UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

OR

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

Commission file number 001-40407

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.)**
8000 Marina Boulevard, Suite 120 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

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, 2022, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $163.2 million based on the closing price of the Registrant's Class A common stock on the Nasdaq Global Select Market of $13.61 per share.

As of March 23, 2023, the registrant had 44,261,109 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 2023 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, 2022, 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 the United States 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 atacicept, MAU868 and any other product candidates we may develop;
- our ability to retain the continued service of our key personnel and to identify, hire, and then retain additional qualified personnel; and
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (JOBS Act) and as a smaller reporting company under the Securities Exchange Act of 1934, as amended (Exchange Act).

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 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 Class A 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, are set forth under Part I, Item 1A, "Risk Factors" in this Annual Report.

- We have not completed any 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 we expect to continue to incur net losses for the foreseeable future. In addition, we may be unable to continue as a going concern over the long-term.

- We are substantially dependent on the success of our product candidates, atacicept and MAU868, which are currently in the clinical development stage. 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 patients 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 (IgAN), the availability of competitive products, and significant competition for recruiting patients in clinical trials.
- The incidence and prevalence for target patient populations of atacicept in specific indications are based on estimates and third-party sources. If the market opportunities for atacicept, or any future product candidate we may develop, 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 patient 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.
- Biosimilars to our product candidates may provide competition sooner than anticipated.
- Unfavorable geopolitical and global economic conditions could adversely affect our business, financial condition and results of operations.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies. 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.
- 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.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and 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.
- If we breach our license agreement (Ares Agreement) with Ares Trading S.A. (Ares), an affiliate of Merck KGaA, Darmstadt, Germany, related to atacicept, or the license agreement with Novartis International Pharmaceutical AG (Novartis) related to MAU868, we could lose the ability to continue the development and commercialization of atacicept or MAU868, respectively.

- We may be required to make significant payments under our license agreements related to atacicept and MAU868.
- 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 atacicept, MAU868 or any future product candidates we may develop 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 (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 atacicept, MAU868 or future product candidates we may develop 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 Class A common stock may be volatile, and you could lose all or part of your investment.
- If we experience additional material weaknesses 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 Class A common stock.
- Our principal stockholders and management own a significant percentage of our outstanding voting stock and will be able to exert significant control over matters subject to stockholder approval.
- 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.

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 a self-administered fusion protein that blocks both B lymphocyte stimulator (BLyS) and a proliferation-inducing ligand (APRIL) with best-in-class potential for the treatment of IgA nephropathy (IgAN). The Phase 2b ORIGIN clinical trial evaluating the safety and efficacy of atacicept in patients with IgAN completed enrollment in mid-2022 and reported positive 24-week topline results in January 2023. Atacicept met its primary endpoint at 24 weeks, achieved statistical significance in the 150 mg dose group, and showed a trend towards deeper reductions in proteinuria with available data at 36 weeks, for which full results will read out in the second quarter of 2023. Additionally, atacicept's safety profile was comparable to placebo. The trial will remain blinded through 36 weeks, after which all patients will roll onto the open label portion of the study and receive atacicept 150 mg through 96 weeks. We plan to advance atacicept 150 mg in a pivotal Phase 3 clinical trial in IgAN in the second quarter of 2023. We also are planning a Phase 3 clinical trial of atacicept in lupus nephritis (LN), a severe renal manifestation of systemic lupus erythematosus (SLE), based on feedback from the FDA's review of clinical results in a Phase 2 clinical trial of atacicept in SLE patients with high disease activity (HDA). In December 2021, we obtained worldwide, exclusive development and commercial rights to MAU868, a potentially first-in-class monoclonal antibody to treat reactivated BK virus (BKV) infections. MAU868 is a clinical-stage neutralizing monoclonal antibody that is directed against BKV, a polyoma virus that can have devastating consequences in certain settings such as kidney transplant and hematopoietic stem cell transplant (HSCT). In final results from the Phase 2 clinical trial of MAU868 versus placebo in BK viremia among kidney transplant recipients, MAU868 was shown to be well tolerated and demonstrated a clinically meaningful BKV antiviral activity through 36 weeks. We believe that our current pipeline programs leverage the deep expertise of our team and have strong commercial synergies. We hold global developmental and commercial rights to all of our pipeline molecules.

In January 2023, we announced our plan to prioritize and focus our current resources on the advancement of atacicept in IgAN into a pivotal Phase 3 trial. As a result, we are delaying enrollment in the pivotal Phase 3 trial for LN and commitment of resources to the MAU868 program.

Atacicept in IgAN

IgAN is a serious and progressive autoimmune disease of the kidney that is driven by the production of immunogenic galactose-deficient IgA1 (Gd-IgA1), which is associated with increased risk of kidney-related morbidity and mortality. We estimate there are approximately 126,000 biopsy-confirmed IgAN patients in the United States, 136,000 in the European Union, and 130,000 in Japan. Up to 50% of patients diagnosed with IgAN develop end-stage renal disease (ESRD) within 20 years from initial diagnosis, requiring dialysis or kidney transplant. ESRD causes considerable morbidity and impact on patients' lives and represents a significant health economic burden, which was estimated to be $49.2 billion in the United States in 2018. Despite this high level of morbidity, only two treatments have been approved for this indication: TARPEYO™ (developed by Calliditas Therapeutics AB under the name Nefecon), a recently approved reformulated steroid, and FILSPARI™ (developed by Travere Therapeutics under the name sparsentan), a recently approved dual endothelin angiotensin receptor antagonist. The current standard of care continues to consist of off-label use of renin-angiotensin-aldosterone system (RAAS) inhibitors, including angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs), and potentially steroids. We estimate the U.S. market opportunity for novel therapeutics in IgAN is approximately $4.0 billion to $8.0 billion annually, based on the disease prevalence and the segment of IgAN patients at high risk of progressing to ESRD. In Europe and Japan, we estimate the annual market opportunity for novel IgAN therapeutics to be $1.0 billion and $600 million, respectively.

Atacicept is a fusion protein self-administered as a subcutaneous injection once weekly that blocks both BLyS and APRIL, which stimulate B cells and plasma cells to produce autoantibodies contributing to certain autoimmune diseases. We believe that atacicept's mechanism has the potential to drive clinical success by measures designed to assess efficacy in IgAN and other immunologic diseases. BLyS 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 BLyS and APRIL may provide improved clinical outcomes, measured by endpoints designed to assess efficacy, compared to inhibiting either signal alone. Atacicept has the potential to be the first disease-modifying therapy for IgAN due to its ability to act on core pathophysiology processes. As reported in a Phase 2a clinical trial of 16 patients conducted by Merck KGaA, Darmstadt, Germany, atacicept is the first and only molecule in development to demonstrate a 60% reduction in serum Gd-IgA1, which is central to the pathogenesis of IgAN, in a randomized controlled study in IgAN patients.

We have worldwide, exclusive rights to atacicept from Ares, an affiliate of Merck KGaA, Darmstadt, Germany, pursuant to the 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. In IgAN, Merck KGaA, Darmstadt, Germany, conducted a randomized, double-blind, placebo-controlled Phase 2a trial 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) conference in 2022, atacicept is also the first known therapeutic in IgAN to show reduction in all first three hits of disease pathogenesis—serum Gd-IgA1, anti-Gd-IgA1, and immune complex levels.

We are conducting a multinational, randomized, double-blind, placebo-controlled Phase 2b clinical trial in IgAN, which we refer to as ORIGIN. The ORIGIN trial is evaluating three subcutaneous weekly doses of atacicept (25 mg, 75 mg and 150 mg) and their impact on the reduction of proteinuria as the primary endpoint. A significant reduction in proteinuria, as measured by urine protein: creatinine ratio (UPCR) in a 24-hour urine collection, is associated with improved renal outcomes in patients with IgAN. UPCR is a surrogate endpoint endorsed by the FDA for primary glomerular diseases associated with significant proteinuria, including IgAN. The ORIGIN trial is powered to demonstrate a statistically significant difference between atacicept and placebo in decrease of proteinuria. Given the FDA's recent approval of TARPEYO, we believe this validates the use of proteinuria as a surrogate for accelerated approval. Secondary endpoints include the difference in kidney function between treated and placebo patients as measured by estimated glomerular filtration rate (eGFR) and reduction in Gd-IgA1. We completed enrollment of the Phase 2b ORIGIN trial in mid-2022, enrolling a total of 116 patients at multiple global sites. In January 2023, we announced that atacicept met the primary endpoint: the pooled 75 mg and 150 mg arms achieved a statistically significant reduction in proteinuria versus placebo at 24 weeks. In a prespecified per-protocol (PP) analysis, a blinded third-party CRO identified patients with protocol deviations that potentially confounded proteinuria measure. In the PP population excluding these patients, atacicept 150 mg achieved a 41% mean reduction in proteinuria versus baseline, resulting in a statistically significant 34% placebo-adjusted reduction. Available data show a trend towards deeper reductions in proteinuria at 36 weeks for patients on atacicept, for which full results will read out in the second quarter of 2023. Atacicept was well tolerated, and its safety profile in IgAN patients was also comparable to placebo. The ORIGIN trial will remain blinded through 36 weeks, after which all patients will roll onto the open label portion of the trial and receive atacicept 150 mg through 96 weeks, allowing for the evaluation of long-term safety and durability of response of atacicept in IgAN.

We plan to advance atacicept into a pivotal Phase 3 trial in the second quarter of 2023, using the same formulation of the 150 mg dose. Phase 2b learnings will inform the Phase 3 study design and management to ensure a de-risked trial that accurately assesses treatment efficacy. With the ongoing data from the Phase 2b trial through 2024 and Phase 3 topline results expected in the first half of 2025, if positive, we expect to submit a biologics license application (BLA) for atacicept in IgAN to the FDA in the second half of 2025.

Atacicept in LN

Based on feedback from the FDA's review of clinical results in a Phase 2 clinical trial of atacicept in HDA SLE patients, we are planning a Phase 3 clinical trial of atacicept as a potential treatment for patients with LN, a severe renal manifestation of SLE. We estimate that there are approximately 120,000 LN patients in the United States, 70,000 in the European Union, and 21,000 in Japan. We estimate the market for novel LN therapeutics annually to be approximately $2.0 to $5.0 billion, $600 million and $200 million in United States, Europe and Japan, respectively. Significant unmet need for improved efficacy persists for these patients despite the recent approval of the first two LN-specific therapies. Fewer than half of patients treated for LN have a complete response to therapy, and among patients without a complete response, over half will have non-functioning kidneys within five years. Benlysta (belimumab), a BlyS-only inhibitor, is one of the two therapies approved for patients with LN. Both BLyS and APRIL levels are increased in patients with SLE, suggesting that dual inhibition by atacicept may be more potent than blocking BLyS alone and has the benefit of targeting plasma cells in addition to B cells. Merck KGaA, Darmstadt, Germany previously initiated a randomized, double-blind, placebo-controlled Phase 2/3 clinical trial of atacicept in LN, the APRIL-LN trial, evaluating the efficacy and safety of atacicept 150 mg twice weekly for four weeks—then weekly—in patients with active LN. However, this trial was terminated early due to three patients developing hypogammaglobulinemia with induction therapy (mycophenolate mofetil (MMF) and corticosteroids (CS)) which continued to worsen when initiating atacicept and subsequently two patients developed pneumonia. In prior Phase 2 clinical trials of atacicept in SLE also conducted by Merck KGaA, Darmstadt, Germany, despite missing its primary endpoint in the broader SLE study population, atacicept achieved positive clinical data on multiple measures within the pre-specified patient segment with HDA (defined as Systemic Lupus Erythematosus Disease Activity Index 2000 [SLEDAI-2K] $\geq$10 at screening), including reduction of renal flares, which we believe supports atacicept's applicability in LN. Because both preclinical and clinical evidence suggest atacicept's dual inhibition of BLyS and APRIL may provide improved clinical outcomes, measured by endpoints designed to assess efficacy, compared to inhibiting either signal alone, we believe there is a strong rationale to conduct a clinical trial of atacicept in LN.

Our Phase 3, randomized, parallel-group, double-blind, placebo-controlled, multicenter, multinational study will evaluate the efficacy and safety of atacicept vs placebo in patients with LN. The clinical trial consists of a 104-week double blind treatment period, followed by a 52-week open label treatment period and a 26-week safety follow-up period. The trial will assess once weekly subcutaneous injections of 150 mg atacicept versus placebo. The primary endpoint is complete renal response at 52 weeks.

MAU868 in BK viremia among kidney transplant recipients

We are developing MAU868 as 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. BKV is a polyoma virus that can cause BKV nephropathy (BKVN), a condition in which BK infection, typically first identified as BK viremia, triggers inflammation, which then progresses to

fibrosis and tubular injury; BKVN is a leading cause of allograft loss. Currently, there are no approved treatment options for BK viremia or BKVN. We estimate that approximately 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 15% of kidney transplant recipients develop BK viremia; 3–4% of kidney transplant recipients develop BKVN. We estimate the market for a novel agent to treat reactivated BK infection in kidney transplant recipients to be a large commercial opportunity worldwide. 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.

At ASN 2022, 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.

MAU868 in BK cystitis among HSCT patients

We are exploring the development of MAU868 to treat BKV cystitis in HSCT patients. Patients undergoing HSCT are at risk for BKV reactivation due to immunodeficiency; in this setting, BK reactivation and subsequent viruria and viremia can lead to cystitis, including hemorrhagic cystitis. Cystitis is characterized by dysuria, urgency, and/or frequency, while hemorrhagic cystitis indicates the presence of microscopic or gross hematuria. Both BKV cystitis and hemorrhagic cystitis are associated with high patient morbidity and prolonged hospitalization, yet there are no approved treatment options. An estimated 50,000 allogeneic HSCTs are conducted globally each year, with approximately 10,000 in the United States, 16,000 in Europe, 3,500 in Japan, and 2,500 in China. An estimated 57,000 autologous HSCTs are conducted globally each year, with approximately 17,000 in the United States, 27,000 in Europe, 2,500 in Japan, and 1,800 in China. Approximately 15% of allogeneic recipients and 5% of autologous recipients develop BK cystitis, including hemorrhagic cystitis. We believe that MAU868 may represent an important future treatment option for these patients.

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 for treatment. The non-specific immunologic 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 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 team is 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 12 medicines from leading companies, including Gilead Sciences and Genentech. 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 and obtaining the rights to MAU868 from Amplyx, in each case with worldwide rights for development and commercialization in all indications. 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.

The near- and long-term objectives to achieve our goal include:

- **Complete global development of atacicept in IgAN.** We reported positive 24-week topline results from the ORIGIN Phase 2b clinical trial in January 2023, will report results from 36-week data in the second quarter of 2023, and plan to initiate a pivotal Phase 3 clinical trial in the second quarter of 2023.
- **Complete global development of atacicept in LN.** We are planning a Phase 3 clinical trial of atacicept as a potential treatment for patients with LN. LN is a frequent but devastating complication of SLE. The FDA approval of the anti-BLyS antibody, Benlysta (belimumab), provides clinical and regulatory precedent upon which to build our program. We believe

that atacicept could offer a significant efficacy advantage for LN patients with its dual anti-BLyS and anti-APRIL mechanism.

- **Complete global development of MAU868 in BK viremia in kidney transplant recipients and explore treatment of BK cystitis in HSCT patients**. We reported final results from our Phase 2 clinical trial in kidney transplant recipients in 2022. Pending alignment with regulatory authorities, we plan to initiate a Phase 2b or Phase 3 clinical trial.
- **Build and scale organizational capabilities to support commercialization of atacicept and MAU868.** Under the leadership of our experienced management team, we have begun building a specialized commercial organization with deep launch experience in nephrology, B-cell, autoimmune, and transplant therapeutics, to launch atacicept and MAU868 in the United States and other key markets, if approved.
- **Explore additional disease areas where atacicept holds significant therapeutic promise.** By targeting BLyS and APRIL, atacicept's ability to reduce disease-causing autoantibodies may provide clinical benefit. We intend to explore additional immunologic diseases where BLyS and APRIL are abnormally elevated, or where autoantibodies play an important role.
- **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 immunologic diseases.

Management team

We were founded and are led by a team of experienced drug development professionals who have proven track records in clinical and commercial development and have led or been involved in the approvals of 10 medicines from Gilead Sciences, Inc. (Gilead) and Genentech, Inc. (Genentech), including numerous drugs within Gilead's multi-billion-dollar blockbuster HIV and HCV franchises. Our President and Chief Executive Officer, Marshall Fordyce, M.D., brings more than 15 years of experience leading teams in clinical translation, development, and commercialization of new treatments. Earlier in his career, Dr. Fordyce served as Gilead's Senior Director of Clinical Research where he contributed to seven new drug approvals and served as project lead for Gilead's tenofovir alafenamide development program that led to five commercial products, including Genvoya and Descovy, which collectively generated over $12.0 billion in worldwide sales in 2019. Our senior management team also includes: Chief Financial Officer, Sean Grant, who was previously Vice President, Corporate Strategy and Business Development at CareDx, Inc. and Vice President in the Global Healthcare Investment Banking Division at Citigroup where he specialized in public and private capital raising as well as M&A, and executed a broad range of transactions for many of the world's leading life sciences companies; Chief Medical Officer, Celia Lin, M.D., who joined from Genentech and was previously at Amgen Inc., where she led Phase 3 global trial execution in various therapeutic areas, as well as a regulatory filing in an orphan disease; Chief Development Officer, Joanne Curley, Ph.D., who was formerly head of Portfolio Management at Gilead; Chief Business Officer, Lauren Frenz, who held positions of increasing responsibility within Gilead's commercial organization; Senior Vice President, Development Operations, Tom Doan, who was formerly Executive Director of Clinical Operations and Therapeutic Area Head of Inflammation and Respiratory at Gilead; Senior Vice President and Head of Product Development and Manufacturing, Neeraj Pakala, PhD, MBA, who served most recently as the VP of Product Development and Manufacturing at Aimmune Therapeutics (acquired by Nestlé), and prior to Aimmune, spent six years at Alexza Pharmaceuticals culminating as their Executive Director of Manufacturing and Engineering; and Senior Vice President, Finance and Chief Accounting Officer, Joseph Young, who was formerly Senior Vice President, Finance and Treasurer at Plexxikon Inc.

Intellectual property

As of December 31, 2022, our licensed patent portfolio related to atacicept contains approximately seven issued U.S. patents, one pending U.S. patent application, as well as foreign counterparts of a subset of these patents and pending U.S. patent application in several foreign countries, including countries within the European Patent Convention, the Eurasian Patent Organization, and Taiwan. 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. Additionally, we plan to seek orphan drug designation for atacicept in IgAN from the FDA and European Medicines Agency (EMA), which would allow us to obtain regulatory exclusivity protection from the approval date for seven years in the United States and ten years in the European Union. Our licensed patent portfolio covering MAU868 includes three issued U.S. patents, a pending U.S. patent application, as well as certain foreign counterparts of a subset of these patents and pending U.S. patent application, in Australia, China, Mexico, Japan, Europe and Canada. The pending U.S. application and foreign counterpart applications are co-owned by Novartis.

