales, selling, general, and administrative expenses, and research and development). The ASU is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company will adopt the standard as of and for the year ending December 31, 2027 and for the interim

reporting periods within the year ending December 31, 2028. This ASU will result in the required additional disclosures being included in the Company's financial statements upon adoption.

In July 2025, the FASB issued ASU 2025-05, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets. This update will provide all entities with a practical expedient in developing reasonable and supportable forecasts as part of estimating expected credit losses by assuming that current conditions as of the balance sheet date do not change for the remaining life of the asset. The ASU is effective for annual reporting periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods, with early adoption permitted in both interim and annual reporting periods for which financial statements have not yet been issued or made available for issuance. The Company will adopt the standard as of and for the year ending December 31, 2026 and interim periods within that period, starting with the first quarter of 2026. The Company does not expect that the adoption of this standard will have a material impact on its financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-06, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software. This update will introduce changes to the timing of software cost capitalization based on likelihood of completion for all entities subject to the internal-use software guidance in Subtopic 350-40 and the guidance on website development costs in Subtopic 350-50. The ASU will be effective for annual reporting periods beginning after December 15, 2027, and interim reporting periods within those annual reporting periods, with early adoption permitted as of the beginning of an annual reporting period. The Company is currently evaluating the timing of adoption and the impact of adoption on its financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, Interim Reporting (Topic 270): Narrow Scope Improvements. This update will improve the navigability of required interim disclosures and clarify when that guidance is applicable, and will require entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. The ASU will be effective for interim periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The Company will adopt the standard for the interim periods within the year ending December 31, 2028. The Company is currently evaluating the impact of the adoption on its financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-12, Codification Improvements. This update will make a number of amendments to the Accounting Standards Codification and improvements to GAAP arising from technical corrections, unintended application of the Codification, clarifications, and other minor improvements. The ASU will be effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods, with early adoption permitted in both interim and annual reporting periods for which financial statements have not yet been issued or made available for issuance. Entities may elect to early adopt the amendments on an issue-by-issue basis. The Company is currently evaluating the timing of adoption and the impact of adoption on its financial statements and related disclosures.

Income Taxes

On July 4, 2025, President Trump signed "An Act to provide for reconciliation pursuant to title II of H. Con. Res. 14," commonly referred to as the "One Big Beautiful Bill Act" (OBBB), into law. The OBBB makes key elements of the Tax Cuts and Jobs Act permanent, including 100% bonus depreciation and domestic research cost expensing, and raises the limit on business interest expense deductions. Accounting Standards Codification Topic No. 740, Income Taxes, requires that the Company recognize the effects of changes in tax rates and laws in the period in which the legislation is enacted. In accordance with GAAP, the Company accounted for the effects of the changes in the tax law in the year ended December 31, 2025. The OBBB did not have a material impact on the Company's effective income tax rate for the year ended December 31, 2025.

3. OTHER FINANCIAL STATEMENT INFORMATION

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2025	2024
Prepaid clinical trial costs	$ 3,435	$ 2,228
Interest income receivable	3,285	3,773
Prepaid software costs	1,669	660
Prepaid drug manufacturing costs	1,637	21
Prepaid professional services fees	838	659
Prepaid insurance	536	709
Prepaid commercial planning costs	359	933
Other	2,535	1,383
Total prepaid expenses and other current assets	$ 14,294	$ 10,366

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following *(in thousands)*:

	December 31,	
	2025	2024
Accrued payroll	$ 18,700	$ 6,822
Accrued drug manufacturing costs	8,424	3,059
Accrued clinical trial costs	1,333	3,683
Accrued commercial expenses	1,181	689
Related party payable	3	217
Other	1,367	1,753
Total accrued expenses and other current liabilities	$ 31,008	$ 16,223

4. CASH, CASH EQUIVALENTS, AND MARKETABLE SECURITIES

The Company's cash equivalents and available-for-sale investment securities are classified within the fair value hierarchy as defined by authoritative guidance. Level 1 securities consist of highly liquid money market funds for which the carrying amount approximates the fair value of identical assets as quoted in the active markets. Level 2 securities, consisting of U.S. Treasuries, U.S. agency securities and corporate debt securities, are measured based on other observable inputs, including broker or dealer quotations or other valuations using observable market data. The Company's debt securities are accounted for as available-for-sale securities.

Unrealized gains and losses are reported as a component of other comprehensive income (loss). Fair value of the debt securities was $367.1 million and $552.8 million as of December 31, 2025 and 2024, respectively.

The following table presents the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy *(in thousands)*:

	December 31, 2025						
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Money market funds	Level 1	$ 342,915	$ —	$ —	$ 342,915	$ 342,915	$ —
U.S. Government bonds	Level 2	166,736	480	—	167,216	—	167,216
U.S. Government agency securities	Level 2	9,997	1	(23)	9,975	—	9,975
Corporate debt securities	Level 2	189,536	329	(1)	189,864	7,191	182,673
Total cash equivalents and marketable securities		709,184	810	(24)	709,970	350,106	359,864
Cash		4,619	—	—	4,619	4,619	—
Total		$ 713,803	$ 810	$ (24)	$ 714,589	$ 354,725	$ 359,864

	December 31, 2024						
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Money market funds	Level 1	$ 85,135	$ —	$ —	$ 85,135	$ 85,135	$ —
U.S. Government bonds	Level 2	322,960	389	(16)	323,333	—	323,333
U.S. Government agency securities	Level 2	999	1	—	1,000	—	1,000
Corporate debt securities	Level 2	228,446	182	(163)	228,465	4,592	223,873
Total cash equivalents and marketable securities		637,540	572	(179)	637,933	89,727	548,206
Cash		2,919	—	—	2,919	2,919	—
Total		$ 640,459	$ 572	$ (179)	$ 640,852	$ 92,646	$ 548,206

Marketable debt securities that had been in unrealized loss positions as of December 31, 2025 and 2024 were in an unrealized loss position for less than 12 months. Unrealized losses from marketable debt securities are primarily attributable to changes in interest rates. Management does not believe any remaining unrealized losses represent impairments based on evaluation of available evidence.

The following table classifies the estimated fair value of investments in available-for-sale marketable debt securities by effective contractual maturity dates *(in thousands)*:

	December 31, 2025
Due within one year	$ 306,363
Due after one year to two years	53,501
Total marketable securities	$ 359,864

5. LEASES

The Company has entered into non-cancellable operating leases, including a sublease for an office facility serving as its corporate headquarters in Brisbane, California, that expires in 2029. The Company was the primary leaseholder of a facility in South San Francisco, California, that was later subleased to a third party and for which both the lease and the sublease ended concurrently in September 2025.

Components of net lease cost are as follows *(in thousands)*:

	Year Ended December 31,		
	2025	2024	2023
Operating lease cost	$ 2,261	$ 2,728	$ 2,577
Variable lease cost	(4)	45	14
Total operating lease cost	$ 2,257	$ 2,773	$ 2,591
Less: Sublease income	(1,496)	(1,954)	(1,928)
Net lease cost	$ 761	$ 819	$ 663

Other supplemental information related to operating leases is as follows *(in thousands)*:

	Year Ended December 31,		
	2025	2024	2023
Cash paid for operating lease liabilities	$ 2,141	$ 3,116	$ 3,000
Addition to right-of-use assets obtained from operating lease liabilities	—	2,487	—

	December 31,	
	2025	2024
Weighted-average discount rate for operating leases	12.5%	11.3%
Weighted-average remaining lease term	3.3 years	3.0 years

As of December 31, 2025, the maturities of operating lease liabilities are as follows *(in thousands)*:

2026	$ 830
2027	966
2028	995
2029	254
Total minimum lease payments	3,045
Less: Imputed interest	(577)
Present value of operating lease liabilities	2,468
Less: Current portion of operating lease liabilities	(549)
Non-current operating lease liabilities	$ 1,919

As of December 31, 2025, the Company had not executed any leases that were yet to commence.

6. NOTES PAYABLE

Notes payable consist of the following *(in thousands)*:

		December 31,			
		2025		2024	
	Maturity	Effective Interest Rate	Amount	Effective Interest Rate	Amount
Collateralized note 2021-12	N/A	N/A	$ —	13.96%	$ 5,000
Collateralized note 2022-11	N/A	N/A	—	14.09%	20,000
Collateralized note 2023-12	N/A	N/A	—	14.59%	25,000
Collateralized note 2025-06	2030	9.85%	75,000	N/A	—
Total borrowings			75,000		50,000
Unamortized issuance costs net of accrued exit fees			(162)		687
Net carrying amount of debt			$ 74,838		$ 50,687

2021 Loan Agreement

In June 2025, the Company refinanced its debt under the non-revolving loan and security agreement (2021 Loan Agreement) with a loan syndicate involving Oxford Finance LLC (Oxford Finance), Oxford Finance Credit Fund II LP (OFCF II), and Oxford Finance Credit Fund III LP (OFCF III) entered into in December 2021, by entering into a new non-revolving loan and security agreement, the proceeds of which were partially used to prepay the outstanding principal balance of the 2021 Loan Agreement in full. The Company paid an exit fee of $3.0 million, equal to 6% on the aggregate principal amount of the loan, as 1% of the original 7% exit fee was waived in connection with the refinancing. The entirety of the 2% prepayment fee that would have applied to the prepayment of the $25.0 million of debt drawn in December 2023 was also waived in connection with the refinancing.

2025 Loan Agreement

On June 2, 2025, the Company entered into a new non-revolving loan and security agreement (2025 Loan Agreement) with a loan syndicate involving Oxford Finance, OFCF II, OFCF III, and Oxford Finance Credit Fund IV LP (OFCF IV) (collectively, Oxford). The 2025 Loan Agreement has a total borrowing capacity of up to $500.0 million, of which $75.0 million was funded at closing and $50.0 million remains available for draw at the Company's discretion from January 1, 2026 through December 31, 2026. The Company also has the option to draw up to $75.0 million upon accelerated approval of atacicept in immunoglobulin A nephropathy (IgAN), two tranches of a maximum of $50.0 million upon achievement of certain commercial milestones related to atacicept in IgAN once approved, and up to $200.0 million available at the mutual discretion of the Company and Oxford. As of December 31, 2025, the Company's outstanding borrowing under the 2025 Loan Agreement was $75.0 million.

The Company accounted for the loan syndicate on a creditor-by-creditor basis. With respect to the continuing creditors, Oxford Finance, OFCF II, and OFCF III, the Company accounted for this transaction as a loan modification, and with respect to the new lender, OFCF IV, the Company accounted for this transaction as an issuance of debt. Of the $3.7 million in exit fees on the 2021 Loan Agreement and fees paid to creditors as part of the refinancing, $1.6 million was recorded as a reduction to the net carrying amount of the debt drawn under the 2025 Loan Agreement at close, and $2.0 million was recorded as noncurrent deferred debt issuance costs. Of the $2.3 million in fees paid by the Company to third parties in connection with the refinancing, $0.8 million was recorded as other expense, and $1.4 million was recorded as noncurrent deferred debt issuance costs. Deferred debt issuance costs will be amortized over the respective draw periods of each of the loan commitment tranches on a straight-line basis.