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. Up to 50% of confirmed IgAN patients progress to ESRD, requiring dialysis or kidney transplant. ESRD causes significant morbidity and impact on patients' lives and represents a

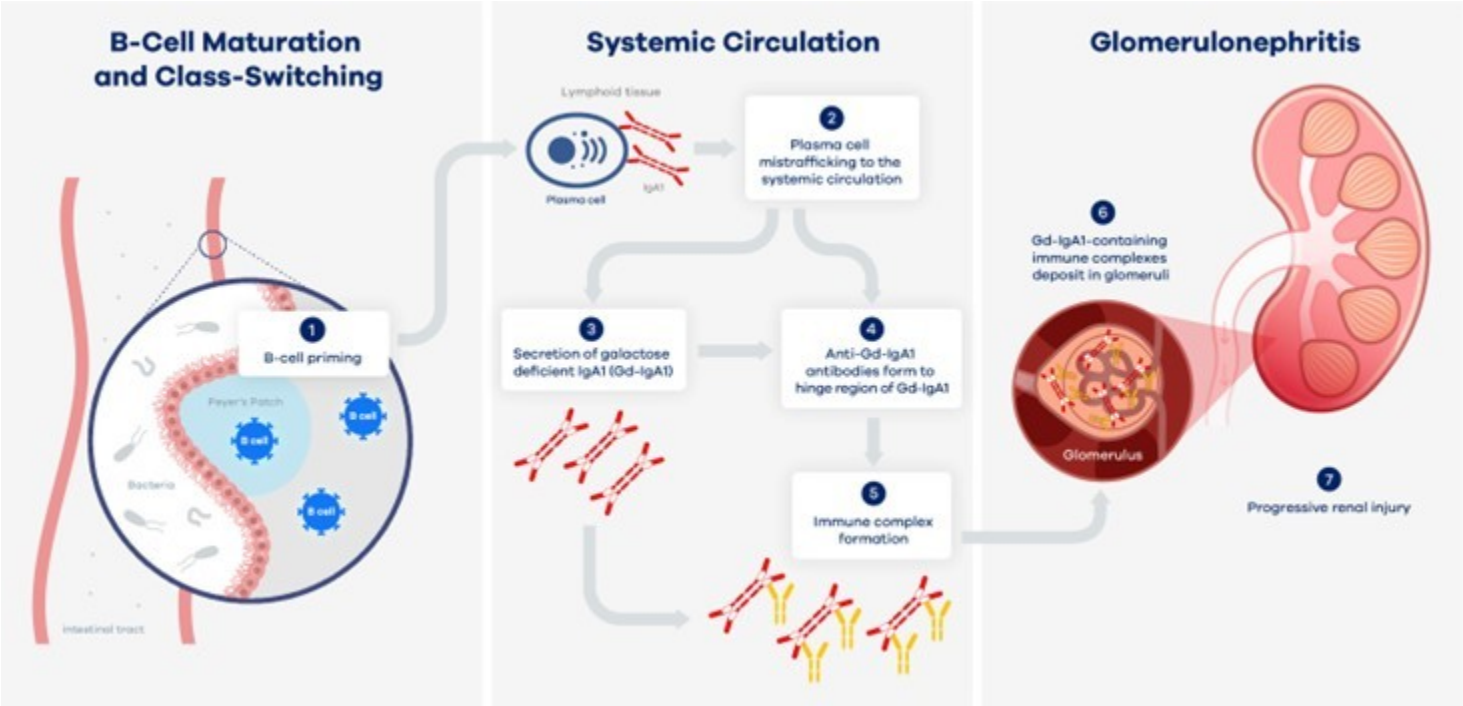
significant health economic burden estimated to be over $40 billion annually in the United States. Despite this high level of morbidity, the current standard of care consists of off-label use of RAAS inhibitors, including ACE inhibitors and ARBs, and potentially steroids. IgAN is driven by the production of pathogenic Gd-IgA1, and patients with elevated Gd-IgA1 are at increased risk of kidney-related morbidity and mortality. As reported in the Phase 2a JANUS trial, atacicept is the first molecule in development to demonstrate a 60% or greater reduction in serum Gd-IgA1 in IgAN patients, suggesting atacicept targets the source of disease in these patients. Based on these encouraging results, we are conducting the randomized, double-blind, placebo-controlled Phase 2b ORIGIN trial to further evaluate the efficacy and safety of atacicept in patients with IgAN. We reported positive topline results in January 2023, and we plan to initiate a pivotal Phase 3 clinical trial in the second quarter of 2023. We believe that atacicept has the potential to be the best-in-class and the leading B cell-targeted therapy for IgAN.

Pathophysiology of IgAN

The IgA antibody plays a key role in the immune system by protecting the body from foreign substances such as bacteria and viruses. Patients with IgAN produce elevated levels of Gd-IgA1. This abnormal glycosylation pattern of IgA1 is of central importance to the disease etiology.

As shown in Figure 1 below, a multi-step process leads to the ultimate development of progressive renal injury.

Figure 1: IgAN pathophysiology—overview



(1) B cells, which mature into plasma cells, are abnormally primed in the Peyer's patch region of the ileum of the intestines, potentially due to a combination of genetic predisposition and environmental, bacterial or dietary factors. BLyS promotes B cell maturation and survival, increasing the number of disease-causing B cells.

(2) APRIL, a factor important for plasma cell survival, becomes upregulated, resulting in increased numbers of disease-causing plasma cells.

(3) APRIL increases the number of plasma cells and increases antibody class switching, a mechanism that changes cells' production from one immunoglobulin to another, causing an increase in the production of immunogenic Gd-IgA1.

(4) The Gd-IgA1 antibodies are immunogenic when found in the systemic circulation, which triggers autoantibodies, or antibodies created by the body in response to a constituent of its own tissue.

(5) Autoantibodies against Gd-IgA1 lead to the formation of pathogenic immune complexes, or clusters of antibodies.

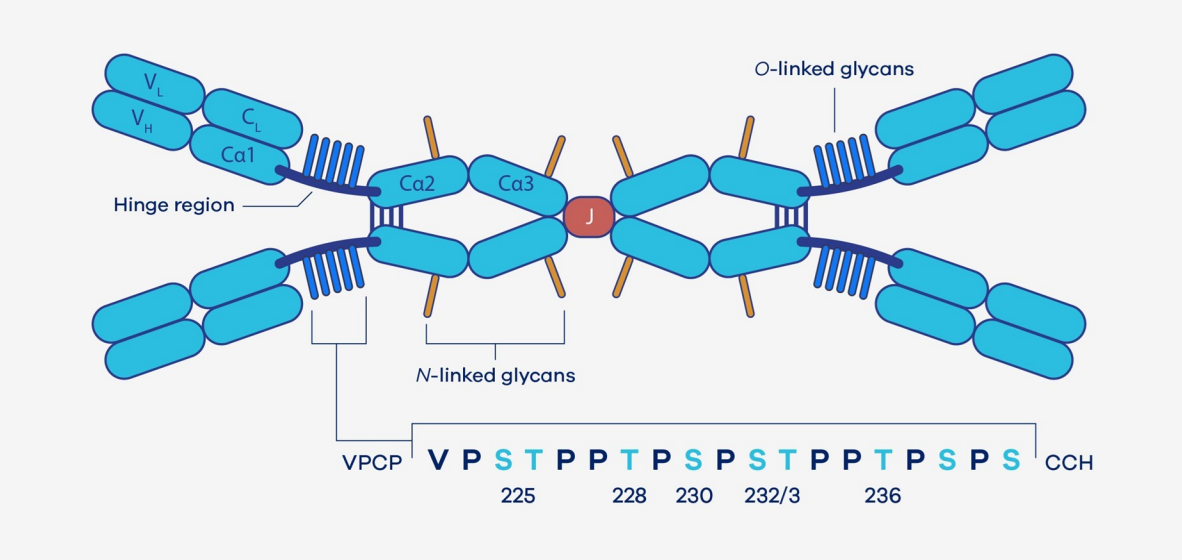
(6) Pathogenic immune complexes are deposited, become trapped in the kidney's glomeruli, and initiate an inflammatory response that damages the membranes, resulting in protein and blood leaking into the urine.

(7) As the glomeruli are destroyed, the kidney's ability to remove waste products from the blood is reduced, which can result in potentially life-threatening complications that lead to the need for dialysis or kidney transplant in many patients.

Gd-IgA1 is central to the pathogenesis of IgAN

Gd-IgA1 is a subclass of IgA antibodies that lack units of galactose, a type of sugar, at the O-linked glycans of their hinge region, as shown in Figure 2 below. The hinge region is a stretch of amino acids in the IgA antibody. Circulating immune complex-containing Gd-IgA1 proteins have been shown to be the target antigens for IgG antibodies with specificity for the hinge region.

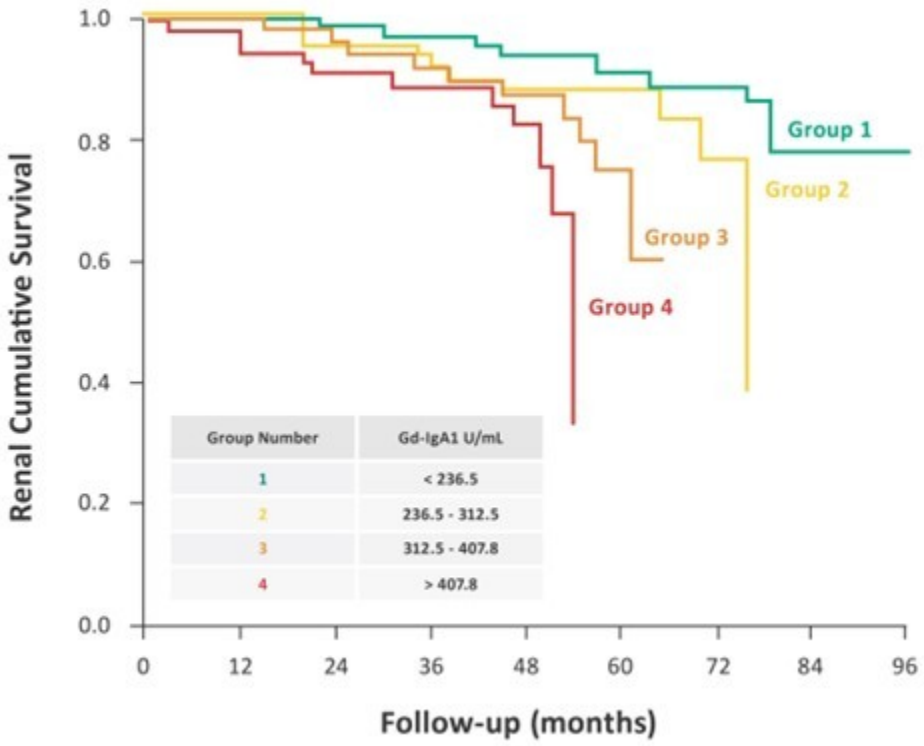
Figure 2: Components of Gd-IgA1



A histopathological hallmark of IgAN is deposition of Gd-IgA1 in the glomerular mesangium, either alone or in combination with IgG and/or IgM. Sampling of the serum of patients with IgAN has confirmed the presence of elevated levels of circulating immune complex-containing Gd-IgA1.

Clinical trials of patients with IgAN have correlated higher serum levels of Gd-IgA1 with greater severity of IgAN disease, suggesting that reduction in serum Gd-IgA1 may slow disease progression. Compared with healthy subjects, patients with IgAN have an increased proportion of Gd-IgA1 O-glycoforms in the serum. As published in Kidney International, in a prospective study of 275 patients with IgAN, higher serum levels of aberrantly glycosylated IgA1 demonstrated correlation with a higher likelihood of developing progressive renal failure, as shown in Figure 3 below. 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 ESRD or death.

Figure 3: Renal survival by serum Gd-IgA1 quartiles in IgAN patients



In addition, high serum APRIL levels correlate with increased expression of serum Gd-IgA1 in IgAN patients and high serum BLyS levels are associated with more severe clinical features, as well as more severe histopathological features. For these reasons, we believe a fusion protein that blocks both BLyS 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.

Disease burden, diagnosis, and predictors of disease progression

IgAN is a rare disease in the United States and European Union and is also the predominant cause of primary glomerulonephritis. Patients with IgAN are diagnosed throughout life, but most commonly in the second and third decades. There are three common ways in which patients present:

- 40–50% present with one or more episodes of gross (visible) hematuria, often linked to an upper respiratory tract infection.
- 30–40% present with microscopic hematuria and mild proteinuria, which is detected in a routine physical or during chronic kidney disease evaluation.
- Less than 10% present with either nephrotic syndrome or an acute, rapidly progressive glomerulonephritis with symptoms including edema, hypertension, renal insufficiency, and hematuria.

Once IgAN is suspected based on clinical history and laboratory data, kidney biopsy, which is the gold standard for IgAN diagnosis, is performed.

IgAN market opportunity

We estimate there are approximately 126,000 biopsy-confirmed IgAN patients in the United States, 136,000 in the European Union, and 130,000 in Japan, 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 U.S. market opportunity for novel therapeutics in IgAN is approximately $4.0 billion to $8.0 billion annually, based on the prevalence of the disease in the United States and the segment of IgAN patients at high risk of progressing to ESRD. In Europe and Japan, we estimate the annual market opportunity for novel IgAN therapeutics to be $1.0 billion and $600 million, respectively.

Current standard of care for IgAN patients

Despite the high unmet medical need in IgAN, there are limited treatment options available. The following two general approaches are typically employed for the treatment of patients with IgAN:

- Non-specific measures to slow progression, including blood pressure control, and in patients with proteinuria, RAAS inhibitors, including ACE inhibitors or ARBs.
- Steroids with or without other immunosuppressive agents to non-specifically reduce inflammation as a result of immune complex deposition in the glomeruli.

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. The current standard of care is seen as insufficient by physicians and patients; these treatment approaches have limited clinical efficacy and are not well tolerated. Approximately 50% of patients fail to achieve controlled UPCR on ACE inhibitors, ARBS, or steroids. 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 impact the underlying disease pathophysiology and more tolerable, steroid-sparing treatment options for IgAN patients.

Emerging therapies in development

There are two agents approved for the treatment of IgAN and there are several treatments in clinical development. The multistep IgAN pathogenesis hypothesis offers potential target points and approaches for therapeutic intervention. Most therapeutic candidates in clinical development have employed various approaches to target inflammation and the downstream effects. Atacicept is the first agent in development for IgAN that has demonstrated a 60% reduction of Gd-IgA1, the upstream source of IgAN pathogenesis.

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 earlier in 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 renal 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. Currently in a Phase 3 clinical trial in IgAN, reformulated budesonide has demonstrated statistically meaningful reduction of proteinuria, though systemic steroid side effects have been observed in prior clinical trials and the ongoing Phase 3 clinical trial.

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. Several ERAs, which have previously been approved for the treatment of pulmonary arterial hypertension and erectile dysfunction and make use of a vasodilatory effect, are currently in Phase 3 development and have been shown to reduce proteinuria in patients with IgAN. However, ERAs have been associated with edema, significant liver toxicity and increased risk of heart failure.

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. Several agents that inhibit complement activation are in clinical development for IgAN. Modest reduction of proteinuria has been observed in early clinical trials. 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 and plasma 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 BLyS and APRIL offers improved suppression of B-cell activities than blocking BLyS or APRIL alone. Atacicept blocks both BLyS and APRIL and has shown substantial reduction (60%) in Gd-IgA1. We believe that dual inhibition may also confer a potential dosing advantage versus APRIL-only inhibition.

Our solution: Atacicept

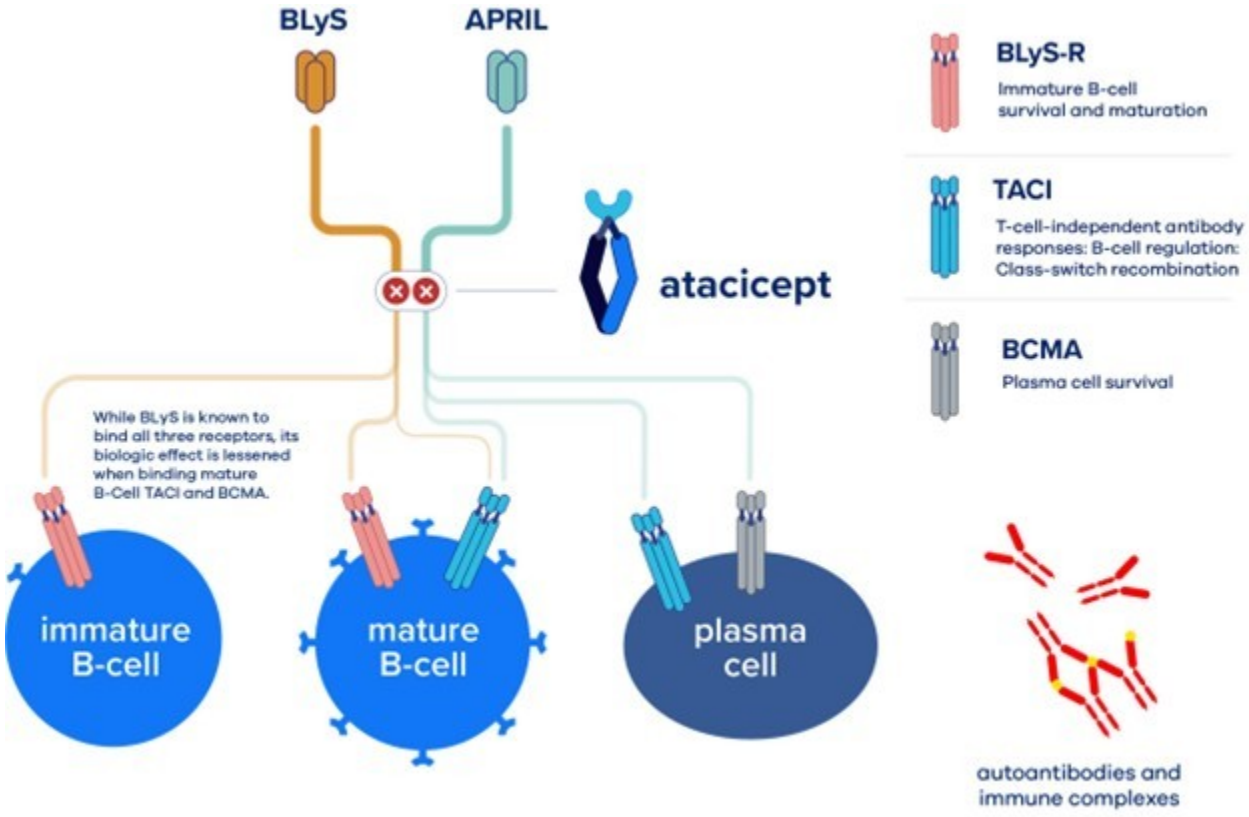
Atacicept is a fusion protein that blocks both BLyS and APRIL, which play key roles in the upstream pathway that causes IgAN, and is dosed once weekly via a 1-mL subcutaneous injection. As a result, we believe atacicept has the potential to be the first disease-modifying therapy for IgAN. Through an integrated analysis of randomized, double-blind, placebo-controlled clinical trials in multiple autoimmune diseases with over 1,500 patients to date, atacicept has a well-characterized clinical safety profile. In a Phase 2a clinical trial in patients with IgAN, atacicept substantially reduced Gd-IgA1 and demonstrated a clinically meaningful reduction in proteinuria

and stable eGFR parameters at week 24. We completed enrollment of patients in the Phase 2b ORIGIN trial in 2022, and we reported positive topline results in January 2023.

Our approach to IgAN: Reducing Gd-IgA1, the source of autoantibodies

Atacicept is a fully humanized fusion protein that impacts the B-cell pathway, which has well characterized implications in immunologic diseases. Specifically, as shown in Figure 4 below, atacicept contains the soluble transmembrane activator and CAML interactor (TACI) receptor that binds to the cytokines BLyS and APRIL. These cytokines are 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 BLyS and APRIL by TACI has been shown to be more potent than blocking BLyS alone or APRIL alone and has the benefit of targeting long-lived plasma cells, in addition to B cells, thus reducing autoantibody production, including Gd-IgA1, IgA, IgG and IgM. Therefore, atacicept's mechanism acts directly on the source of IgAN, which we believe will significantly mitigate the downstream effects of the disease.

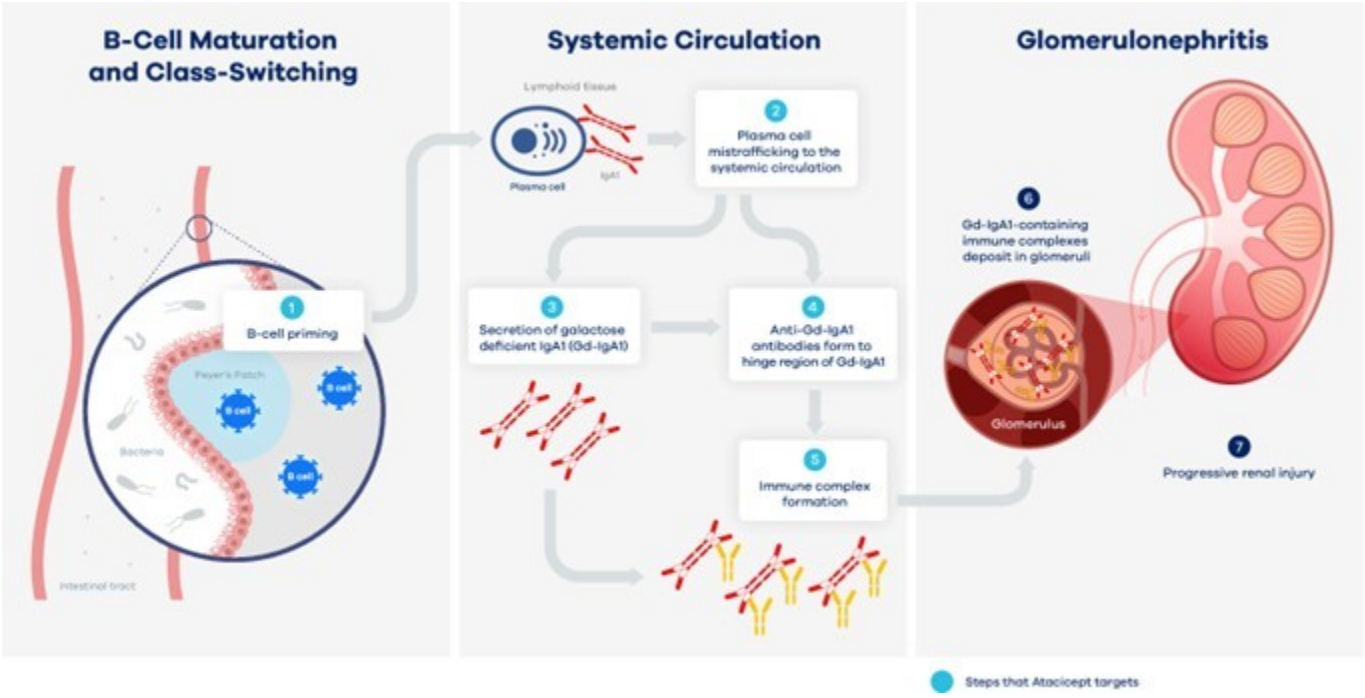
Figure 4: Atacicept blocks both BLyS and APRIL



Atacicept: Potential to address the core processes underlying IgAN pathogenesis

Atacicept's specific actions on IgAN disease pathogenesis are shown in Figure 5 below.

Figure 5: Atacicept impact on IgAN pathogenesis



(1) Atacicept blocks BLyS, a factor important for B cell survival and maturation, resulting in reduced numbers of disease-causing B cells.

(2) Atacicept blocks APRIL, a factor important for plasma cell survival, resulting in reduced numbers of disease-causing plasma cells.

(3) Reductions in plasma cells and in antibody class switching to IgA reduce production of immunogenic Gd-IgA1.

(4) Reductions in B cells, plasma cells, and Gd-IgA1 work together to reduce production of autoantibodies to Gd-IgA1.

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

(6) This in turn, reduces immune complex deposition in glomeruli and reduces complement activation.

(7) Ultimately, progressive renal injury is reduced, which we believe will significantly lower the morbidity and mortality associated with IgAN.

Atacicept's disease-modifying mechanism addresses the upstream processes that cause IgAN, while most other molecules in development act downstream. 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 demonstrated tolerability profile. Once weekly 1 mL subcutaneous dosing 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, Darmstadt, Germany, in clinical trials for several autoimmune diseases, including rheumatoid arthritis (RA), multiple sclerosis, SLE, and IgAN, and in totality studied in double-blind placebo-controlled clinical trials in over 1,500 patients to date. Safety, tolerability, pharmacokinetics, pharmacodynamics, and clinical efficacy of the weekly 25 mg, 75 mg and 150 mg doses administered subcutaneously have been studied.

Atacicept is being studied in the Phase 2b ORIGIN clinical trial, a multinational, 36-week randomized, placebo-controlled, double-blind trial, with a 60-week open label extension.

On January 3, 2023, and January 30, 2023, Vera reported positive week 24 primary results and shared the following results:

- Atacicept met its primary endpoint with a statistically significant reduction in proteinuria in the pooled 75/150 mg arms versus placebo
- In a prespecified per-protocol (PP) analysis, a blinded third-party CRO identified patients with protocol deviations that potentially confounded proteinuria measure. In the PP population excluding these patients, atacicept 150 mg achieved a 41%

mean reduction in proteinuria versus baseline, resulting in a statistically significant 34% placebo-adjusted reduction (p=0.025) at an early week 24 timepoint

- There was a trend towards deepening reductions in proteinuria at week 36 with available data in patients on atacicept.
- eGFR was stable through week 24 for all patients on atacicept
- Atacicept was well tolerated, and its safety profile in IgAN patients was comparable to placebo
- There was a 60% reduction in Gd-IgA1 at week 24 with atacicept 150 mg

Based on these Phase 2b ORIGIN trial results, the atacicept 150 mg dose was selected for a forthcoming Phase 3 clinical trial, which we expect to initiate in the second quarter of 2023. We will use the same formulation as the Phase 2b trial, while incorporating learnings from Phase 2b subgroup analyses to design a de-risked Phase 3 trial that accurately assesses treatment efficacy while minimizing potential confounders for proteinuria measure.

Atacicept safety and tolerability profile: Integrated analysis

Though there was a limited number of patients in the JANUS trial, in an integrated safety analysis of clinical trials in multiple indications with over 1,500 patients in a number of indications, atacicept was well tolerated, shown in Figure 6 below. Serious treatment-emergent adverse events (TEAEs) reported in the highest proportions were those in infections and infestations (placebo 3.9% versus atacicept 4.4%), musculoskeletal and connective tissue disorders (placebo 1.9% versus atacicept 1.3%), and nervous system disorders (placebo 2.1% versus atacicept 1.2%). The most frequently reported TEAE was pneumonia (placebo 1.2% versus atacicept 1.3%). We believe that this large and established data set is a competitive advantage for atacicept versus other approved and emerging therapies in development, many of which lack extensive safety data.

Figure 6. Integrated safety analysis: Summary of treatment-emergent adverse events > 5% in any arm, by dose

Patients, %	Placebo n=483	Atacicept 25 mg n=129	Atacicept 75 mg n=384	Atacicept 150 mg n=572	All Atacicept n=1085	Overall n=1568
Infections and infestations	211 (43.7)	43 (33.3)	180 (46.9)	281 (49.1)	504 (46.5)	715 (45.6)
General disorders and administration site conditions	100 (20.7)	42 (32.6)	145 (37.8)	201 (35.1)	388 (35.8)	488 (31.1)
Gastrointestinal disorders	97 (20.1)	20 (15.5)	98 (25.5)	129 (22.6)	247 (22.8)	344 (21.9)
Nervous system disorders	92 (19.0)	28 (21.7)	83 (21.6)	100 (17.5)	211 (19.4)	303 (19.3)
Musculoskeletal and connective tissue disorders	86 (17.8)	21 (16.3)	70 (18.2)	105 (18.4)	196 (18.1)	282 (18.0)
Respiratory, thoracic and mediastinal disorders	50 (10.4)	7 (5.4)	45 (11.7)	66 (11.5)	118 (10.9)	168 (10.7)
Serious TEAE	51 (18.9)	15 (30.0)	51 (23.9)	61 (21.8)	127 (23.4)	178 (21.9)

The safety profile of atacicept 25 mg, 75 mg and 150 mg has been characterized in healthy subjects and patients with RA, multiple sclerosis, optic neuritis, SLE, and B-cell malignancies, and is considered acceptable in IgAN. Over 1,940 individuals have been enrolled in 22 clinical trials, of which over 1,425 individuals have received at least one dose of atacicept. In the three Phase 2/3 clinical trials, 590 patients with SLE and 11 patients with IgAN have received at least one dose of atacicept.

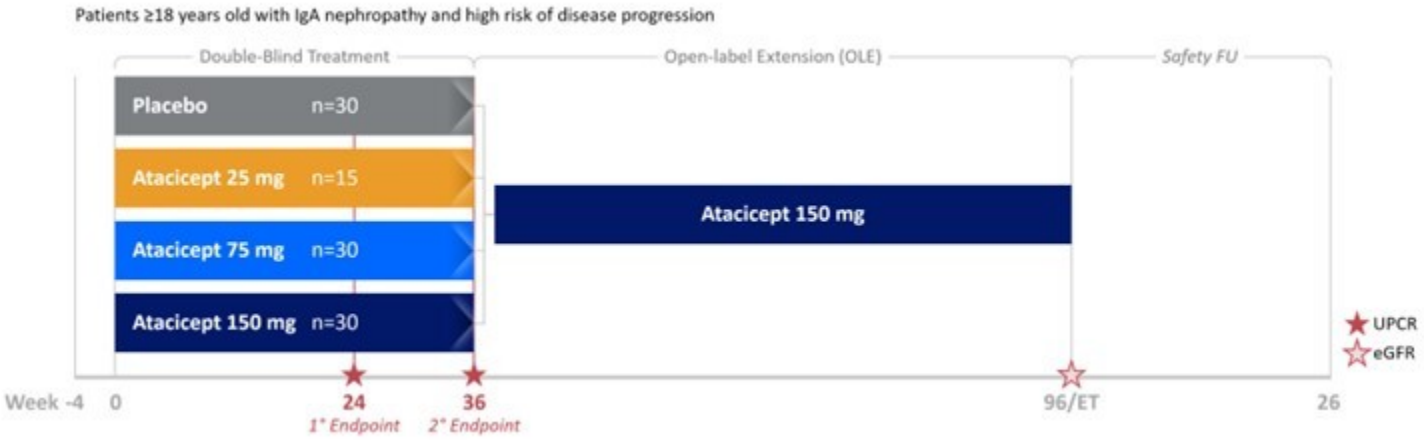
We believe the benefit-risk balance of atacicept to be favorable for further development in IgAN and certain additional autoimmune diseases, and we intend to explore additional immunologic diseases where BLyS and APRIL are abnormally elevated, or where autoantibodies play an important role.

Ongoing phase 2b ORIGIN clinical trial design

ORIGIN, our ongoing Phase 2b randomized, double-blind, placebo-controlled, dose-ranging trial, will evaluate the efficacy and safety of atacicept in patients with IgAN. The clinical trial consists 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 assesses multiple doses (25 mg, 75 mg and 150 mg) of once weekly 1-mL subcutaneous injections of atacicept versus placebo on impact of renal function as measured by proteinuria. The primary endpoint is change from baseline in UPCR at 24 weeks based on 24-hour urine collection, with a secondary endpoint of UPCR at 36 weeks. Other endpoints include change from baseline in UPCR at 12, 48, and 96 weeks, change from baseline in eGFR at 12, 24, 36, 48, and 96 weeks, change from baseline in IgA, IgG, IgM, C3, C4, and Gd-IgA1 levels at 12, 24, 36, 48, and 96 weeks, number of

participants with adverse events during the double-blind treatment period through 36 weeks, and the serum concentration of atacicept through study completion.

Figure 7. Phase 2b ORIGIN trial design



UPCR is an accepted surrogate primary endpoint for clinical trials in IgAN, which allows for a faster path to commercialization than rate of change/slope in eGFR, which is measured after two years. The recommendation for usage of this surrogate endpoint was put forward by the ASN, partnering with the FDA under the auspices of the Kidney Health Initiative, and the EMA, and has now been implemented in five Phase 3 clinical trials in IgAN and in the two FDA approvals granted. Accelerated and/or conditional approval may be granted on the UPCR endpoint, with full approval to be granted upon longer-term data demonstrating stabilization of eGFR with treatment.

In mid-2022 we completed enrollment of the Phase 2b ORIGIN trial, enrolling a total of 116 patients at multiple global sites. In January 2023, we announced positive topline 24-week results. Atacicept met the primary endpoint: the pooled 75 mg and 150 mg arms achieved a statistically significant reduction in proteinuria versus placebo at 24 weeks. In a prespecified PP analysis, a blinded third-party CRO identified patients with protocol deviations that potentially confounded proteinuria measure. In the PP population excluding these patients, atacicept 150 mg achieved a 41% mean reduction in proteinuria versus baseline, resulting in a statistically significant 34% placebo-adjusted reduction (p=0.025) at an early week 24 timepoint. Available data show a trend towards deeper reductions in proteinuria with atacicept at 36 weeks, for which full results will read out in the second quarter of 2023. eGFR was stable through week 24 for all patients on atacicept. The 150 mg dose achieved a 60% reduction in Gd-IgA1 at week 24. Atacicept was well tolerated, and its safety profile in IgAN patients was also comparable to placebo. Treatment will remain blinded through 36 weeks, after which all patients will roll onto the open label portion of the study and receive atacicept 150 mg through 96 weeks, providing the opportunity to assess long-term safety of atacicept in patients with IgAN.

We plan to advance atacicept 150 mg into a pivotal Phase 3 trial in the second quarter of 2023, using the same formulation from the Phase 2b trial and learnings from the Phase 2b subgroup analyses to design a de-risked Phase 3 trial that accurately assesses treatment efficacy while minimizing potential confounders for proteinuria measure. With the ongoing data from the Phase 2b trial through 2024 and Phase 3 topline results expected in the first half of 2025, if positive, we expect to submit a BLA for atacicept in IgAN to the FDA in the second half of 2025.

Atacicept in LN: A severe renal manifestation of SLE

Based on discussions with the FDA following the review of Phase 2 data in SLE, we are planning a Phase 3 clinical trial of atacicept as a potential treatment for patients with LN, a severe renal manifestation of SLE. We estimate that there are approximately 120,000 LN patients in the United States, 70,000 in the European Union, and 21,000 in Japan. Significant unmet need for improved efficacy persists for these patients despite the recent approval of the first two LN-specific therapies. Fewer than half of patients treated for LN have a complete response to therapy, and among patients without a complete response, over half will have non-functioning kidneys within five years. Benlysta (belimumab), a BLyS-only inhibitor, is one of the two therapies approved for patients with LN. Both BLyS and APRIL levels are increased in patients with SLE, suggesting that dual inhibition by atacicept may be more potent than blocking BLyS alone and has the benefit of targeting plasma cells in addition to B cells. Merck KGaA, Darmstadt, Germany previously initiated a randomized, double-blind, placebo-controlled Phase 2/3 clinical trial of atacicept in LN, the APRIL-LN trial, aimed to evaluate the efficacy and safety of atacicept at 150 mg twice weekly for four weeks—then weekly—in patients with active LN. However, this trial was terminated early due to three patients developing hypogammaglobulinemia with induction therapy (MMF and CS) which continued to worsen when initiating atacicept and subsequently two patients developed pneumonia. In prior Phase 2 clinical

trials of atacicept in SLE also conducted by Merck KGaA, Darmstadt, Germany, despite missing its primary endpoint of improved SLE responder index 4 (SRI-4) at week 24, in the broader SLE study population, atacicept achieved positive clinical data on multiple measures within the prespecified HDA patient segment, including reduction of renal flares, which we believe supports atacicept's applicability in LN. Because both preclinical and clinical evidence suggests atacicept's dual inhibition of BLyS and APRIL may provide improved clinical outcomes, measured by endpoints designed to assess efficacy, compared to inhibiting either signal alone, we believe there is a strong rationale to conduct a clinical trial of atacicept in LN.

Pathophysiology of LN

LN is a severe renal manifestation of SLE (also referred to as lupus). SLE is a chronic and disabling autoimmune disease in which the body's own immune system attacks itself. SLE predominantly affects women and is more prevalent in women of color. When LN is diagnosed in a patient, mortality risk dramatically increases.

LN pathogenesis involves a variety of disease-causing mechanisms, including the formation of immune deposits within the kidneys that are primarily due to anti-double stranded DNA (anti-dsDNA) antibodies, which atacicept has been shown to reduce in a dose-dependent manner. However, there are also instances in which induction of LN by anti-dsDNA may not require immune complex formation— autoreactive plasma cells in the kidney may be another cause of nephritis. Certain genes and genetic factors may also predispose patients.

LN disease burden and diagnosis

LN has a strong influence on morbidity and mortality within SLE, with up to 26% of patients progressing to ESRD within 15 to 20 years from initial diagnosis. LN is characterized by abnormal proteinuria, hematuria, and impaired kidney function.