The 2025 Loan Agreement is scheduled to mature in June 2030, provided that the Company has not achieved a revenue-based interest-only extension milestone as of the end of the initial interest-only period in August 2029. If the Company achieves this interest-only extension milestone, the maturity date and end of the interest-only period will be extended to June 2031 and August 2030, respectively. The Company is permitted to prepay the loan, subject to certain conditions, and will incur prepayment fees of 2% if the loan is prepaid prior to June 4, 2027 or 1% if the loan is prepaid between June 5, 2027 and June 4, 2028. No prepayment fee shall be applicable after June 4, 2028. Additionally, upon maturity date, acceleration of the loan in the event of default, or prepayment of the loan, the Company is required to pay an exit fee equal to 5% of the aggregate principal amount of the loan. The Company will accrue for this exit fee over the life of the loan as an increase to the net carrying amount of debt using the effective interest rate method.

The variable interest rate on the drawn amount is 1-Month CME Term SOFR (subject to a per annum floor rate of 3.75%) plus 4.95% per annum. At the initial funding of the 2025 Loan Agreement on June 4, 2025, the nominal interest rate was 9.27%. There are two financial covenants: (i) commencing on March 31, 2027, the Company is required to maintain certain levels of unrestricted cash subject to control agreements provided that such liquidity covenant shall not apply at any given time if the market capitalization of the Company is at least $1.0 billion on the measurement date, and (ii) commencing with the last day of the month in which the aggregate amount of Term Loans funded exceeds $200.0 million, the Company will be required to maintain a loan coverage ratio, which will replace the minimum cash covenant. The loan coverage ratio should not apply at any given time if the market capitalization of the Company is at least $1.25 billion on the measurement date. The loan is secured by substantially all of the Company's assets. The proceeds from the 2025 Loan Agreement were partially used to prepay the outstanding principal balance of the 2021 Loan Agreement in full, with the remaining proceeds available for working capital, capital expenditures, and other general corporate purposes.

Principal installments due on the notes are as follows *(in thousands)*:

2026	—
2027	—
2028	—
2029	34,091
2030	40,909
Total long-term debt	$ 75,000

7. STOCKHOLDERS' EQUITY

As of December 31, 2025 and 2024, the Company's amended and restated certificate of incorporation authorized the Company to issue 500,000,000 shares of Class A common stock, 14,600,000 shares of Class B common stock, and 10,000,000 shares of preferred stock, each with a par value of $0.001 per share. Each share of Class A common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. There were no shares of Class B common stock or preferred stock issued and outstanding as of December 31, 2025 and 2024. Common stockholders are entitled to receive dividends, as may be declared by the board of directors. Through December 31, 2025, no cash dividends have been declared or paid.

In February 2023, the Company completed a follow-on public offering pursuant to which the Company issued and sold 16,428,572 shares of its Class A common stock at a public offering price of $7.00 per share, including 2,142,857 shares of Class A common stock pursuant to the full exercise of the underwriters' option to purchase additional shares.

In February 2024, the Company completed a follow-on public offering pursuant to which the Company issued and sold 9,274,194 shares of its Class A common stock at a public offering price of $31.00 per share, including 1,209,677 shares of Class A common stock pursuant to the full exercise of the underwriters' option to purchase additional shares.

In October 2024, the Company completed a follow-on public offering pursuant to which the Company issued and sold 7,142,858 shares of its Class A common stock at a public offering price of $42.00 per share, and in November 2024, the Company issued and sold an additional 1,071,428 shares of Class A common stock, pursuant to the full exercise of the underwriters' option to purchase additional shares at the public offering price.

In December 2025, the Company completed a follow-on public offering pursuant to which the Company issued and sold 7,058,824 shares of its Class A common stock at a public offering price of $42.50 per share, including 920,716 shares of Class A common stock pursuant to the full exercise of the underwriters' option to purchase additional shares.

8. STOCK COMPENSATION

Equity Plans

2024 Inducement Plan

In February 2024, the Company adopted the 2024 Inducement Plan (Inducement Plan). The Inducement Plan was adopted by the compensation committee of the Company's board of directors without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4) and subsequently amended in August 2024, January 2025, and September 2025. In accordance with Rule 5635(c)(4), awards made under the Inducement Plan, including stock options and restricted stock units, may only be granted to newly hired employees as a material inducement to accept employment with the Company. Stock options granted under the Inducement Plan expire no later than ten years from the date of grant.

2021 Equity Incentive Plan and 2017 Equity Incentive Plan

The 2021 Equity Incentive Plan (2021 EIP) and the 2017 Equity Incentive Plan (2017 EIP) became effective in May 2021 and February 2017, respectively. The Company may not grant any additional awards under the 2017 EIP. The 2017 EIP will continue to govern outstanding equity awards granted thereunder. Stock options granted under the 2021 EIP and 2017 EIP expire no later than ten years from the date of grant.

2021 Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan (ESPP) became effective in May 2021. As of December 31, 2025, 150,090 shares have been issued pursuant to the ESPP. The ESPP generally provides for six-month consecutive offering periods beginning every September 14 and March 14. The ESPP is a compensatory plan as defined by the authoritative guidance for stock compensation.

The table below summarizes the Company's equity plans as of December 31, 2025:

Plan	Maximum Number of Shares Authorized	Shares Available for Future Issuance
2024 Inducement Plan	3,440,000	468,665
2021 Equity Incentive Plan	10,051,396	2,381,813
2017 Equity Incentive Plan	2,275,305	—
2021 Employee Stock Purchase Plan	1,588,946	1,438,856

Option Activity

Stock option activity under the 2017 EIP, 2021 EIP, and 2024 Inducement Plan for the year ended December 31, 2025 is summarized as follows:

	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (000s)
Outstanding as of December 31, 2024	6,611,797	$ 16.44	8.11	$ 172,630
Granted	2,309,060	27.88		
Exercised	(429,571)	13.19		
Cancelled and forfeited	(95,996)	30.62		
Outstanding as of December 31, 2025	8,395,290	$ 19.59	7.58	$ 260,696
Options exercisable as of December 31, 2025	4,195,226	$ 14.58	6.63	$ 151,267
Vested and expected to vest as of December 31, 2025	8,395,290	$ 19.59	7.58	$ 260,696

The aggregate intrinsic value of stock options exercised during the years ended December 31, 2025, 2024, and 2023 was $12.0 million, $46.8 million, and $1.0 million, respectively. The weighted-average grant date fair value of options granted during the years ended December 31, 2025, 2024, and 2023 was $22.59 per share, $19.65 per share, and $5.92 per share, respectively.