Diagnosed SLE patients are routinely monitored by rheumatologists, who will refer to nephrologists upon suspicion of renal manifestations. In the United States and European Union, LN patients without a prior SLE diagnosis will typically first present to a primary care physician (U.S.) or internist (EU) with hematuria or proteinuria before ultimate referral to a nephrologist. For confirmatory diagnosis, nephrologists perform renal biopsy—of which the results are analyzed to determine histologic class and relevant treatment course.

LN patients are segmented in Classes I–VI based on histopathology and degree of renal impairment, and this classification drives treatment decisions. Class I, or Minimal mesangial LN, is rarely diagnosed as these patients have normal urinalysis and therefore biopsy is not typically performed. Class II, Mesangial proliferative LN, refers to microscopic hematuria and/or proteinuria. Patients with Class III, or Focal LN, tend to have both hematuria and proteinuria, and may have hypertension, decreased eGFR, and nephrotic syndrome. Class IV, or Diffuse LN, is the most commonly diagnosed and severe form of LN, with patients exhibiting hematuria, proteinuria, nephrotic syndrome, hypertension, and decreased eGFR. Patients with Class V, or lupus membranous nephropathy, tend to have nephrotic syndrome, and may have microscopic hematuria and hypertension, but normal UPCR. Class VI, or advanced sclerosing LN, refers to a slow progression of kidney dysfunction correlated with proteinuria.

As shown in Figure 8 below, LN typically develops early in the disease course, though the rate of SLE patients who develop LN increases over time.

Figure 8: LN progression

LN market opportunity

According to the Centers for Disease Control and Prevention, there are approximately 322,000 people living with SLE in the United States.

Approximately half of individuals living with SLE develop LN within 15 years of their initial diagnosis, as shown in Figure 8 above.

We estimate that there are approximately 120,000 LN patients in the United States, 70,000 in the European Union, and 21,000 in Japan at present. In the United States, higher prevalence rates occur in the heterogeneous population, as both SLE and LN occur more frequently among non-White patients—with the highest frequency of LN occurring in Black and Hispanic populations after adjustment for socioeconomic factors. In all three geographies, women account for the majority of LN cases.

Based on primary market research with physicians and payors and extensive secondary research, we estimate the market for novel LN therapeutics annually to be approximately $2.0 to $5.0 billion, $600 million and $200 million in United States, Europe and Japan, respectively.

Current standard of care for LN patients

Current LN treatment is largely cyclical, with induction versus maintenance therapy dictated by the severity of disease and frequency of flares. Treatment is driven by histologic class and can be influenced by the treatments that the patient has been on since SLE diagnosis. Class I and II LN do not generally need LN-specific treatment. Within Class III–V, patients tend to receive induction therapy for approximately one year to achieve complete or partial remission. Induction therapy for Class III–IV patients include several immunosuppressive agents, such as MMF ± CS or cylophosphamide (CYC) ± CS in the first line of treatment, switching to either CYC or MMF in the second line, whichever was not administered first line. Third line induction therapy has generally consisted of rituximab for Class III–V patients. For induction therapy of Class V LN patients, patients typically receive MMF ± steroids in the first line, a calcineurin inhibitor in the second line, and rituximab for third line. Maintenance therapy, which typically consists of MMF, azathioprine (AZA), or hydroxychloroquine (HCQ), is typically prescribed to well controlled patients after any line of induction to reduce flares. Immunosuppressive therapy is unlikely to be beneficial for Class VI, or advanced sclerosing LN.

Patients on maintenance still experience flares approximately every year, resulting in cycling back to induction therapy. Many of the therapies used in the treatment paradigm today have limited efficacy and poor tolerability profiles—and therefore there is significant unmet need for safe and specific therapies that have a direct impact on LN disease activity without a high risk of infection.

Recently approved and emerging therapies in development

Until recently, there were no approved therapies for the treatment of LN. In December 2020, the FDA approved Benlysta (belimumab), an anti-BLyS antibody, for treatment of adult patients with active LN who are receiving standard therapy. In January 2021, the FDA approved Lupkynis (voclosporin), a calcineurin inhibitor, to be used in combination with a background immunosuppressive therapy regimen for adult patients with active LN. Clinical guidelines on how these two medicines may be incorporated into standard of care remain to be updated. In addition to Benlysta (belimumab) and Lupkynis (voclosporin), there are several other cytokine inhibitors and complement inhibitors in development for LN.

B-cell Modulators. Benlysta (belimumab) is an anti-BLyS antibody, belonging to the class of B-cell modulators. Within the B-cell modulator class, there is a desire for different mechanisms to target the complex pathophysiology of LN. The results shared to date for these agents reveal statistically significant efficacy, but complete response rates are only achieved in fewer than 50% of the patients studied.

Calcineurin Inhibition. Lupkynis (voclosporin) is a calcineurin inhibitor, a mechanism which has been commonly used in generic form as induction therapy for Class V patients. Calcineurin inhibition has been shown to reduce cytokine activation of T-cells and protect against proteinuria, however it may pose serious infection risks and nephrotoxicity is a known class effect.

Cytokine Inhibitors. The other cytokine inhibitors under investigation offer blockade of key pro-inflammatory cytokines (IL17A, IL23, Type 1 IFNs) involved in the pathogenesis of LN, however, they are early in their development.

Complement Pathway Inhibitors. Complement pathway inhibitors are also early in their development, but unlikely to be disease-modifying, since complement activation is one result of the inflammation caused by immune-complex deposition in the kidneys, downstream of key steps in disease pathophysiology.

Our solution: Atacicept

Targeting both BLyS and APRIL is key to reduce autoantibodies produced by B cells and plasma cells in LN. Autoantibodies play a large role in the pathogenesis of LN. Autoantibodies target tissue or form immune complexes, leading to tissue and organ damage. Both short-lived and long-lived plasma cells are responsible for generating high levels of autoantibodies in LN.

Short-lived plasma blasts are the main B cell effector subset dependent on activation of various B cell receptors such as TACI, B cell maturation agent (BCMA) and BLyS. Therefore, B cell blocking agents such as Rituxan (rituximab; anti-CD20) and Benlysta (belimumab; anti-BLyS) can reduce short-lived plasma cells and the resulting autoantibody production.

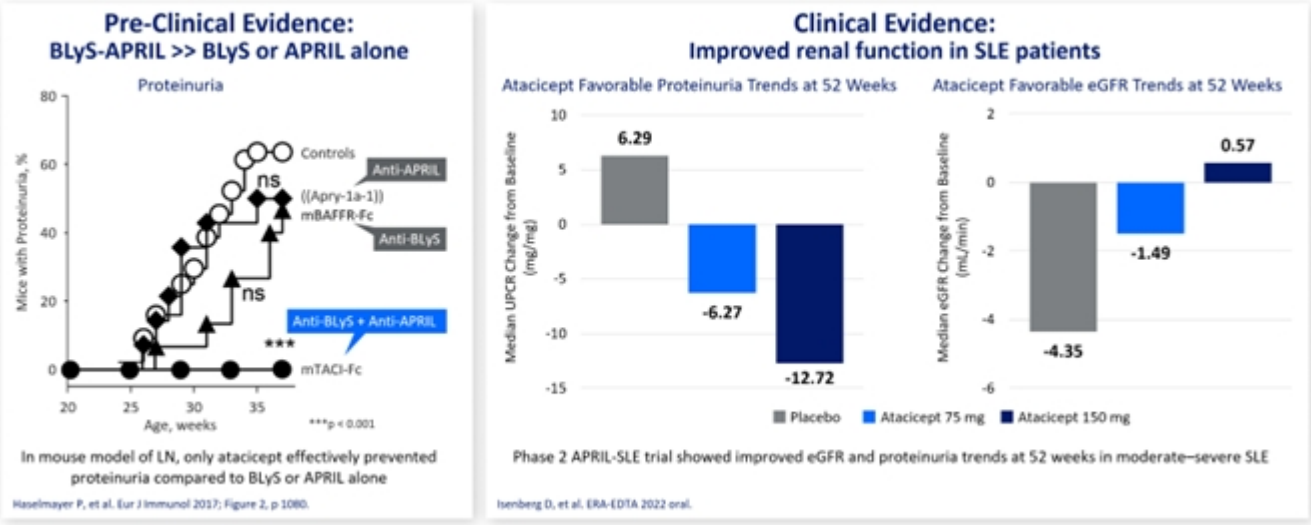
Long-lived plasma cells are in bone marrow and inflammatory tissue niches, and form antibodies in the absence of B-cell activation. Inflammatory tissue has high levels of BLyS and APRIL, which serve to maintain long-lived plasma cells. Inhibiting APRIL blocks long-lived nonproliferating plasma cell activities to further reduce autoantibody formations in LN.

Atacicept contains the soluble TACI receptor that binds to the cytokines BLyS and APRIL and prevents their interaction with TACI, BCMA and BLyS receptors (BLyS-R is also known as B cell activating factor receptor or BAFF-R). Atacicept thus inhibits survival of immature and mature B cells and antibody-producing plasma cells and prevents immunoglobulin class switching. In contrast to a range of available biologics directed at B cells only, we believe atacicept has a prompt and marked effect on antibody production by inhibiting both short-lived and long-lived plasma cells.

Preclinical evidence indicates that dual inhibition of BLyS and APRIL is superior to either BLyS or APRIL alone. Animal models of kidney disease have confirmed that atacicept reduces plasma cell numbers and reduces autoantibodies more effectively than BLyS and APRIL antibodies given individually. In a mouse model of collagen-induced arthritis, soluble atacicept inhibited development of collagen-specific antibodies and reduced the incidence of the disease better than BLyS (also known as BAFF) agents alone. In a mouse model of SLE, soluble atacicept decreased the number of B cells, increased survival time and reduced severity of disease symptoms. Furthermore, in a mouse model of SLE, atacicept administered after onset of autoimmunity decreased the number of bone marrow plasma cells and slowed down further formation of autoantibodies. Atacicept prevented renal damage during a 12-week treatment period regardless of autoantibody levels, while the BLyS-only inhibitor did not. Atacicept also decreased established plasma cells in an immunization model better than single inhibitors of BLyS or APRIL.

In patients with active SLE, targeting BLyS and APRIL with atacicept appears to have improved clinical outcomes, measured by endpoints designed to assess efficacy, compared to BLyS alone (Benlysta [belimumab]). While atacicept and Benlysta (belimumab) have not been studied head-to-head in clinical trials, each has been studied in similar populations of patients with SLE, and results of a Phase 2 clinical trial of 150 mg of atacicept compared favorably to published reports on changes in SLE responder index (SRI-4) of belimumab. In a Phase 2 clinical trial of atacicept, the magnitude of efficacy as measured by the difference between treatment and placebo in SRI-4 at 24 weeks was approximately 39% (25% placebo, 64% atacicept 75 mg, 65% atacicept 150 mg, both p=0.005). For Benlysta (belimumab), in a Phase 3 clinical trial of SLE patients, a published analysis of patients with HDA and serologically active disease, clinical efficacy for Benlysta (belimumab) 10 mg/kg showed a difference between treatment and placebo in SRI-4 at 24 weeks of approximately 12%.

Figure 9: Evidence for atacicept performance in SLE



Atacicept consistently demonstrated improved clinical outcomes, measured by endpoints designed to assess efficacy, versus placebo in SLE patients with HDA (SLEDAI-2K ≥10) across additional clinical measures, and consistently across all SRI cut-offs, as well as using the separate clinical assessment, British Isles Lupus Assessment Group (BILAG)-based Combined Lupus Assessment (BICLA). In the HDA population in ADDRESS II, the BICLA delta at week 24 was 20% (atacicept 150 mg 49%, placebo 29.2%, p=0.035), which compares very favorably to BICLA data from other late-stage SLE clinical trials, such as anifrolumab (week 24 BICLA in 16%). We believe that based on these results, an improved clinical benefit may be observed in patients with LN.

Prior clinical development of atacicept in LN

Merck KGaA, Darmstadt, Germany conducted a randomized, double-blind, placebo-controlled Phase 2/3 clinical trial of atacicept in LN, the APRIL-LN trial, aimed to evaluate the efficacy and safety of atacicept in patients with active LN. As per trial protocol, patients initiated high-dose CS (the lesser of 0.8 mg/kg/day or 60 mg/day prednisone) and MMF (1 g daily, increased by 1 g/day each week to 3 g daily) at the time of screening (day -14). From day 1, atacicept (150 mg, subcutaneously, twice weekly for four weeks, then weekly) was initiated with MMF along with a tapered dose of CS.

Four of the six enrolled LN patients developed decreases in serum IgG levels following the initiation of MMF and CS in the setting of significant proteinuria, which are contributing factors of hypogammaglobulinemia. After initiation of atacicept, serum IgG levels further declined; two patients developed severe hypogammaglobulinemia, defined as IgG <3 g/L, and pneumonia. These two patients recovered after treatment discontinuation and received antibiotics therapy. This trial was terminated. Based on the detailed assessment of results from this trial, plans to develop atacicept for the treatment of LN will explore alternatives to the induction regimen studied previously, including not dosing atacicept 150 mg twice weekly; clearly defining the dosing regimen for CS and MMF; and closely monitoring immunoglobulin levels during induction therapy.

Evaluation of safety and efficacy profile of atacicept in SLE

Atacicept 75 mg and 150 mg, dosed once per week with subcutaneous auto-injection, have demonstrated improved clinical outcomes, measured by endpoints designed to assess efficacy, in patients with SLE in the Phase 2 APRIL-SLE and ADDRESS II trials. In these trials, autoantibody titers were significantly reduced, and prespecified and post hoc analyses revealed prevention of flare and reduction of active disease with atacicept treatment, despite the fact that the primary endpoints in these trials were not met.

In ADDRESS II, SLE patients with HDA (SLEDAI-2K ≥10) had an increase in SRI-6 response, attainment of low disease activity (LDA), or SLEDAI-2K ≤2, and a reduction of the risk of a first new severe flare (defined by SLEDAI Flare Index [SFI] or by BILAG A) when treated with atacicept 150 mg. Furthermore, the 024 long-term extension (LTE) trial showed durability of these effects through a median duration of treatment of 96 weeks.

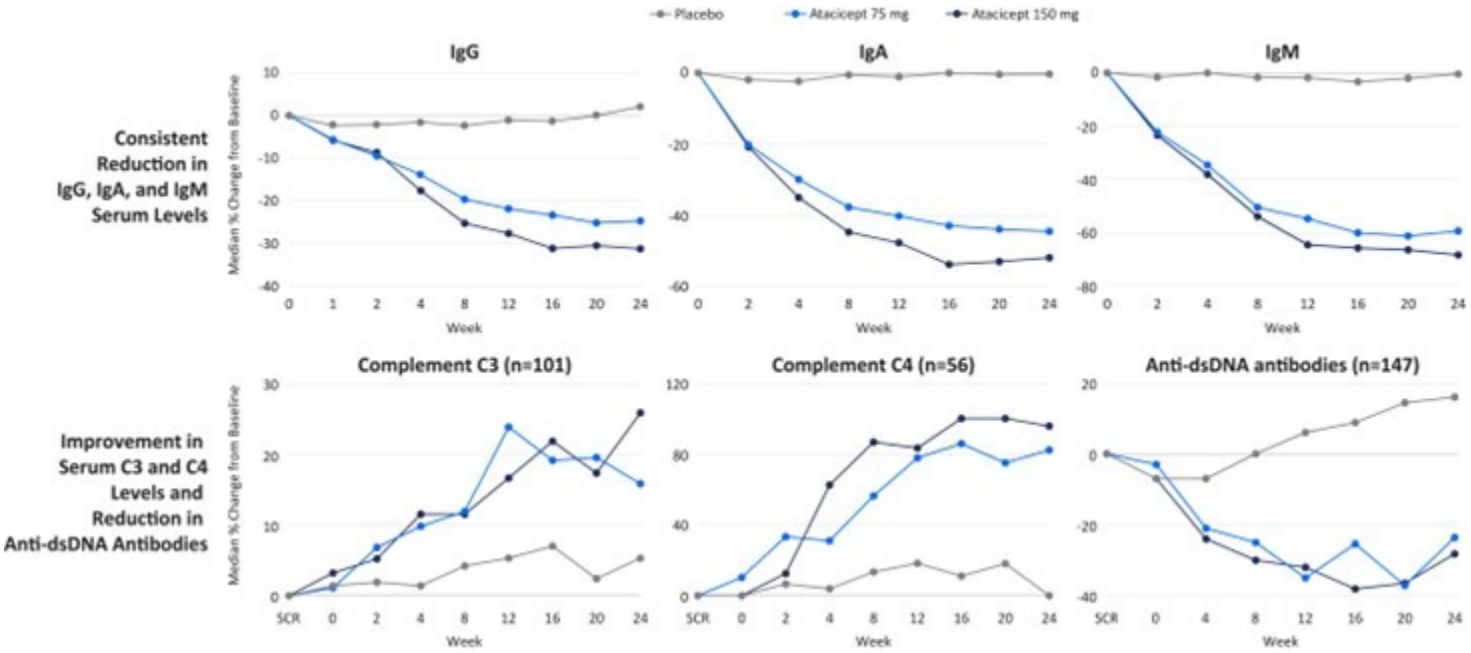
Following the release of the HDA data, Merck KGaA, Darmstadt, Germany pursued the planning and initiation of a global Phase 3 registrational program for atacicept 150 mg once per week in SLE. This program, including two large Phase 3 randomized placebo-controlled trials of atacicept 150 mg compared to placebo, were reviewed by FDA via end-of-phase-2 communication and scientific advice communication with EMA, prior to Merck KGaA, Darmstadt, Germany terminating the SLE program and the IgAN program for business strategy reasons.

Phase 2 clinical trial in patients with SLE for 24 weeks

ADDRESS II, a Phase 2b SLE trial of 306 patients, evaluated the efficacy and safety of atacicept at two subcutaneous doses (150 mg and 75 mg) versus placebo over the course of 24 weeks, with an LTE arm continuing an additional 96 weeks.

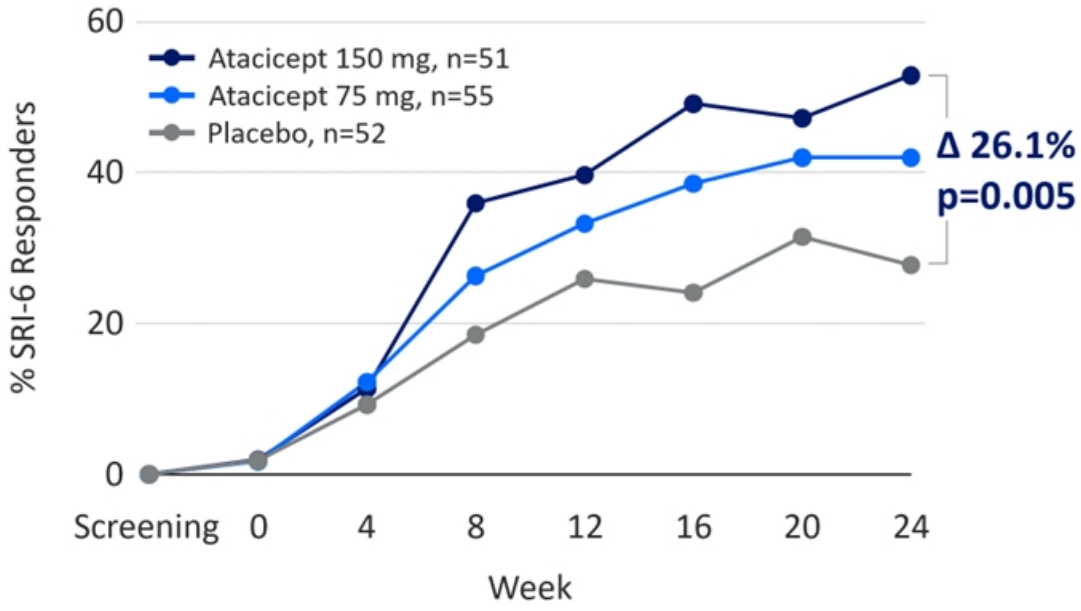
Atacicept demonstrated consistent reductions in IgG, IgA, and IgM serum levels, and reductions in anti-dsDNA antibodies, as well as improvements in serum C3 and C4 levels, as shown in Figure 10 below.

Figure 10: Atacicept impact on key biomarkers in the phase 2 ADDRESS II trial



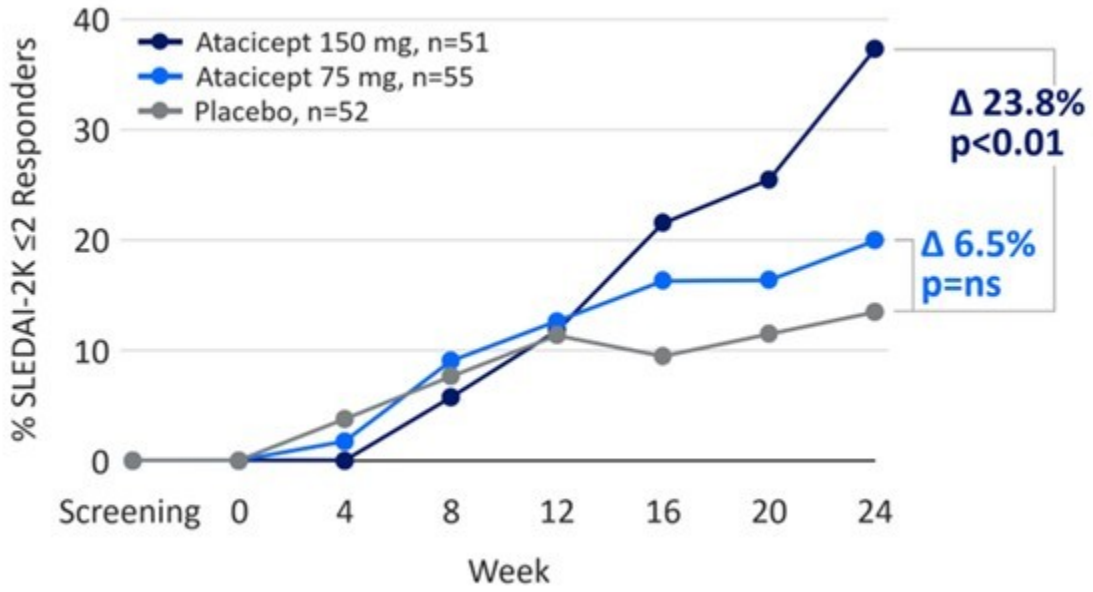
Though atacicept missed its primary endpoint of SRI-6 reduction versus placebo in all comers, in a prespecified analysis of HDA patients, which comprised approximately half of those enrolled, atacicept 150 mg showed improved clinical outcomes, measured by multiple endpoints designed to assess efficacy, including a 26% improvement (p=0.005) in SRI-6 versus placebo, flare risk reduction, and serologic marker normalization. SRI-6 response is defined as ≥6-point reduction in the SELENA-SLEDAI score, no new BILAG A organ domain score or two new BILAG B organ domain scores, and no worsening (<0.30-point increase) in Physician's Global Assessment score.

Figure 11: SRI-6 response among HDA patients in the phase 2 ADDRESS II trial



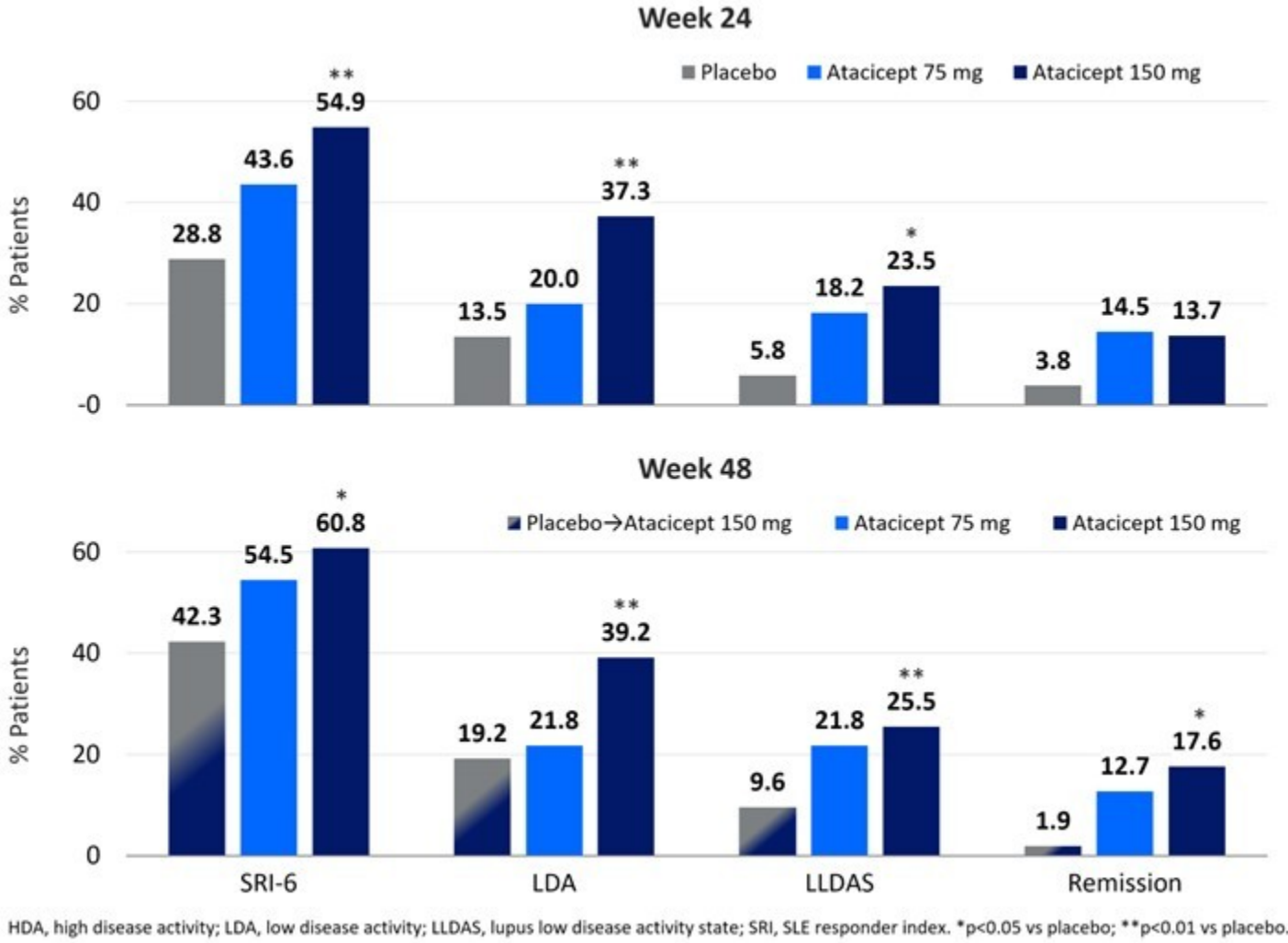
Also, among this HDA patient segment, significantly more patients on the atacicept 150 mg arm reached LDA, as measured by SLEDAI-2K ≤2, as shown in Figure 12 below.

Figure 12: HDA patients reaching LDA in the phase 2 ADDRESS II trial



Furthermore, Figure 13 below demonstrates the durable clinical outcomes observed in the HDA segment: more patients reached LDA by multiple measures at both week 24 and week 48. Significantly more patients treated with atacicept 150 mg once weekly versus placebo demonstrated clinical improvement (as shown by SRI-6), achieved LDA, and remission.

Figure 13: Durable clinical outcomes observed in HDA patients in the phase 2 ADDRESS II trial



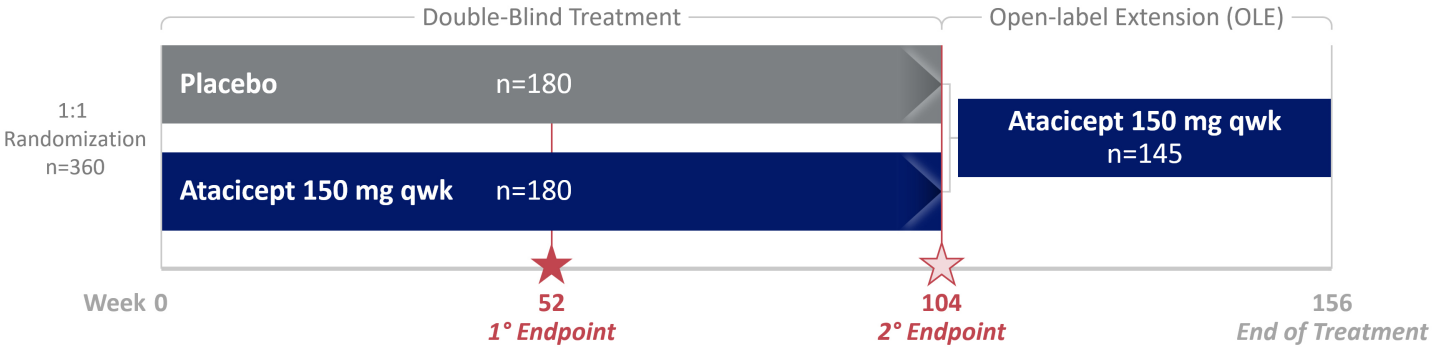
HDA, high disease activity; LDA, low disease activity; LLDAS, lupus low disease activity state; SRI, SLE responder index. *p<0.05 vs placebo; **p<0.01 vs placebo.

We believe that the clinical outcomes, measured by multiple endpoints designed to assess efficacy within the HDA segment of the SLE population in the ADDRESS II trial—and a favorable tolerability profile observed in ADDRESS II, as well as the integrated safety analysis in over 1,500 patients—provide the foundation of our rationale for developing atacicept further in LN, a severe renal manifestation of SLE.

Planned phase 3 clinical trial design

Our Phase 3, randomized, parallel-group, double-blind, placebo-controlled, multicenter, multinational study will evaluate the efficacy and safety of atacicept vs placebo in patients with LN. The clinical trial consists of a 104-week double blind treatment period, followed by a 52-week open label treatment period and a 26-week safety follow-up period. The trial, as shown in Figure 14 below, will assess atacicept 150 mg once weekly subcutaneous injections versus placebo. The primary endpoint is complete renal response at 52 weeks.

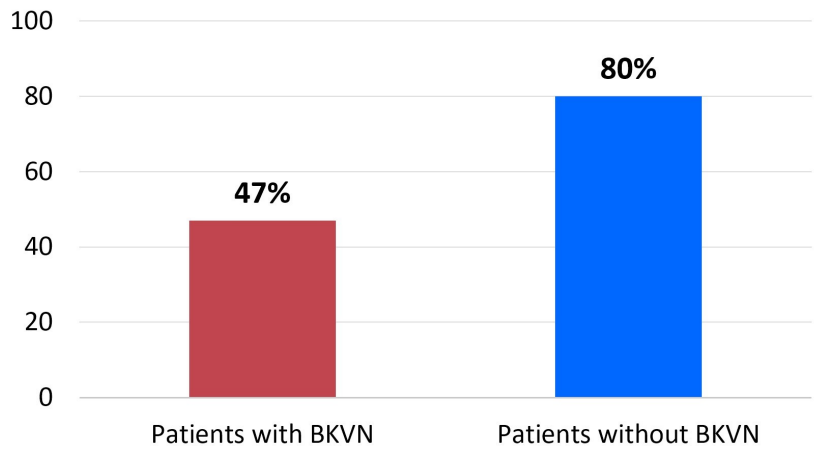
Figure 14: Planned phase 3 clinical trial design



MAU868 in reactivated BK infection among kidney transplant recipients

We are developing MAU868 as 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 15, BKVN is a leading cause of allograft loss, a devastating outcome for kidney transplant recipients.

Figure 15: 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, and plan to initiate a Phase 2b or Phase 3 clinical trial, pending alignment with regulatory authorities. 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 BK virus 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 immunosuppressants can displace. 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. Up to 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 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.

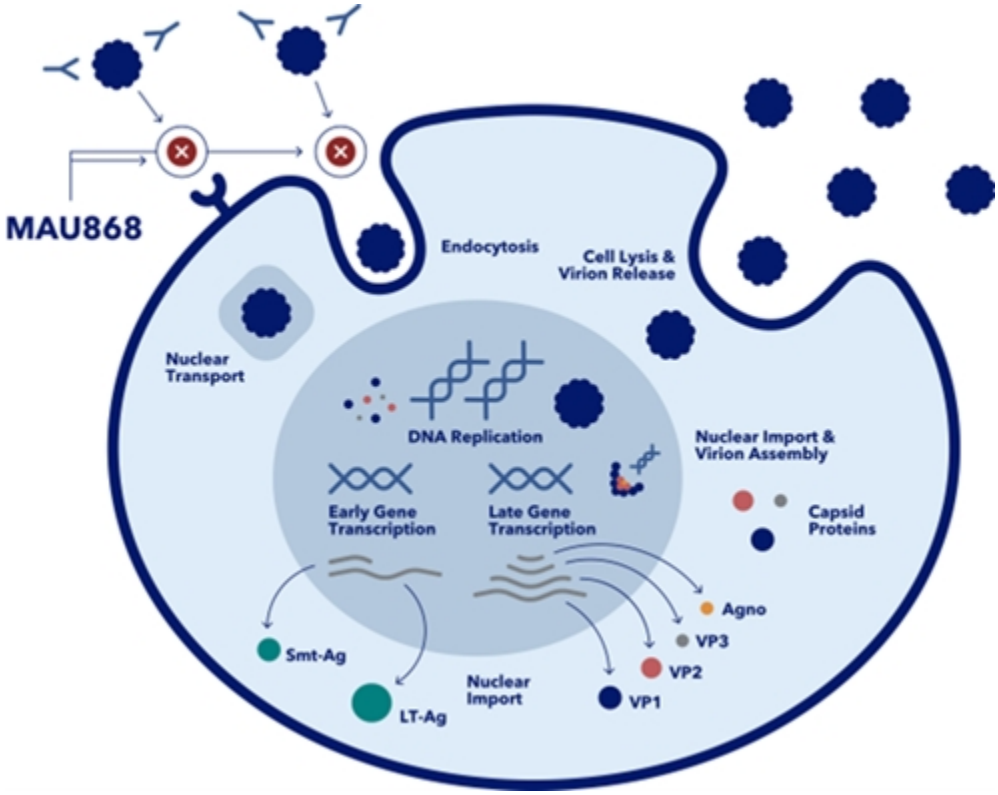
Emerging therapies in development

Despite the high level of unmet need in treating BK viremia and preventing devastating consequences, there is limited development in the space. There is only one alternate industry-sponsored program in clinical development: Allovir's posoleucel (formerly known as ALVR-105 and Viralym-M), a multi-virus specific T-cell therapy, which is currently being evaluated in a Phase 2 clinical trial. While this approach may have the potential to treat BKV and other opportunistic infections, logistics and distribution are likely to render this approach less feasible than a monoclonal antibody, for instance. Therefore, posoleucel may be reserved for second line of therapy and/or treatment of presumptive BKVN rather than BK viremia.

Our solution: MAU868 / scientific rationale

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 16. 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 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 16: 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 safe and 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.

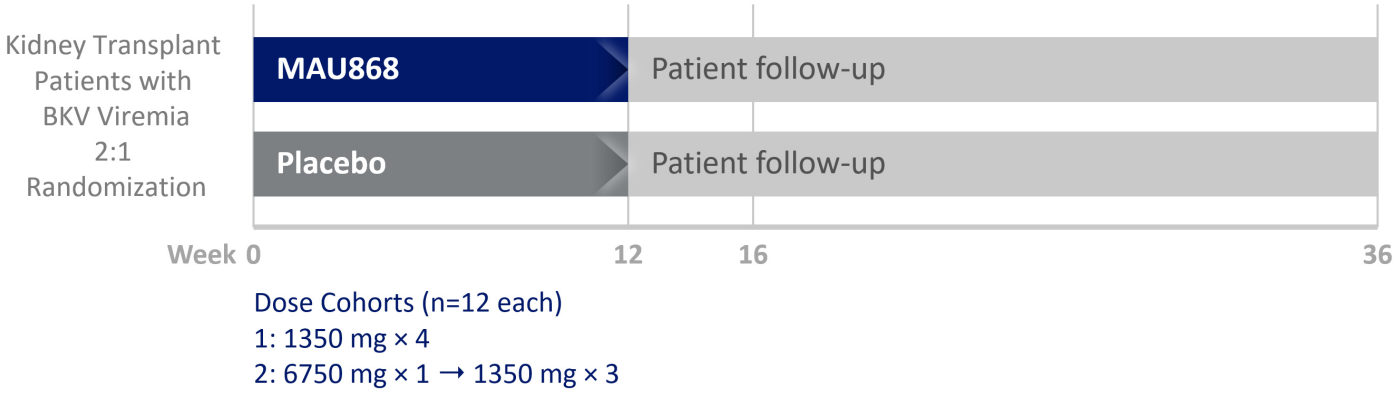
Ongoing phase 2

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 is ongoing. Up to 36 patients with BK viremia will participate in 1 of 3 sequential cohorts. As shown in Figure 17, each cohort was designed to randomize approximately 12 patients (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 is 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 patients with decrease in BK plasma viral load versus placebo.

At ASN 2022, 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 17: MAU868 phase 2 clinical trial design



Future clinical trials

We plan to initiate a Phase 2b or Phase 3 clinical trial.

MAU868 in BKV cystitis among HSCT recipients

We are exploring development of MAU868 to treat BKV cystitis in HSCT patients. Patients undergoing HSCT are at risk for BKV reactivation due to immunodeficiency; in this setting, BK reactivation and subsequent viruria and viremia can lead to cystitis, including hemorrhagic cystitis. Cystitis is characterized by dysuria, urgency, and/or frequency, while hemorrhagic cystitis indicates the presence of microscopic or gross hematuria. Both BKV cystitis and hemorrhagic cystitis are associated with high patient morbidity and prolonged hospitalization, yet there are no approved treatment options. We believe that MAU868 may represent an important future treatment option for these patients.