Award Activity

The Company grants restricted stock units (RSU) pursuant to the 2021 EIP and satisfies such grants through the issuance of the Company's Class A common stock. The following table shows RSU activity for the period ending December 31, 2025:

	NUMBER OF SHARES	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE PER SHARE
Unvested balance at December 31, 2024	696,888	$ 29.63
Granted	1,104,755	27.98
Vested	(154,851)	26.66
Cancelled and forfeited	(46,952)	31.13
Unvested balance at December 31, 2025	1,599,840	$ 28.67

Stock-Based Compensation Expense

The following tables summarize the stock-based compensation expense for stock options and restricted stock units granted to employees and nonemployees and for ESPP stock-based compensation that was recorded in the Company's statements of operations and comprehensive loss for the years ended December 31, 2025, 2024, and 2023 *(in thousands)*:

	Year Ended December 31,		
	2025	2024	2023
Research and development	$ 17,237	$ 8,537	$ 4,845
General and administrative	20,689	12,265	6,648
Total stock-based compensation expense	$ 37,926	$ 20,802	$ 11,493

	Year Ended December 31,		
	2025	2024	2023
Employees	$ 35,572	$ 18,356	$ 10,494
Nonemployees	2,354	2,446	999
Total stock-based compensation expense	$ 37,926	$ 20,802	$ 11,493

As of December 31, 2025, the Company had $66.0 million of unrecognized stock-based compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.5 years. For the years ended December 31, 2025, 2024, and 2023, the Company recognized $27.3 million, $17.1 million, and $10.0 million of stock-based compensation expense for stock options, respectively.

As of December 31, 2025, the Company had $38.0 million of unrecognized stock-based compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 3.1 years. For the years ended December 31, 2025, 2024, and 2023, the Company recognized $9.9 million, $3.4 million, and $1.6 million of stock-based compensation expense for RSUs, respectively.

Stock-based compensation expense related to the ESPP for the years ended December 31, 2025, 2024, and 2023 was $0.9 million, $0.3 million, and $0.2 million, respectively.

No tax benefit was recognized related to stock-based compensation expense since the Company has never reported taxable income and has established a full valuation allowance to offset all of the potential tax benefits associated with its deferred tax assets.

The fair value of stock options granted during the years ended December 31, 2025, 2024, and 2023 was estimated using the Black-Scholes option pricing model based on the following assumptions:

	Year Ended December 31,		
	2025	2024	2023
Expected term (in years)	5.5 - 6.1	5.4 – 6.1	5.5 – 6.1
Expected volatility	81.8% – 83.9%	69.7% – 73.2%	79.5% – 80.5%
Risk-free rate	3.7% – 4.5%	3.6% – 4.6%	3.4% – 4.7%
Dividend yield	—	—	—

9. LICENSES AND COLLABORATIONS

Ares Trading S.A.

In October 2020, the Company entered into a license agreement (Ares Agreement) with Ares Trading S.A. (Ares), pursuant to which the Company obtained an exclusive worldwide license to certain patents and related know-how to research, develop, manufacture, use and commercialize therapeutic products containing atacicept, a recombinant fusion protein used to inhibit B cell growth and differentiation, which could potentially treat some autoimmune diseases.

As consideration for the Ares Agreement, the Company paid a non-refundable license issue fee to Ares in the form of shares of redeemable convertible preferred stock valued at $13.1 million. The redeemable convertible preferred stock subsequently converted into 1,913,501 shares of common stock in May 2021. In December 2020, the Company paid Ares a milestone payment of $25.0 million upon delivery and initiation of the transfer of specified information and materials. The non-refundable license issue fee and milestone payment were recorded to research and development expense in the period incurred. In January 2026, upon filing of the Company's Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) for treatment of atacicept in IgAN, the Company achieved a specified regulatory milestone and paid $15.0 million to Ares.

The Company is obligated to pay Ares additional milestone payments, including $20.0 million upon regulatory approval for IgAN in the U.S., and other potential milestone payments of up to $141.5 million in aggregate upon the achievement of regulatory filing and approval milestones for other geographic regions and indications, and up to $515.0 million upon the achievement of specified worldwide aggregate annual net sales milestones, beginning with $15.0 million if net sales reach $250.0 million and $50.0 million if net sales reach $500.0 million.

Subsequent to the effective date of the Ares Agreement, Ares has performed transfer of manufacturing technology and know-how to the Company. The Company recorded expenses of $0.3 million and $2.8 million to Ares for these services during the years ended December 31, 2024, and 2023, respectively. These amounts are included in research and development expenses on the statements of operations and comprehensive loss.

Commencing on the first commercial sale of licensed products, the Company is obligated to pay Ares tiered royalties of low double-digit to mid-teen percentages on annual net sales of the licensed products covered by the license. The Company is obligated to pay royalties on a licensed product-by-licensed product and country-by-country basis from the first commercial sale of a product in a country until the latest of (i) 15 years after the first commercial sale of such licensed product in such country; (ii) the expiration of the last valid claim of a licensed patent that covers such licensed product in, or its use, importation or manufacture with respect to, such country; and (iii) expiration of all applicable regulatory exclusivity periods, including data exclusivity, in such country with respect to such product. If the Company were to sublicense its rights under the Ares Agreement, the Company would be obligated to pay Ares a percentage ranging from the mid-single-digit to the low double-digits of specified sublicensing income received.