Pathophysiology of BK virus reactivation in HSCT

HSCT patients, particularly those who have received allogeneic transplants, are at high risk of various infectious diseases due to immunodeficiency. During the early post-engraftment period, BKV is a common cause of hemorrhagic cystitis. Patients are at highest risk for BKV cystitis three to six weeks following HSCT. Myeloablative conditioning regimen in the setting of human leukocyte antigen (HLA) mismatch is a particular risk factor for BK reactivation. Viruria occurs in approximately half of allogeneic and less than 10% of autologous HSCT recipients. BK viremia > 10,000 copies/mL has been shown to be predictive of renal and urologic outcomes in HSCT patients.

BKV cystitis disease burden and diagnosis

Moderate to severe BKV cystitis may occur prior to discharge and prolong hospital stay and/or result in readmission to the hospital if already discharged. Currently HSCT patients are not routinely monitored for BKV reactivation given the lack of treatments available. BKV testing and monitoring is initiated only in patients who become symptomatic and present with cystitis symptoms, which may emerge several weeks or months following engraftment. Patients who are symptomatic would then be monitored for BKV via urine and/or blood testing monthly for six months, and then at longer intervals. BK viruria alone is not concerning unless the viral load is rapidly accelerating; BKV viremia is more concerning and may trigger physicians to actively treat the cystitis symptoms. In our market research, physicians estimate that 15% of allogeneic HSCT patients and approximately 5% of autologous HSCT patients develop BKV cystitis, including hemorrhagic cystitis.

HSCT market opportunity

The primary addressable patient segment initially is for the treatment of symptomatic BKV cystitis, including hemorrhagic cystitis. Other potential segments may include prophylaxis in high-risk patients and treatment of BK viremia. BK viremia is not currently screened for until symptoms of cystitis occur, but this is likely to change once physicians have an effective treatment available.

An estimated 50,000 allogeneic HSCTs are conducted globally each year, with approximately 10,000 in the United States, 16,000 in Europe, 3,500 in Japan, and 2,500 in China. An estimated 57,000 autologous HSCTs are conducted globally each year, with approximately 17,000 in the United States, 27,000 in Europe, 2,500 in Japan, and 1,800 in China. Approximately 15% of allogeneic recipients and 5% of autologous recipients develop BK cystitis, including hemorrhagic cystitis.

Current standard of care for BKV cystitis in HSCT patients

Upon diagnosis of BKV-associated cystitis, physicians consider reducing immunosuppression—with initial modification typically consisting of lowering MMF by 50% or modifying the tacrolimus dose. This reduction of immunosuppression must be balanced with

consideration for increased risk of acute Graft versus Host Disease (GvHD). Antivirals such as low-dose cidofovir and leflunomide as well as IVIG are used in patients whose BKV does not resolve after a reduction of immunosuppression, or in patients where reduction in immunosuppression is viewed as too high risk (i.e., instances of HLA mismatch or prior history of GvHD). However, there is not robust clinical trial evidence supporting use of these agents in this setting. Symptomatic treatments for severe bleeding due to hematuria include red blood cell transfusions, bladder embolization or cystectomy. For HSCT patients, physicians' primary concerns are acute GvHD and cytomegalovirus (CMV) reactivation moreso than BKV, though they continue to view BKV cystitis as an area of high unmet need.

Emerging therapies in development

There is limited clinical development of new agents targeting BKV in the HSCT setting. Allovir's posoleucel (formerly known as ALVR-105 and Viralym-M), a multi-virus specific T-cell therapy, is currently in a Phase 3 clinical trial for the treatment of virus-associated hemorrhagic cystitis. This therapy has the potential to treat six viral pathogens: BKV, CMV, adenovirus, Epstein-Barr virus, human herpesvirus 6 and JC virus, and therefore may have utility when physicians are concerned about multiple viral reactivations. Posoleucel is also in two Phase 2 clinical trials: one in kidney transplant recipients with BK viremia and another in multi-virus prevention following allogeneic HSCT.

We believe that MAU868 may represent an important future treatment option for HSCT patients with BKV cystitis and that its relative ease of distribution and administration may provide a competitive advantage over other emerging therapies.

Exclusive license agreement with Ares Trading S.A.

On October 29, 2020, we entered into the Ares Agreement with Ares, an affiliate of Merck KGaA, Darmstadt, Germany, 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.

In consideration for the rights granted under the Ares Agreement, we issued 22,171,553 shares of our Series C redeemable convertible preferred stock to Ares at the time of the initial closing of our Series C redeemable convertible preferred stock financing in October 2020, representing ownership of approximately 10% on a fully diluted basis. As additional 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 we are required to pay Ares aggregate milestone payments of up to $ 176.5 million upon the achievement of specified BLA filing or regulatory approvals in the United States, Europe and Japan (the first of which consists of a $15.0 million payment upon filing of the BLA), and aggregate milestone payments of up to $515.0 million upon the achievement of specified commercial milestones. 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 will expire on a licensed product-by-licensed product and country-by-country basis 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 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 (the Amplyx Agreement) with Amplyx, a wholly-owned subsidiary of Pfizer.

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 (the 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.

In partial consideration for the Asset Acquisition, we made an upfront initial payment of $5.0 million to Amplyx. In addition, we are also 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 $69.0 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.

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, 2022, we have licensed, including pursuant to sublicenses, from Ares, an affiliate of Merck KGaA, Darmstadt, Germany, a patent portfolio related to atacicept that contains approximately seven issued U.S. patents, 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.

There is also a pending U.S. application as well as certain foreign counterparts directed to treatment of IgAN and proteinuria. Patents that issue in this family are expected to expire in 2041.

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 and EMA, which, if secured, would provide seven and ten years, in the United States and European Union, respectively, of regulatory exclusivity protection from the approval date.

As of December 31, 2022, 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. The U.S. patents are expected to expire in 2036. Corresponding foreign counterparts are granted in Australia, China, Japan, Mexico, Macau and Taiwan, and pending in other jurisdictions such as Canada, Mexico, Europe, Israel and Japan. The foreign patents are expected to expire in 2036.

In addition, an application co-owned with and licensed from Novartis that is directed to dosing regimens for MAU868 is pending as a U.S. application as well as certain foreign counterparts. Patents that issue in this family are expected to expire in 2041.

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.

Manufacturing and supply

We manage a number of external CMOs to develop and manufacture our product candidates.

Atacicept is a fully humanized 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 manufactured following cGMPs using a process that is 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 prefilled 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. An atacicept prefilled syringe/autoinjector combination is in late-stage development and will be introduced into future clinical trials when appropriate.

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, representing all three strengths, 25 mg, 75 mg and 150 mg, of atacicept and approximately 25,000 PFS of placebo, as part of the Ares Agreement. This drug product was used to initiate the Phase 2b ORIGIN trial. Additionally, we acquired 6 kg of atacicept drug substance which has subsequently been converted into drug product to supply both the ongoing Phase 2b ORIGIN trial and to support our future clinical trials through the first quarter of 2026.

MAU868 is an IgG1 monoclonal antibody that binds to BKV protein VP1. It is manufactured according to cGMP using a high expression 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.

The Amplyx Agreement includes the transfer of all existing inventory and work-in-process of MAU868 drug product for use in clinical trials. This includes 2,777 unlabeled vials and work-in-process expected to yield approximately 5,300 vials with release targeted for March 2022. These materials will support both the completion of the ongoing Phase 2 clinical trial and initiation of a future clinical trial.

Commercialization plans

Atacicept

We estimate the market opportunity for novel therapeutics in IgAN across the United States, Europe and Japan to be approximately $5.6 billion to $9.6 billion annually, based on our assumptions, secondary research, and primary market research with physicians and payors. In order to capitalize on this opportunity, we plan to build a specialty commercial infrastructure focused on IgAN, engaging treating physicians, including nephrologists, educating and engaging patients, and ensuring market access for patients.

For novel therapeutics in LN, we estimate the market opportunity across the United States, Europe and Japan to be $2.8 billion to $5.8 billion annually, based on a similar methodology. If we receive regulatory approval for atacicept in both IgAN and LN, we plan to assess call point overlap for the two indications and selectively build out our future commercial infrastructure to address any gaps to optimize our coverage of LN treating physicians. We also plan to build out LN-specific patient and market access programs, leveraging synergies where possible.

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.

MAU868

We plan to develop MAU868 for the treatment of BK viremia in kidney transplant as an initial indication, which has strong commercial synergies with our plans for atacicept. We believe that the prescribing physicians for MAU868 in renal transplant, if approved, will be a subset of the IgAN treating physicians, and plan to conduct an assessment of call point overlap. The launch of this indication, if prior to the atacicept launch, would require a smaller specialty commercial infrastructure build focused on educating and engaging treating physicians, including transplant nephrologists, partnering with kidney transplant organizations, and ensuring market access for patients. If prior to the atacicept launch, we would plan to leverage this infrastructure for eventual atacicept sales and marketing activities.

Through the Amplyx Agreement, we obtained worldwide rights to the development and commercialization of MAU868 in all indications.

Similar to our plans with atacicept, we intend to commercialize MAU868 ourselves in the United States and other key markets, if approved.

We also may consider strategic collaborations to facilitate commercialization in certain ex-U.S. markets.

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 a high level of morbidity for IgAN, the current standard of care consists of off-label use of RAAS inhibitors, including ACE inhibitors and ARBs, and potentially steroids. Atacicept, if and when approved and successfully commercialized, may compete with these existing approaches and with any new therapies that may become available in the future. Sodium-glucose cotransporter-2 (SGLT2) inhibitors, including AstraZeneca plc's (AstraZeneca) 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 Calliditas Therapeutics AB, and endothelin and angiotensin II receptor antagonist from Travere Therapeutics, Inc.; programs in Phase 3 clinical development: Visterra Inc., Otsuka Pharmaceutical Co., Ltd., Novartis, Omeros Corporation, Alnylam Pharmaceuticals Inc., and Chinook Therapeutics Inc.; and the following companies with programs in Phase 2 of clinical development: Chinook Therapeutics Inc., Reata Pharmaceuticals, Inc., RemeGen Co., Ltd., Ionis Pharmaceuticals, Inc., AstraZeneca, and DiaMedica Therapeutics, Inc.

Atacicept in LN

In LN, prior to December 2020, there had been no approved therapies, and the standard-of-care has consisted of a number of non-specific therapies, including MMF, steroids, CYC, rituximab, calcineurin inhibitors, AZA, and HCQ, dependent on class of disease and whether a patient was cycling through the induction or maintenance phase of therapy. Paradigms are evolving with the FDA approvals of GlaxoSmithKline plc's Benlysta (belimumab) and Aurinia Pharmaceuticals Inc.'s Lupkynis (voclosporin), both of which we consider to be direct competitors. Our competitors include: Roche Holding AG and Novartis Pharmaceuticals Corporation, each of which have programs in Phase 3 clinical development; and BeiGene Ltd., Janssen Pharmaceuticals, Inc., AstraZeneca, Alexion Pharmaceuticals Inc. (Alexion), Omeros Corporation, Kezar Life Science Inc., Bristol Myers Squibb, Boehringer, and Novartis Pharmaceuticals Corporation, each of which have programs in Phase 2 clinical development.

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 Allovir's multi-virus specific T-cell therapy, posoleucel, which is in a Phase 2 clinical trial for BK viremia in kidney transplant recipients, a Phase 3 clinical trial for treatment of virus-associated cystitis, and a Phase 2 clinical trial in multi-virus prevention following allogeneic HSCT.

Government regulation

Government authorities in the United States at the federal, state and local level and in other countries and jurisdictions, including the European Union, 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.

Our investigational medicines and any future investigational medicines 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 practices (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 IRB or independent ethics committee at 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, 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 accept the filing 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 current 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;
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee; and
- compliance with any post-approval requirements, including a REMS, where applicable, and post- approval studies required by the FDA as a condition of approval.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, or at all.

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 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 disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. 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, early evidence of effectiveness.
- Phase 2 clinical trials generally involve studies in disease-affected patients to evaluate proof of concept and/or determine the dosing regimen(s) for subsequent investigations. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for 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. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the biologic.

These Phases may overlap or be combined. For example, a Phase 1/2 clinical trial may contain both a dose-escalation stage and a dose-expansion stage, the latter of which may confirm tolerability at the recommended dose for expansion in future clinical trials.

A single Phase 3 or Phase 2 trial with other confirmatory evidence may be sufficient in rare instances to provide substantial evidence of effectiveness (generally subject to the requirement of additional post-approval studies).

In some cases, FDA may require, or firms may voluntary 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.

Phase 1, Phase 2, Phase 3 and other types of clinical trials may not be completed successfully within any specified period, if at all. 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 and efficacy 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 Prescription Drug User Fee Act (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 for a new molecular entity 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 they comply with cGMP requirements. 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. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process.

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 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 is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition.

Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product 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 products that are intended, alone or in combination with one or more other products, to treat a serious or life-threatening condition and 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 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.

Priority review may be granted for products 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 in six months once it is filed, 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.

Accelerated approval may be granted for products that are intended to treat a serious or life-threatening condition and that generally provide a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval 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 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, or 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 a new 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 will 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 agencies 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, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, 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 post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- 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 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

The EMA is a decentralized scientific agency of the European Union. It coordinates the evaluation and monitoring of centrally authorized medicinal products. It is responsible for the scientific evaluation of applications for EU marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors. The EMA decentralizes its scientific assessment of medicines by working through a network of about 4,500 experts throughout the European Union, nominated by the Member States. The EMA draws on resources of over 40 national competent authorities of European Union Member States.

The process regarding approval of medicinal products in the European Union 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 Good Laboratory Practice regulations;
- submission to the relevant national competent authorities of a clinical trial application (CTA) for each trial in humans, which must be approved by such national authorities and at least one independent ethics committee before the trial may begin in each country where patient enrollment 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 (MAA) 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 labelling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced cGMP;
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical studies

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the quality and potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant international, E.U. and national legislation, regulations and guidelines. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

Clinical trials

Clinical Trials Regulation (EU) No 536/2014 is an authorization procedure based on a single submission via a single E.U. portal, an assessment procedure leading to a single decision, as well as transparency requirements (the proactive publication of clinical trial data in the E.U. database).

Manufacturing and import into the E.U. of investigational medicinal products for use in clinical trials is subject to the holding of appropriate authorizations and must be carried out in accordance with cGMP.

Review and approval

Authorization to market a product in the European Economic Area (EEA), comprising the European Union Member States plus Norway, Iceland and Liechtenstein, proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure. Since our products by their virtue of being antibody-based biologics fall under the centralized procedure, only this procedure will be described here.

Certain drugs, including medicinal products developed by means of biotechnological processes, must be approved via the centralized authorization procedure for marketing authorization. The centralized procedure is also mandatory for orphan medicinal products, advanced-therapy medicinal products (i.e. gene-therapy, somatic cell -therapy or tissue-engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health. A successful application under the centralized authorization procedure results in a marketing authorization from the European Commission, which is automatically valid throughout the EEA. The other European Economic Area member states (namely Norway, Iceland and Liechtenstein) are also obligated to recognize the European Commission decision. The EMA and the European Commission administer the centralized authorization procedure.

Under the centralized authorization procedure, the Committee for Medicinal Products for Human Use (CHMP) serves as the scientific committee that renders opinions about the safety, efficacy and quality of human medicinal products on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national drug authority, 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, though the clock is stopped if it is necessary to ask the applicant for clarification or further supporting data. Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days. The process is complex and involves extensive consultation with the regulatory authorities of Member States and a number of experts. Once the procedure is completed, a European Public Assessment Report is produced. If the CHMP concludes that the quality, safety and efficacy of the medicinal product is sufficiently proven, it adopts a positive opinion. 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. The European Commission's decision is issued within 67 days of receipt of the CHMP's recommendation. If the opinion is negative, information is given as to the grounds on which this conclusion was reached

After a drug 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. Sanctions may be imposed for failure to adhere to the conditions of the marketing authorization. In extreme cases, the authorization may be revoked, resulting in withdrawal of the product from sale.

Now that the UK (which comprises Great Britain and Northern Ireland) has left the EU, Great Britain will no longer be covered by centralized MAs (under the Northern Irish Protocol, centralized MAs will continue to be recognized in Northern Ireland). All medicinal products with a current centralized MA were automatically converted to Great Britain MAs on January 1, 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency (MHRA), the UK medicines regulator, may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain MA. A separate application will, however, still be required.

Conditional approval and accelerated assessment

As per Article 14(7) of Regulation (EC) 726/2004, a medicine that would fulfill an unmet medical need may, if its immediate availability is in the interest of public health, be granted a conditional marketing authorization on the basis of less complete clinical data than are normally required, subject to specific obligations with defined timelines being imposed on the authorization holder. The list of these obligations shall be made publicly accessible. In order for a conditional marketing authorization to be granted, the CHMP must find that all of the following criteria are met: (i) the benefit-risk balance of the medicine is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicine fulfils an unmet medical need; and (iv) the benefit of the medicine's immediate availability to patients is greater than the risk inherent in the fact that additional data are still required. Such an authorization shall be valid for one year, on a renewable basis.

When an application is submitted for a marketing authorization in respect of a drug for human use which is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure pursuant to Article 14(9) of Regulation (EC) 726/2004. Under the accelerated assessment procedure, the CHMP is required to issue an opinion within 150 days of receipt of a valid application, subject to clock stops, but it is possible that the CHMP may 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. We believe that some of the disease indications in which our product candidates are currently being or may be developed in the future qualify for this provision, and we will take advantage of this provision as appropriate.

Period of authorization and renewals

A marketing authorization is initially valid for five years and may then be renewed on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the national competent authority of the authorizing Member State (where the centralized procedure is not used). To this end, the marketing authorization holder shall provide the EMA or the competent authority with a version of the file in respect of quality, safety and efficacy, including all variants introduced since the marketing authorization was granted, at least six months before expiry of the initial five year period. Once renewed, the marketing authorization shall be valid for an unlimited period, unless the European Commission or the relevant national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EEA market (if the centralized procedure is used) or on the market of the authorizing Member State (if the centralized procedure is not used) within three years after authorization shall cease to be valid (the so-called sunset clause).

Without prejudice to the law on the protection of industrial and commercial property, marketing authorizations for innovative medicinal products benefit from an 8+2+1 year period of regulatory protection. This regime consists of a regulatory data protection period of eight years plus a concurrent market exclusivity of 10 years plus an additional market exclusivity of one further year if, during the first eight years of those 10 years, the marketing approval holder obtains an approval for one or more new therapeutic indications which, during the scientific evaluation prior to their approval, are determined to bring a significant clinical benefit in comparison with existing therapies. Under the current rules, a third party making a generic or biosimilar application may not reference the preclinical and clinical data of the reference product until the expiry of eight years after first approval of the reference product, and the third party may only market a generic or biosimilar version of the reference product after 10 (or 11) years have lapsed since the first authorization of the reference product.

Orphan drug designation

Regulation (EC) 141/2000 states that a drug shall be designated as an orphan drug if its sponsor can establish (i) that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) either such condition affects not more than five in 10,000 persons in the European Union when the application is made, or, without incentives, it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment in its development; and (iii) that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation (EC) 847/2000 sets out provisions for the implementation of the criteria for the designation of orphan drugs. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a 10-year period of market exclusivity, which means that no similar medicinal product can be authorized in the same indication. 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. This 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, derogation from market exclusivity may be granted on an individual basis in very select cases, such as with consent from the marketing authorization holder, inability to supply sufficient quantities of the authorized product or demonstration of "clinically relevant superiority" by a similar medicinal product. Medicinal products designated as orphan drugs pursuant to Regulation (EC) 141/2000 are eligible for incentives made available by the European Union and by the Member States to support research into, and the development and availability of, orphan drugs.

If the MAA of a medicinal product designated as an orphan drug pursuant to Regulation (EC) 141/2000 includes the results of all studies conducted in compliance with an agreed pediatric investigation plan, and a corresponding statement is subsequently included in the marketing authorization granted, the 10-year period of market exclusivity will be extended to 12 years.

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 information about clinical trials participants and other individuals in Europe is governed by the European Union's General Data Protection Regulation (GDPR and in the UK, is governed by the European Union (Withdrawal) Act 2018 and the UK Data Protection Act 2018 (UK GDPR)). The GDPR and UK GDPR require companies to, among other things, give detailed disclosures about how they are processing personal information; ensure any consents relied on to process personal information (including special categories of personal information, such as health information) meet the stricter GDPR requirements; contractually impose data protection measures on vendors entrusted with personal information; 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 information; and refrain from transferring personal information from Europe or the UK to most other countries unless specific safeguards can be implemented. Companies that violate the GDPR or UK GDPR can face private litigation, prohibitions on data processing and heavy fines. Complying with the 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 to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the E.U. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of European Union member states and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

Payments made to physicians in certain European Union member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Brexit and the regulatory framework in the United Kingdom

In June 2016, the electorate in the UK voted in favor of leaving the EU (commonly referred to as Brexit). Thereafter, in March 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty and the UK formally

left the EU on January 31, 2020. A transition period began on February 1, 2020, during which EU pharmaceutical law remained applicable to the UK, which ended on December 31, 2020. Since the regulatory framework in the UK covering the quality, safety and efficacy of medicinal products, clinical trials, marketing authorization, commercial sales and distribution of medicinal products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the UK, as UK legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the UK in the long-term. The MHRA, the UK medicines and medical devices regulator, has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now the transition period is over, which will be updated as the UK's regulatory position on medicinal products evolves over time.

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 federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare providers; state 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 laws that prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals; state 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 information in certain circumstances, including state health information privacy and data breach notification laws which govern the processing of health-related and other personal information, 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, 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 providers 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. In 2010, the U.S. Congress enacted the Affordable Care Act, which included changes to the coverage and reimbursement of drug products under government healthcare programs such as:

- increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program;
- established a branded prescription drug fee that pharmaceutical manufacturers of certain branded prescription drugs must pay to the federal government;
- expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program;
- established a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- established a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- created a licensure framework for follow-on biologic products.

There have been executive, judicial and congressional challenges to certain aspects of the Affordable Care Act as well as efforts to repeal or replace certain aspects of the Affordable Care Act. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates 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 possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act.

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 resulted in the imposition of 2% 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 2031, absent additional congressional action. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. 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. At the federal level, in July 2021, the Biden administration

released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, 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, 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 will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. 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 and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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, the principal decisions about reimbursement for new medicines are typically made by the CMS, which decides 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 agencies in Europe may be more restrictive than payors in the United States. In Europe, pricing and reimbursement schemes vary widely from country to country. 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. Other countries require the completion of additional health technology assessments that compare the cost- effectiveness of a particular product candidate to currently available therapies. In addition, the European Union provides options for its 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. European Union 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 or monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. Furthermore, many countries in the European Union 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 countries in the European Union. 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. There can be no assurance that any country that has reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. Accordingly, the reimbursement for any products in Europe may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

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, 2022, we had a total of 46 full-time employees. We employ physicians, professionals in research and development, clinical, regulatory, manufacturing, marketing, finance and 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 centered around our core values of collaboration, accountability, and empathy for patients to enhance the working environment for our current employees and to attract our desired candidates.

Facilities

We are occupying 9,885 square feet of office space at 8000 Marina Boulevard in Brisbane, California though November 2024. We also have leased 24,606 square feet of office and lab space at 170 Harbor Way in South San Francisco, California. This space is currently subleased through the term of the lease, ending September 2025.

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.

Our business involves significant risks, some of which are described below. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the related notes. If any of the following risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our Class A common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report.

Risks related to our financial position and need for additional capital

We have not completed any 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 and efforts to organizing and staffing our company, business planning, executing partnerships, raising capital, acquiring, developing and securing our technology and product candidates, completing the Phase 2b clinical trial of atacicept in patients with IgAN and planning the Phase 3 clinical trial of atacicept in patients with LN, supporting clinical development of MAU868 and manufacturing atacicept and MAU868 clinical drug supply. We have not yet demonstrated our ability to successfully complete any clinical trials with respect to our product candidates, 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 could 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 research focus to a company capable of successfully executing drug development activities and 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 inflammatory 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 atacicept or MAU868, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, 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, 2022, we had $114.7 million in cash, cash equivalents and marketable securities. In December 2021, we entered into the Loan Agreement with Oxford, as amended in November 2022, providing us with up to $25.0 million of borrowing capacity, after $5.0 million was funded at closing of the Loan Agreement in December 2021, and $20.0 million was funded in November 2022. We expect that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next 12 months subsequent to the issuance date of the financial statements appearing elsewhere in 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:

- continue our ongoing and planned research and development of atacicept for the treatment of IgAN and LN;

- initiate or continue nonclinical studies and clinical trials for atacicept, MAU868 and any additional product candidates that we may pursue in the future;
- continue our ongoing and planned research and development of MAU868 for the treatment of BKV viremia in kidney transplant recipients and other indications;
- 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, and manufacturing management and administrative personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

Advancing the development of atacicept, MAU868 and any future product candidates we may develop 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.

In January 2023, we announced our plan to prioritize and focus our current resources on the advancement of atacicept in IgAN into a pivotal Phase 3 trial. As a result, we are delaying enrollment in the pivotal Phase 3 trial for LN and commitment of resources to the MAU868 program.

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 the recent and potential future disruptions in access to bank deposits and lending commitments due to bank failures, the ongoing military conflict between Russia and Ukraine and related sanctions, actual and anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, and ongoing effects of the COVID-19 pandemic, 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 we expect to continue to incur net losses for the foreseeable future. In addition, we may be unable to continue as a going concern over the long-term.

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 $89.1 million and $32.6 million for the years ended December 31, 2022 and 2021, respectively. We had an accumulated deficit of $213.1 million as of December 31, 2022. Our losses have resulted principally from expenses incurred in research and development and from management and administrative costs and other expenses that we have incurred while building our business infrastructure, a significant portion of which were incurred resulting from our efforts to develop gamma-PNA chemistry and triplex gene editing for therapeutic use, which we discontinued in September 2020. Our product candidates are in clinical trials. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing our product candidates in one of our lead 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 a good 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 until regulatory approval is granted for our product candidates. Regulatory approval is not guaranteed and may never be obtained. As a result, these conditions raise substantial doubt about our ability to continue as a going concern over the long-term.

We have never generated revenue from product sales and 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, atacicept, MAU868 and any future product candidates we may develop. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate revenue from product sales depends heavily on our and our current and 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 agreement with Ares, Novartis 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 atacicept, MAU868, or any future product candidate that we may develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any 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.

The Loan Agreement provides us with up to $25.0 million of borrowing capacity, after $5.0 million was funded at closing of the Loan Agreement in December 2021 and $20.0 million was funded in November 2022. 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 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 Loan Agreement, Oxford may accelerate all of our repayment obligations and exercise all of their rights and remedies under the 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 Class A

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 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 Class A 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, atacicept and MAU868, which are currently in the clinical development stage. 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 be devoted to the development of atacicept in our ongoing clinical trials of atacicept in patients with IgAN and LN, as well as our efforts to evaluate atacicept in MAU868 in kidney transplant recipients. In the near-term, we plan to prioritize and focus our current resources on the advancement of atacicept in IgAN into a pivotal Phase 3 trial. As a result, we are delaying enrollment in the pivotal Phase 3 trial for LN and any commitment of resources to the MAU868 program.

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 government regulators, 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. Should our planned clinical development of atacicept in patients with IgAN and LN or MAU868 in kidney transplant recipients fail to be completed in a timely manner or at all, we will need to rely on clinical development of atacicept or MAU868 in additional indications, which will require more time and resources to obtain regulatory approval and proceed with commercialization, and may ultimately be unsuccessful. 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 atacicept or MAU868 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. We have never completed a clinical trial or submitted a BLA to the FDA or similar drug approval filings to comparable foreign authorities. 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 to date have not demonstrated our ability to complete 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 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, or regulators may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. 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. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. 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 any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

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 may rely in part on nonclinical, clinical and quality data generated by CROs and other third parties for 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 patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- obtaining regulatory authorizations to commence a 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);
- IRBs refusing to approve, 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 protocol;
- 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 by subjects, or completion of the trial by subjects, or delays in manufacturing due to the continuing effects of the COVID-19 pandemic;
- 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), 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 patients 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 atacicept, MAU868 or any other product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of atacicept, MAU868 or other 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 patients 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 and LN, the availability of competitive products, and significant competition for recruiting patients 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 patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. In particular, as a result of the inherent difficulties in diagnosing IgAN, the availability of competitive products such as TARPEYO and FILSPARI, and the significant competition for recruiting the limited number of patients who have the diseases for which our product candidates are being developed, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all. Although we have engaged certain third-party investigators to assist with patient 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 patient 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 patient 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 patients 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 a sufficient number of patients 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. In January 2023, we announced our plan to prioritize and focus our current resources on the advancement of atacicept in IgAN into a pivotal Phase 3 trial. As a result, we are delaying enrollment in the pivotal Phase 3 trial for LN and are any commitment of resources to the MAU868 program. 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 atacicept, MAU868 and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.

We may develop atacicept, MAU868 and future product candidates in combination with one or more currently approved therapies. Even if atacicept, MAU868 or any product candidate we develop, were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate atacicept, MAU868 or any other future 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 atacicept, MAU868 or any 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 atacicept, MAU868 or any other product candidate we develop, we may be unable to obtain approval of or market atacicept, MAU868 or any other product candidate we develop.

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 atacicept, MAU868 or any future product candidate we may develop, 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.

The incidence and prevalence for target patient populations of our product candidates in specific indications are based on estimates and third-party sources. 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 atacicept, MAU868, or any future product candidate we may develop, 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 patient 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 patient data become available or as patients 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 Class A common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of 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 RAAS inhibitors, (ACE inhibitors or ARBs), to control blood pressure, or steroids with or without other immunosuppressive agents to non-specifically reduce inflammation. SGLT2 inhibitors, including AztraZeneca'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 Calliditas Therapeutics AB, and endothelin and angiotensin II receptor antagonist from Travere Therapeutics, Inc.; programs in Phase 3 clinical development: Visterra Inc., Otsuka Pharmaceutical Co, Ltd., Novartis Pharmaceuticals Corporation, Omeros Corporation, and Chinook Therapeutics Inc.; and the following companies with programs in Phase 2 of clinical development: Chinook Therapeutics Inc., Reata Pharmaceuticals, Inc., RemeGen Co., Ltd., Ionis Pharmaceuticals, Inc., AstraZeneca, and DiaMedica Therapeutics, Inc.

In LN, prior to December 2020, there had been no approved therapies, and the standard-of-care has consisted of a number of non-specific therapies, including MMF, steroids, cyclophosphamide, rituximab, calcineurin inhibitors, azathioprine, and hydroxychloroquine, dependent on class of disease and whether a patient was cycling through the induction or maintenance phase of therapy. Paradigms are evolving with the FDA approvals of GlaxoSmithKline plc's Benlysta (belimumab) and Aurinia Pharmaceuticals Inc.'s Lupkynis (voclosporin), both of which we consider to be direct competitors. Our competitors include: Roche Holding AG, Novartis Pharmaceuticals Corporation, and RemeGen Co., Ltd., each of which have programs in Phase 3 clinical development; and BeiGene Ltd., Janssen Pharmaceuticals, Inc., AstraZeneca, Alexion, Omeros Corporation, Kezar Life Science Inc., Bristol Myers Squibb, Boehringer, and Novartis Pharmaceuticals Corporation, each of which have programs in Phase 2 clinical development.

In the kidney transplant or HSCT setting, there are currently no 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; for example, Memo Therapeutics AG's MTX-005, a monoclonal antibody targeting BKV has recently commenced Phase I clinical trials. Additionally, Allovir's multi-virus specific T-cell therapy, Posoleucel is

in a Phase 2 clinical trial for BK viremia in kidney transplant recipients, a Phase 3 clinical trial for treatment of virus-associated cystitis, and a Phase 2 clinical trial in multi-virus prevention following allogeneic HSCT.

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.

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.

Applications for atacicept or MAU868 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 candidate is not safe and 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, 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 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; and
- 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.

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 a lead indication, regulatory authorities may not approve them 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 and FILSPARI;
- the clinical indications for which the product candidate is approved;
- restrictions on use, such as boxed warnings or contraindications in labeling, or a REMS, 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 atacicept or MAU868 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 providers, government agencies 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 if we are unable to obtain sufficient insurance coverage, such inability 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 marketing products, 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 prior to marketing any product candidate, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that 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 atacicept, MAU868 or any future product candidates we may develop. 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 KGaA, Darmstadt, Germany previously conducted APRIL-LN, a study aimed to evaluate the efficacy and safety of atacicept in patients with active LN, receiving newly initiated CS and MMF. 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. The drug-related side effects could affect patient recruitment or the ability of enrolled patients 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 new 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 patient 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.

Patients 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 agencies. In addition, if atacicept, MAU868 or any future product candidates we may develop, are used in combination with other therapies, atacicept, MAU868 or any future product candidates we may develop may exacerbate adverse events associated with the therapy and it may not be possible to determine whether it was caused by our product or the one with which it was combined. Patients treated with our product candidates may also be undergoing surgical, radiation, chemotherapy or other treatments, which can cause side effects or adverse events that are unrelated to our product candidates, but may still impact the success of our clinical trials. 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 patients to the clinical trials, patients 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 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 atacicept or MAU868, 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 atacicept, MAU868 or any product candidate we develop in the future, 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 agency 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 agency 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 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 atacicept, MAU868, or any product candidate we may develop in the future, 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 atacicept, MAU868 or any product candidate we may develop in the future. 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 are currently seeking orphan drug designation for atacicept for the treatment of IgAN, but even if designated we may not ultimately realize the potential benefits of orphan drug designation.

We are currently seeking orphan drug designation from the FDA for atacicept for the treatment of IgAN. We are required to provide evidence that IgAN meets the orphan criteria as specified by the FDA and the EMA. 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. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. 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.

In addition, if a product receives the first FDA approval for the indication 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 indication 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 an indication broader than the orphan designated indication 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 indication 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.

Similarly, in Europe, a medicinal product may receive orphan designation under Article 3 of Regulation (EC) 141/2000. This applies to products that are intended for a life-threatening or chronically debilitating condition and 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. In the EU, orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and applicants can benefit from specific regulatory assistance and scientific advice. Products receiving orphan designation in the EU can receive 10 years of market exclusivity, during which time no "similar medicinal product" for the same indication may be placed on the market. 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. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. However, the 10-year market exclusivity may 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 designation—for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar medicinal product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the first marketing authorization holder for the authorized product consents to a second orphan medicinal product application; or
- the marketing authorization holder for the authorized product cannot supply enough orphan medicinal product.

If we do not receive or maintain orphan drug designation for atacicept for the treatment of IgAN, 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, and nonclinical or clinical data demonstrate the potential to address an unmet medical need, the product may qualify for FDA Fast Track designation, for which sponsors must apply. The FDA has broad discretion whether or not to grant this designation. 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.

We may in the future seek an accelerated approval for atacicept, MAU868 or future product candidates we may develop. For example, if the results from our Phase 3 trial of atacicept in patients with IgAN are positive, we may seek accelerated approval with the FDA based on this trial, which we may not be granted. 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, UPCR is an accepted surrogate primary endpoint for clinical trials in IgAN, which could allow for a faster path to commercialization than rate of change/slope in glomerular filtration rate (GFR). We may seek accelerated approval based on the UPCR endpoint. 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. Use of the accelerated approval pathway would entail submission of a BLA under Subpart E of the FDA regulations with week 36 UPCR surrogate endpoint data while completing the Phase 3 trial to collect eGFR data to demonstrate improvement in kidney function. 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 verity and describe the drug's clinical benefit and to report regulatory to the FDA on progress on 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, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for atacicept or MAU868, 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 or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for atacicept, there can be no assurance that such submission or application will be accepted or that any expedited development, 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 development, review or approval for atacicept or MAU868 would result in a longer time period to commercialization of such product candidate, could increase the cost of development of atacicept or MAU868 and could harm our competitive position in the marketplace.

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. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

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. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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.

Any product candidate we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

We intend to seek approval to market atacicept and MAU868 in both the United States, in the EU and in certain foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for atacicept or MAU868, 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 atacicept or MAU868. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of a product candidate will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for the product candidate and may be affected by existing and future healthcare reform measures.

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 expensive 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 high enough to allow us to establish or maintain pricing sufficient to realize 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, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (CMS) an agency within the U.S. Department of Health and Human Services (HHS). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and 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. Factors payors consider in determining reimbursement are based on whether the 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.

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, atacicept, MAU868 or any future product candidates we may develop 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, what the level of reimbursement will be.

Outside the United States, international operations 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 atacicept, MAU868 or any future product candidates we may develop. 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 trial that compares the cost-effectiveness of atacicept, MAU868 or any future product candidates we may develop to other available therapies. 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 atacicept, MAU868 or any future product candidates we may develop. 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.

We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of atacicept, MAU868 or any future product candidates we may develop. 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 lose any marketing approval that we may have obtained and we may not be able to achieve or sustain profitability.