Amplyx Pharmaceuticals, Inc.

In December 2021, the Company entered into an asset purchase agreement (Amplyx Agreement) with Amplyx Pharmaceuticals,

Inc. (Amplyx), a wholly owned subsidiary of Pfizer Inc. Pursuant to the terms of the Amplyx Agreement, the Company paid $5.0 million to Amplyx to purchase assets relating to an anti-BK virus monoclonal antibody referred to as MAU868 for the treatment of reactivated BK virus (BKV) infection pursuant to a License Agreement between Amplyx and Novartis International Pharmaceutical AG (Novartis). In addition, the Company recognized a $2.0 million contingent milestone obligation as an assumed liability related to the asset purchase. The acquisition cost of $7.0 million was recorded as research and development expense in the statement of operations and comprehensive loss on the acquisition date.

In connection with the Amplyx asset purchase, Amplyx assigned the Exclusive License Agreement between Amplyx and Novartis (Novartis License) and Manufacturing and Supply Agreements to the Company. Under the Novartis License, the Company has exclusive worldwide rights from Novartis to develop, manufacture and commercialize MAU868. The Company will be solely responsible for all research, development, regulatory, manufacturing and commercialization activities of MAU868.

Under the Amplyx Agreement, the Company is obligated to make future milestone payments to Amplyx and Novartis upon the achievement of specified development, regulatory and commercial milestones. In September 2022, the Company and Novartis entered into an amendment to the Novartis License to modify the terms of future milestone payments. Pursuant to this amendment, the Company issued 283,034 shares of Class A common stock to Novartis in exchange for a reduction of $7.0 million in contingent future development milestones, including the $2.0 million contingent milestone obligation accrued by the Company in December 2021. The value of the shares issued was $5.7 million based on the closing market value of the Company's Class A common stock as of the effective date of the amendment.

The Company is obligated to make future milestone payments of up to $7.0 million to Amplyx, contingent upon the achievement of certain regulatory milestones. The Company is also obligated to make future milestone payments of up to $62.0 million to Novartis, contingent upon the achievement of specified development, regulatory and commercial milestones. In the event that MAU868 is commercialized, the Company will be obligated to pay royalties to Amplyx and Novartis based on net sales by country and by product.

Stanford University

In January 2025, the Company entered into a license agreement (Stanford Agreement) with the Board of Trustees of Leland Stanford Junior University (Stanford). Pursuant to the terms of the Stanford Agreement, as amended in April 2025, the Company acquired worldwide development and commercial rights to a fusion protein in preclinical development referred to as VT-109, with therapeutic potential in B cell mediated diseases, in exchange for license issue fees of $0.8 million, annual license maintenance fees, and potential future license fees, milestone payments and royalties if the compound advances to certain clinical development and commercial milestones.

10. INCOME TAXES

For financial reporting purposes, loss before provision for income taxes includes the following components *(in thousands)*:

	Year Ended December 31,		
	2025	2024	2023
Domestic	$ (299,614)	$ (152,147)	$ (95,989)
Foreign	—	—	—
Loss before income taxes	$ (299,614)	$ (152,147)	$ (95,989)

Income Taxes Paid

The following table presents income taxes paid, net of refunds received *(in thousands)*:

	Year Ended December 31,		
	2025	2024	2023
U.S. State and Local:			
California	1	1	1
New Jersey	1	—	—
Massachusetts	15	—	—
Total income taxes paid	$ 17	$ 1	$ 1

Provision for Income Taxes

Current and deferred provision for income taxes was de minimis for the years ended December 31, 2025, 2024, and 2023.

A reconciliation of the provision for income taxes computed using the U.S. statutory federal income tax rate compared to the income tax provision included in the statement of operations and comprehensive loss is as follows (in thousands):

	Year Ended December 31,					
	2025	%	2024	%	2023	%
Tax at U.S. statutory rate on income before income taxes	$ (62,919)	21.00%	$ (31,951)	21.00%	$ (20,158)	21.00%
State income taxes, net of federal effect	(166)	0.06%	(210)	0.14%	(122)	0.13%
Change in valuation allowance	64,058	-21.38%	34,448	-22.64%	21,250	-22.14%
Nontaxzable or nondeductible items:						
Stock based compensation	(1,132)	0.38%	(1,965)	1.29%	485	-0.51%
Other	1,160	-0.39%	762	-0.50%	21	-0.02%
Tax credits:						
Federal research & development credits	(1,618)	0.54%	(1,618)	1.06%	(2,015)	2.10%
Worldwide changes in unrecognized tax benefits	554	-0.19%	535	-0.35%	540	-0.56%
Other	64	-0.02%	—	0.00%	—	0.00%
Provision for income taxes	$ 1	0.00%	$ 1	0.00%	$ 1	0.00%

For the years ended December 31, 2025, 2024, and 2023, state and local income taxes in California comprise the majority of the state and local income taxes, net of federal effect category.

Deferred Tax Assets and Liabilities

Deferred tax assets and liabilities are determined based on the differences between financial reporting and income tax bases of assets and liabilities, as well as net operating loss carryforwards and are measured using the enacted tax rates and laws in effect when the differences are expected to reverse. The significant components of the Company's net deferred tax assets and liabilities are as follows *(in thousands)*:

	December 31,		
	2025	2024	2023
Deferred tax assets:			
Federal and state net operating loss carryforward	$ 84,624	$ 38,736	$ 27,539
Research and other credits	10,330	8,190	6,051
Capitalized research & development	59,062	46,225	25,264
Fixed assets	30	5	3
Reserves and accruals	916	1,310	755
Stock based compensation	9,809	4,311	2,978
Other intangibles	7,141	7,641	8,313
Other deferred tax assets	406	400	384
Lease liability	521	831	804
Total gross deferred tax assets	172,839	107,649	72,091
Less: valuation allowance	(172,267)	(106,857)	(71,372)
Total deferred tax assets	572	792	719
Deferred tax liabilities:			
Right of use	(406)	(709)	(619)
Other deferred tax liabilities	(166)	(83)	(100)
Total gross deferred tax liabilities	(572)	(792)	(719)
Net deferred tax assets	$ —	$ —	$ —

As of December 31, 2025, the Company has federal and state net operating loss carryforwards of $389.9 million and $42.3 million, respectively, of which $10.2 million of federal net operating loss carryforwards and $37.0 million of state net operating carryforwards will begin expiring in the year 2032 and 2036, respectively, if not utilized. The Company also has $379.6 million of federal net operating loss carryforwards as of December 31, 2025 that do not expire. The Company has $8.6 million of federal research and development tax credit carryforwards, which begin to expire in the year 2037. The Company has $4.3 million of state research and development tax credit carryforwards, which have no expiration date.

Utilization of the federal and state net operating loss and tax credit carryforwards may be subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986. The annual limitation may result in the expiration of net operating losses and credits before utilization. The Company has not performed an analysis to determine if such ownership changes have occurred. An analysis will be performed prior to recognizing the benefits of any losses or credits in the financial statements.

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. Based on the weight of all evidence including a history of operating losses, management has determined that it is not more likely than not that the net deferred tax assets will be realized. A valuation allowance of $172.3 million and $106.9 million as of December 31, 2025 and 2024, respectively, has been established to offset the deferred tax assets as realization of such assets is uncertain.

As required under ASU 2023-09, the Company has included only the portion of the valuation allowance related to federal deferred tax assets in the "change in valuation allowance" line of the rate reconciliation. The following table presents a reconciliation of the total change in the valuation allowance *(in thousands)*:

	Year Ended December 31,		
	2025	2024	2023
Beginning balance	$ 106,857	$ 71,372	$ 49,648
Change charged to income tax expense	65,492	35,460	21,871
Changes charged to other comprehensive income	(82)	25	(147)
Ending balance	$ 172,267	$ 106,857	$ 71,372

Uncertain Tax Benefits

The Company has the following activity relating to the gross amount of unrecognized tax benefits *(in thousands)*:

	Year Ended December 31,		
	2025	2024	2023
Beginning balance	$ 2,048	$ 1,513	$ 941
Additions based on tax positions related to prior year	63	—	—
Additions based on tax positions related to current year	535	535	572
Ending balance	$ 2,646	$ 2,048	$ 1,513

During the years ended December 31, 2025, 2024, and 2023, no interest or penalties were required to be recognized relating to unrecognized tax benefits.

The Company accounts for income taxes in accordance with authoritative accounting guidance which states the impact of an uncertain income tax position is recognized at the largest amount that is "more likely than not" to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained. None of these uncertain tax positions will impact the Company's effective tax rate if assessed. The Company's policy is to classify interest and penalties associated with unrecognized tax benefits as income tax expense.

The Company files income tax returns in the U.S. and various states. The Company is not currently under examination by any major tax jurisdictions nor has it been in the past. Because of net operating losses and research credit carryovers, substantially all of our tax years remain open to examination. Although it is reasonably possible that certain unrecognized tax benefits may increase or decrease within the next 12 months due to tax examination changes, settlement activities, expirations of statute of limitations, or the impact on recognition and measurement considerations related to the results of published tax cases or other similar activities, the Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months.

11. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

The Company believes that there are no actions pending which would have a material adverse effect on its results of operations, financial condition, or cash flows.

Indemnifications

As of December 31, 2025, the Company did not have any material indemnification claims that were probable or reasonably possible, and consequently no related liabilities have been recorded.

Employee Agreements

The Company has signed employment agreements with certain key employees pursuant to which, if their employment is terminated following a change of control of the Company, the employees are entitled to receive certain benefits, including severance and accelerated vesting of equity incentives.

Development and Manufacturing Services Agreements

The Company enters into development and manufacturing contracts with vendors in the conduct of its business. Contracts with these vendors may be terminated at the Company's option, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would be obligated to pay for the products or services that had been provided or received at the time the termination became effective, and potentially additional compensation based upon the period of time remaining between the date of notice of cancellation and the scheduled manufacturing.

12. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following outstanding potentially dilutive shares were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented, because including them would have been anti-dilutive (on an as-converted basis).

	Year Ended December 31,		
	2025	2024	2023
Class A common stock options issued and outstanding	8,395,290	6,611,797	5,762,236
Unvested restricted stock units	1,599,840	696,888	131,679
Vested but unsettled stock units	—	2,987	—
Shares reserved for ESPP purchases	29,533	6,034	229
Total	10,024,663	7,317,706	5,894,144

13. RELATED PARTY TRANSACTIONS

Sofinnova Venture Partners X, L.P. (SVP X) is an investment fund in which Maha Katabi (Dr. Katabi), a member of the Company's board of directors, has a pecuniary interest. SVP X completed transactions in the Company's common stock within a six-month period ended March 25, 2024. The transactions included both purchases and sales of shares of the Company's common stock that may be matchable for purposes of Section 16(b) of the Securities Exchange Act of 1934, as amended. A complaint filed in October 2024 in a legal action pending in the U.S. District Court for the Southern District of New York in the case captioned *Calenture, LLC et al. v. Sofinnova Venture Partners X, L.P. et al.*, alleged that SVP X, Sofinnova Management X, L.P., and Sofinnova Management X-A, L.L.C. (collectively, Sofinnova) was liable to the Company for damages in the form of short-swing profits realized from transactions in the Company's equity securities. In November 2025, the Company entered into a settlement agreement with Sofinnova to settle the legal action, which resulted in a payment by Sofinnova to the Company of $0.5 million in December 2025, which was recorded to additional paid-in capital.

14. SEGMENT REPORTING

The Company has one reportable segment: Therapeutics. This segment is dedicated to developing and commercializing transformative treatments for patients with serious immunological diseases. The Company's lead product candidate, atacicept, is currently being evaluated for the treatment of IgAN and other autoimmune kidney diseases. Atacicept is a native human TACI-Fc fusion protein that binds both the B-cell activating factor (BAFF) and A proliferation-inducing ligand (APRIL) cytokines and is self-administered subcutaneously at home. The Company also holds worldwide, exclusive development and commercial rights to MAU868, a monoclonal antibody to treat BKV infections for which the Company completed a Phase 2 clinical trial in 2022, and worldwide, exclusive development and commercial rights to VT-109, a novel, next generation dual BAFF/APRIL inhibitor that is in preclinical development.

Since inception, the Company has devoted substantially all its resources to research and development efforts, pre-clinical studies and clinical trials, building a sales, marketing and distribution infrastructure to support anticipated commercial activities, establishing and maintaining intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. The Company does not have any product candidates approved for commercial sale and has not generated any revenue from product sales.

The accounting policies used in the segment reporting are the same as those described in the summary of significant accounting policies (Note 2). The Company's Chief Operating Decision Maker (CODM) is the Chief Executive Officer. The CODM assesses

performance for the single reportable segment and decides how to allocate resources based on net loss and total operating expenses. As the Company has not generated any revenue, total operating expenses is equivalent to loss from operations on the statements of operations and comprehensive loss. The measure of segment assets is reported on the balance sheet as total assets.

The CODM uses net loss as the reportable segment's primary measure of profit or loss to evaluate the segment's financial position and to determine the need for additional financing or equity offerings. The CODM also uses total operating expenses as a measure to evaluate controllable spend from total current assets, in deciding how to allocate resources within the Therapeutics segment.

As of December 31, 2025 and 2024, all of the Company's property and equipment was located in the United States.

The Company's reportable segment total operating expenses (including significant segment expenses) and net loss, consisted of the following (in thousands):

	Therapeutics		
	Year Ended December 31,		
	2025	2024	2023
Operating expenses:			
Payroll and related	$ 112,132	$ 48,843	$ 28,878
Direct research and development - clinical trials	46,743	32,279	19,611
Direct research and development - contract manufacturing	74,193	50,753	35,049
Commercial planning	20,801	5,584	2,229
Depreciation and amortization	468	105	22
Other segment items*	61,136	29,606	16,223
Total operating expenses	315,473	167,170	102,012
Loss from operations	(315,473)	(167,170)	(102,012)
Other income (expense):			
Interest income	24,479	20,714	7,979
Interest expense	(7,531)	(7,626)	(3,786)
Other segment items**	(1,089)	1,935	1,830
Loss before provision for income taxes	(299,614)	(152,147)	(95,989)
Provision for income taxes	(1)	(1)	(1)
Segment and consolidated net loss	$ (299,615)	$ (152,148)	$ (95,990)
Other Significant Items:			
Expenditures for additions to long-lived assets	$ (630)	$ (972)	$ (63)

**Other segment items included in total operating expenses primarily consist of consulting and contractors, professional services, equipment and software, travel and entertainment, facilities, medical affairs, and corporate communications.*

***Other segment items included in loss before provision for income taxes consist of currency exchange gains and losses and other income/expense.*

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 and supervision of our Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial officer, respectively), have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of December 31, 2025, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

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 Exchange Act Rules 13a-15(f) and 15d-15(f).

Under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2025 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 that evaluation, our management concluded that the Company's internal control over financial reporting was effective as of December 31, 2025.

The effectiveness of our internal control over financial reporting as of December 31, 2025 has been audited by KPMG LLP, an independent registered public accounting firm, and they have issued an attestation report on our internal control over financial reporting, which appears in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act) during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Inherent Limitations of Internal Controls

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations of internal controls, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information

(a) None.

(b) The following table describes for the quarterly period covered by this report each trading arrangement for the purchase or sale of Company securities adopted, modified or terminated by our directors and officers that is either (1) a contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c), or a "Rule 10b5-1 trading arrangement," or (2) a "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K):

				Type of Trading Arrangement				
Name	**Position**	**Action**	**Adoption/ Termination Date**	**Rule 10b5-1***	**Non-Rule 10b5-1****	**Total Shares of Class A Common Stock to be Sold*****	**Total Shares of Class A Common Stock to be Purchased**	**Expiration Date**
William Turner	Chief Regulatory Officer	Adoption	December 23, 2025	X		100,000	N/A	December 31, 2026
* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.								
** "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.								
*** Represents the maximum number of shares that may be sold pursuant to the 10b5-1 trading arrangement. The number of shares to be sold is dependent on the satisfaction of certain conditions as set forth in the written plan.								

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 will be included in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with our 2026 Annual Meeting of Stockholders (Definitive Proxy Statement), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2025 and is incorporated herein by reference.

Code of Business Conduct and Ethics

We maintain a Code of Business Conduct and Ethics (Code of Conduct) that applies to all our employees, officers, directors, and contractors. This includes our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Conduct is posted on our website at https://ir.veratx.com/corporate-governance/governance-highlights. If we make any substantive amendments to the Code of Conduct or grant any waiver from a provision of the Code of Conduct to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K.

Item 11. Executive Compensation.

The information required by this item will be included in our Definitive Proxy Statement and 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 will be included in our Definitive Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be included in our Definitive Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be included in our Definitive Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

We have filed the following documents as part of this Annual Report.

1. Financial Statements:

The financial statements filed as part of this Annual Report are included in Part II, Item 8 of this Annual Report.

2. Financial Statement Schedules:

All schedules have been omitted because they are not required, not applicable, not present in amounts sufficient to require submission of the schedule, or the required information is otherwise included.

3. Exhibits:

The exhibits listed in the accompanying Exhibit Index are filed as part of, or incorporated by reference into, this Annual Report.

Item 16. Form 10-K Summary.

None.

EXHIBIT INDEX

Exhibit Number	Description
2.1^	Asset Purchase Agreement between the Registrant and Amplyx Pharmaceuticals, Inc. dated December 16, 2021 (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, filed with the SEC on February 7, 2022).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 18, 2021).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 18, 2021).
4.1	Form of Class A Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on May 10, 2021).
4.2	Second Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated October 29, 2020 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on April 23, 2021).
4.3	Description of Common Stock of the Registrant (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 27, 2024).
10.1†	Vera Therapeutics, Inc. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, filed with the SEC on April 23, 2021).
10.2†	Forms of Grant Notice, Stock Option Agreement and Notice of Exercise under the Vera Therapeutics, Inc. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statements on Form S-1, filed with the SEC on April 23, 2021).
10.3†	Vera Therapeutics, Inc 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021).
10.4†	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Vera Therapeutics, Inc 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021).
10.5†	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the Vera Therapeutics, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021).
10.6†	Vera Therapeutics, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021).
10.7†	Vera Therapeutics, Inc. 2024 Inducement Plan, as amended September 19, 2025 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 5, 2025).

10.8†	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Vera Therapeutics, Inc. 2024 Inducement Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 27, 2024).
10.9†	Form of Restricted Stock Unit Grant Notice and Award Agreement under the Vera Therapeutics, Inc. 2024 Inducement Plan (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 27, 2024).
10.10†*	Vera Therapeutics, Inc. Non-employee Director Compensation Policy, as amended on December 16, 2025.
10.11†	Form of Indemnification Agreement by and between the Registrant and its directors and executive officers (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021).
10.12†¥	Amended and Restated Offer Letter by and between the Registrant and Marshall Fordyce, M.D., dated May 7, 2021 (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021).
10.13†¥	Offer Letter, by and between the Registrant and Sean P. Grant, dated May 30, 2021 (incorporated by reference to Exhibit 10.1 the Registrant's Current Report on Form 8-K, filed with the SEC on July 14, 2021).
10.14^	License Agreement by and between the Registrant and Ares Trading S.A., dated as of October 29, 2020 (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, filed with the SEC on April 23, 2021).
10.15¥^	License Agreement between Novartis International Pharmaceuticals AG and Amplyx Pharmaceuticals, Inc. dated August 26, 2019 (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1, filed with the SEC on February 7, 2022).
10.16^	Amendment No. 1 to License Agreement between Novartis International Pharmaceutics AG and Amplyx Pharmaceuticals, Inc. dated September 24, 2019 (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1, filed with the SEC on February 7, 2022).
10.17^	Amendment to License Agreement, by and between the Registrant and Novartis Pharma AG, dated September 9, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 9, 2022).
10.18†¥	Offer Letter, by and between the Registrant and David Johnson, dated June 26, 2024 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 2, 2024).
10.19†¥	Offer Letter, by and between the Registrant and Robert Brenner, M.D., dated January 3, 2024 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 9, 2024).
10.20†¥	Offer Letter, by and between the Registrant and William Turner, dated December 19, 2023 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 9, 2024).
10.21	Loan and Security Agreement between Vera Therapeutics, Inc. and Oxford Finance LLC, as collateral agent, and certain lenders including Oxford Finance Credit Fund II LP, Oxford Finance Credit Fund III LP, and Oxford Finance Credit Fund IV LP and the other parties thereto, dated June 2, 2025 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 3, 2025).
10.22¥	Sales Agreement, dated August 5, 2025, by and between Vera Therapeutics, Inc. and TD Securities (USA) LLC (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 5, 2025.
19.1	Vera Therapeutics, Inc. Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K, filed with the SEC on February 28, 2025).
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*#	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*#	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Vera Therapeutics, Inc. Incentive Compensation Recoupment Policy (incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 27, 2024).
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104*	Cover Page Interactive Data File – the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

* Filed herewith.

† Indicates management contract or compensatory plan.

¥ Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.
^ Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit (indicated by asterisks) have been omitted.
# The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (including this Annual Report on Form 10-K), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

SIGNATURES

Pursuant to the requirements 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.

Vera Therapeutics, Inc.

Date: February 26, 2026

By:/s/ Marshall Fordyce
Marshall Fordyce, M.D.
President, Chief Executive Officer and Director
(Principal Executive 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 in the capacities and on the dates indicated.

Name	Title	Date
/s/ Marshall Fordyce **Marshall Fordyce, M.D.**	President, Chief Executive Officer and Director (Principal Executive Officer)	February 26, 2026
/s/ Sean Grant **Sean Grant**	Chief Financial Officer (Principal Financial Officer)	February 26, 2026
/s/ Joseph Young **Joseph Young**	Senior Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer)	February 26, 2026
/s/ Michael Morrissey **Michael Morrissey, Ph.D.**	Chairman of the Board	February 26, 2026
/s/ Andrew Cheng **Andrew Cheng, M.D., Ph.D.**	Director	February 26, 2026
/s/ Patrick Enright **Patrick Enright**	Director	February 26, 2026
/s/ Kimball Hall **Kimball Hall**	Director	February 26, 2026
/s/ Maha Katabi **Maha Katabi, Ph.D.**	Director	February 26, 2026
/s/ James Meyers **James Meyers**	Director	February 26, 2026
/s/ Scott Morrison **Scott Morrison**	Director	February 26, 2026
/s/ Christy Oliger **Christy Oliger**	Director	February 26, 2026
/s/ Beth Seidenberg **Beth Seidenberg, M.D.**	Director	February 26, 2026