For example, the Affordable Care Act was passed in March 2010, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed 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; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Moreover, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special

enrollment period coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is also unclear how any healthcare reform measures of the Biden administration will affect the Affordable Care Act and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018 and the Infrastructure Investments and Jobs Act, will remain in effect until 2031, unless additional congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. 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. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement-constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved 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 atacicept, MAU868 or any future product candidates we may develop.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of any product candidates we develop, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for atacicept, MAU868 or future product candidates we may develop. 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.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of atacicept, MAU868 or future product candidates we may develop, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

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 and state 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 providers 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, 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 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 laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information

related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state 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 to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of EU Member States, and the Bribery Act 2010 in the United Kingdom (UK). Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician'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. 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, 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 providers 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, rules, contractual obligations, 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; fines and penalties; disruptions to 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, processing) 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, 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 laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual obligations and other obligations that govern the processing of sensitive information by us and on our behalf.

Outside the United States, an increasing number of laws, regulations and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR and United Kingdom's GDPR, collectively GDRP, Canada's Personal Information Protection and Electronic Documents Act, or PIPEDA, Australia's Privacy Act, India's Information Technology Act, and South Korea's Personal Information Protection Act impose strict requirements to the processing of personal information, 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.

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, or EEA, and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their 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 and UK's standard contractual clauses, 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 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 to recipients outside Europe for allegedly violating the EU GDPR's cross-border data transfer limitations. Additionally, companies that transfer personal data to recipients outside 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.

In the United States federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal information 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 specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, the California Consumer Privacy Act of 2018, or CCPA, applies to personal information of consumers, business representatives, and employees, and requires covered businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA also provides for civil penalties for noncompliance of up to $7,500 per violation 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. In addition, the California Privacy Rights Act of 2020, or CPRA, expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. These developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become directly 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. If these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Our obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. 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.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. 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 and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others. If we 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-related claims); additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. 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 revision or restructuring of our 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 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 global geopolitical and macroeconomic conditions 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 recent and potential future disruptions in access to bank deposits and lending commitments due to bank failures, supply chain challenges, the conflict between Ukraine and Russia and related sanctions, increasing inflation rates and the responses by central banking authorities to control such inflation, and ongoing effects of the COVID-19 pandemic, 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.

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 increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which, coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Recent bank failures have caused significant disruption in certain companies' access to bank deposits and lending commitments and may continue to do so. 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 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.

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 atacicept, MAU868 or any other product candidate will be limited and the potential for successfully growing our business will be harmed.

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market atacicept, MAU868 or any product candidate we may develop in the future, we may not be able to successfully sell or market atacicept, MAU868 or any future product candidate we may develop in the future that obtained regulatory approval.

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 atacicept, MAU868 or any future product candidate we may develop. 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 atacicept, MAU868 or any product candidate we may develop in the future 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 atacicept, MAU868 or any product candidate we may develop in the future that we obtain approval to market, 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 atacicept, MAU868 or any product candidate we may develop in the future which 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 currently have limited marketing and no sales force, market access or 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.

As an organization, we have never commercialized a product candidate. 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 persuading adequate numbers of physicians to prescribe 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 atacicept, MAU868 or any future product candidate we may develop. 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, 2022, we had 46 full-time employees, including 31 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 agencies' review process for atacicept, MAU868 and any other future product candidates we may develop, 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 expect to be conducting multiple clinical trials of atacicept for several different indications concurrently, as well as MAU868 for the treatment of BKV disease in kidney transplant recipients. 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, particularly as we take on additional responsibility associated with being a public company. Our future financial performance and our ability to successfully develop and, if approved, commercialize, atacicept, MAU868 and any other future 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 atacicept, MAU868 and any other future product candidates we may develop 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 atacicept, MAU868 and any other future product candidates we may develop 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, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in 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 ability to conduct our clinical trials, our development plans and business.

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 Tax Cuts and Jobs Act of 2017 (Tax Act) enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) signed into law on March 27, 2020, modified certain provisions of the Tax Act. More recently, the Inflation Reduction Act of 2022 was enacted which 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. 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 the Tax Act or future reform 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. Among the changes made by the Tax Act was a reduction of the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”. We continue to examine the impact this tax reform legislation may have on our business. We urge investors to consult with their legal and tax advisers regarding the implications of the Tax Act and other past and potential future changes in U.S. tax laws on an investment in our Class A 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, 2022, we had federal and state net operating loss (NOL) carryforwards of $92.3 million and $35.7 million, respectively, that will begin expiring in the year 2032 and 2036, respectively, if not utilized. We also have $82.1 million of federal NOL carryforwards as of December 31, 2022, that do not expire as a result of recent tax law changes. Our NOL carryforwards are subject to review and possible adjustment by the U.S. and state tax authorities. Our NOL carryforwards could expire

unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. 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. Under the Tax Act, as modified by the CARES Act, 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. Moreover, under the Tax Act as modified by the CARES Act, federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of current year taxable income for tax years beginning after December 31, 2020. In addition, 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. It is generally uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

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 geo-political 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.

Continuing effects of the COVID-19 pandemic, could adversely impact our business, including our clinical trials.

As a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical trial endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- limitations on our business operations by the local, state, or federal government that could impact our ability to sell or deliver our instruments and consumables;
- interruption of, or delays in receiving, supplies of atacicept or MAU868 from our contract manufacturing organizations (CMO) due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruption of or delays in receiving products and supplies from the third parties we rely on to, among other things, manufacture components of our instruments, due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, which may impair our ability to sell our products and consumables;
- interruptions in nonclinical studies due to restricted or limited operations at our laboratory facility;
- business disruptions caused by workplace, laboratory and office closures and an increased reliance on employees working from home, travel limitations, cyber security and data accessibility limits, or communication or mass transit disruptions; and
- limitations on employee resources that would otherwise be focused on the conduct of our nonclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

The extent to which continuing effects of the COVID-19 pandemic continue to affect our business, clinical development, including our ongoing and planned preclinical studies and clinical trials, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, travel restrictions in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease, including the effectiveness and timing of vaccination programs in the United States and worldwide. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these effects could have negative impacts on our business, financial condition and results of operations.

In addition, to the extent continuing effects of the COVID-19 pandemic adversely affect our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

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 atacicept, MAU868, and any future product candidates that we may develop 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 United States and certain foreign jurisdictions relate to atacicept, MAU868, and other products. 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 atacicept, MAU868, and our other products, 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 atacicept, MAU868, or any future product candidates we may develop 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 atacicept, MAU868, or any future product candidates we may develop 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 KGaA, Darmstadt, Germany, related to atacicept, or the license agreement with Novartis related to MAU868, we could lose the ability to continue the development and commercialization of atacicept or MAU868, respectively.

We are dependent on patents, know-how and proprietary technology licensed or sublicensed to us from Ares and Novartis. 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. Either Ares or Novartis 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 either license agreement 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 KGaA, Darmstadt, Germany, Novartis, 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 Amplyx Agreement, pursuant to which we acquired Amplyx's right, title and interest in the license agreement between Amplyx and Novartis related to MAU868 (the Novartis Agreement). The Ares Agreement and Novartis 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 atacicept and MAU868.

Under the Ares Agreement, in consideration for the license, we issued 22,171,553 shares of our Series C redeemable convertible preferred stock to Ares at the time of the initial closing of our Series C redeemable convertible preferred stock financing in October 2020, which automatically converted into 1,913,501 shares of our Class A common stock upon the closing of our IPO. As additional consideration for the license, we paid Ares $25.0 million upon delivery and initiation of the transfer of specified information and materials and we are required to pay Ares aggregate milestone payments of up to $176.5 million upon the achievement of specified BLA filing or regulatory approval and aggregate milestone payments of up to $515.0 million upon the achievement of specified commercial milestones. 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 made an upfront initial payment of $5.0 million. We are also 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 Agreement, 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. 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 atacicept or MAU868 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 atacicept, or MAU868, or any future product candidates we may develop 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 atacicept, MAU868, or any future product candidates we may develop 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 atacicept, MAU868, or any future product candidates we may develop. 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 atacicept, MAU868, or any future product candidates we may develop, 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 atacicept, MAU868, or any future product candidates we may develop;
- 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 atacicept, MAU868, or any future product candidates we may develop.

Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import atacicept, MAU868, or any future product candidates we may develop and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, 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 and PGR proceedings, 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 atacicept, MAU868, or any future product candidates we may develop. 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 atacicept, MAU868, or any future product candidates we may develop.

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 atacicept, MAU868, or any future product candidates we may develop, 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 atacicept, MAU868, or any future product candidates we may develop, 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 atacicept, MAU868, or any future product candidates we may develop 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 atacicept, MAU868, or any future product candidates we may develop;
- 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 atacicept, MAU868, or any future product candidates we may develop. 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 atacicept, MAU868, or any future product candidates we may develop processes 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 atacicept, MAU868, or any future product candidates we may develop, 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 atacicept, MAU868, and future product candidates and technologies.

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 atacicept and MAU868, 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 atacicept, MAU868, and any future product candidates we may develop. 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 atacicept, MAU868, or any future product candidates we may develop, 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 Class A 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 priority of inventions, 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 the priority of inventions 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 atacicept, MAU868, or any future 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. An inability to obtain, enforce, and defend patents covering our proprietary technologies (including atacicept and MAU868) 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 will likely be introduced by the end of 2023, which would significantly impact

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

We may be 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 atacicept, MAU868, or any future product candidates we may develop 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 atacicept, MAU868, or any future product candidates we may develop 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 atacicept, MAU868, or any future product candidates we may develop, 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 atacicept, MAU868, or any future 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 atacicept, MAU868 or future product candidates we may develop 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 atacicept and MAU868 in clinical development. Regulatory authorities enforce these 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, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. 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 atacicept or MAU868 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 atacicept or MAU868, 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 atacicept or MAU868. As a result, our results of operations and the commercial prospects for atacicept and MAU868 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 atacicept, MAU868 or any future product candidate we may develop. 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. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business and financial condition.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. 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 the 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 an 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 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 atacicept and MAU868 drug products 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 atacicept, MAU868 or other product candidates necessary for the development or commercialization of atacicept, MAU868 or such other product candidates 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. We do not have long-term commercial supply agreements for atacicept or MAU868. Furthermore, the 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 (including, for example, the COVID-19 pandemic); and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have 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. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension 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 are 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 atacicept or MAU868.

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 Class A common stock

An active, liquid and orderly trading market for our Class A common stock may not be developed or sustained.

Prior to the closing of our IPO in May 2021, no public market for shares of our Class A common stock existed. The trading market for our Class A common stock on the Nasdaq Global Market has been limited and an active trading market for our Class A common stock may never develop or be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our Class A common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of Class A common stock as consideration.

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

The trading price of our Class A 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 Class A common stock from January 1, 2022 to March 24, 2023, has ranged from a low of $5.41 to a high of $28.06. 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 Class A 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 KGaA, Darmstadt, Germany, including any termination or other change in our relationship with Ares or Merck KGaA, Darmstadt, Germany;
- developments associated with our license with Novartis, including any termination or other change in our relationship with Novartis or Amplyx;
- 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 the recent and potential future disruptions in access to bank deposits and lending commitments due to bank failures, the conflict between Ukraine and Russia and related sanctions, economic slowdowns, recessions, inflation, rising interest rates, tightening of credit markets and continuing effects of the COVID-19 pandemic.

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 Class A 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 Class A 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 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 Class A common stock.

Prior to our IPO, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. In connection with the audit of our financial statements as of and for the years ended December 31, 2019 and 2020, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weakness related to a lack of sufficient number of qualified personnel within our accounting function to adequately segregate duties, to perform sufficient reviews and approval of manual journal entries posted to the general ledger and to consistently execute review procedures over general ledger account reconciliations, financial statement preparation and accounting for non-routine transactions.

We have implemented measures designed to improve our internal control over financial reporting that have remediated this material weakness, including the following:

- We have formalized our internal control documentation and strengthened supervisory reviews by our management; and

- We have added full-time and contract accounting personnel and segregated duties amongst accounting personnel.

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. The Sarbanes-Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm, to the extent we are no longer an "emerging growth company," as defined in the JOBS Act, and are not a non-accelerated filer. We do not expect our independent registered public accounting firm to attest to our management report on internal control over financial reporting for so long as we are an emerging growth company.

If we identify any additional material weaknesses in our internal control over financial reporting, 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 when required in the future, 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 Class A 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.

Our principal stockholders and management own a significant percentage of our outstanding voting stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding capital stock, beneficially own a significant percentage of our outstanding voting stock. Therefore, these stockholders are able to significantly influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our Class A common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their shares, and might affect the prevailing market price for our Class A common stock.

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

Our Class A common stock price could decline as a result of sales of a large number of shares of Class A 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, 2022, there were 27,800,861 shares of Class A common stock outstanding and held of record by 26 stockholders and no shares of Class B common stock outstanding. The number of record holders of our Class A common stock does not include DTC participants or beneficial owners holding shares through nominee names. Subsequent to our follow-on public offering in February 2023, the resale of shares of Class A common stock held by our officers and directors is currently prohibited or otherwise restricted until April 3, 2023, as a result of lock-up agreements entered into by our officers and directors with the underwriters in connection with such offering. The representatives of the underwriters may release some or all of the shares of common stock subject to lock-up agreements at any time in their sole discretion and without notice, which would allow for earlier sales of shares in the public market.

Further, certain holders of our Class A 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 have also registered all shares of Class A common stock that we may 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, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into Class A 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 Class A common stock to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to atacicept, MAU868 or future product candidates we may develop 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. 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 atacicept, MAU868 or future product candidates we may develop, 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 are an "emerging growth company," and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our Class A common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our Class A common stock less attractive because we may rely on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) December 31, 2026.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have taken advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

Pursuant to Section 404 we will be required to furnish a report by our management on our internal control over financial reporting, including, if required by our filing status, an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company or a non-accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Additionally, we are also a "smaller reporting company," as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter.

Investors may find our Class A common stock less attractive as a result of our reliance on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

We do not currently intend to pay dividends on our Class A common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our Class A 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 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 Class A 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 Class A common stock, thereby depressing the market price of our Class A 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 Class A 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 data, or those of any of our third-party partners (such as contract research organizations and clinical trial sites), 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; disruption 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) may process proprietary, confidential and sensitive information, including personal information (such as health-related information), intellectual property and trade secrets (collectively, sensitive information).

As a result, we and our third party partners (such as contract research organizations and clinical trial sites) are vulnerable to a variety of evolving threats. Cyberattacks, malicious internet-based activity, and online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of our third-party partners. These threats are prevalent, continue to rise, and are becoming 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.

These threat actors, such as personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors 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 cyber-attacks that could materially disrupt our systems, operations, supply chain, and ability to produce, sell and distribute our services.

We and our third party partners may also be 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 of service attacks (such as credential stuffing), social-engineering attacks (including phishing attacks), ransomware attacks, supply-chain attacks, server malfunctions, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods and other similar threats.

In particular, ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of 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 become more common and has increased risk to our information technology systems and sensitive 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 sensitive 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 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.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive 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. 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 sensitive information.

While we have developed systems and processes designed to protect the integrity, confidentiality and security of the sensitive information under our control, we cannot assure you that any security measures that we or our third-party partners have implemented will be effective in preventing cybersecurity incidents. There are many different cybercrime and hacking techniques and as such techniques continue to evolve, we may be unable to anticipate attempted security incidents, identify them before our information is exploited, or react in a timely manner. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit vulnerabilities change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business.

Applicable data privacy and security obligations may require us to notify relevant stakeholders 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 affecting us or our third-party partners (such as contract research organizations and clinical trial sites) could result in 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 information); substantial remediation costs; litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms.

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 for data security liabilities actually incurred, will continue to be available to us on economically reasonable terms, or at all, or that any insurer will not deny coverage as to any future

claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could adversely affect our reputation, business, financial condition and results of operations.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive 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.

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. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations— Recent accounting pronouncements."

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 made in our internal control 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 will become more visible, which we believe 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 Class A 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 Class A 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 2. Properties.

Our corporate headquarters are located in Brisbane, California. We occupy approximately 9,885 square feet of office space for our corporate headquarters under a lease that expires in November 2024. 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 Class A 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 March 23, 2023, there were approximately 26 stockholders of record of our Class A 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.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12 of Part III of this Annual Report for information about our equity compensation plans which is incorporated by reference herein.

Stock Performance Graph

Not applicable.

Use of Proceeds

There has been no material change in the use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on May 17, 2021.

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.

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 on Form 10-K, 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 a self-administered fusion protein that blocks both BLyS and APRIL with best-in-class potential for the treatment of IgAN. The Phase 2b ORIGIN trial evaluating the safety and efficacy of atacicept in patients with IgAN completed enrollment in mid-2022 and reported positive 24-week topline results in January 2023. Atacicept met its primary endpoint at 24 weeks, achieved statistical significance in the 150 mg dose group, and showed a trend towards deeper reductions in proteinuria with available data at 36 weeks, for which full results will read out in the second quarter of 2023. Additionally, atacicept's safety profile was comparable to placebo. The trial will remain blinded through 36 weeks, after which all patients will roll onto the open label portion of the study and receive atacicept 150 mg through 96 weeks. We plan to advance atacicept 150 mg in a pivotal Phase 3 clinical trial in IgAN in the second quarter of 2023. We also are planning a Phase 3 clinical trial of atacicept in LN) a severe renal manifestation of SLE, based on feedback from the FDA's review of clinical results in a Phase 2 clinical trial of atacicept in SLE patients with HDA. We continue to advance the development of MAU868, a potentially first-in-class monoclonal antibody to treat reactivated BKV infections. MAU868 is a clinical-stage neutralizing monoclonal antibody that is directed against BKV, a polyoma virus that can have devastating consequences in certain settings such as kidney transplant and HSCT. In final results from the Phase 2 clinical trial of MAU868 versus placebo in BK viremia among kidney transplant recipients, MAU868 was shown to be well tolerated and demonstrated a clinically meaningful BKV antiviral activity through 36 weeks. Pending discussions with the FDA, we plan to initiate a Phase 2b or Phase 3 clinical trial. We believe that our current pipeline programs leverage the deep expertise of the Vera Therapeutics team and have strong commercial synergies. We hold global developmental and commercial rights to all of our pipeline molecules.

In January 2023, we announced our plan to prioritize and focus our current resources on the advancement of atacicept in IgAN into a pivotal Phase 3 trial. As a result, we are delaying enrollment in the pivotal Phase 3 trial for LN and commitment of resources to the MAU868 program.

Since our inception, 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 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, if ever. 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 Class A common stock, redeemable convertible preferred stock, debt financing and convertible promissory notes. As of December 31, 2022, we had $114.7 million in cash, cash equivalents and marketable securities.

On May 18, 2021, we completed our IPO. In connection with our IPO, we issued and sold 5,002,500 shares of Class A common stock, including 652,500 shares associated with the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $11.00 per share, resulting in net proceeds to us of approximately $48.4 million, after deducting underwriting discounts and commissions and offering related expenses payable by us. Upon the closing of our IPO, all outstanding shares of our redeemable convertible preferred stock converted into 15,464,776 shares of our Class A common stock and 309,238 shares of our Class B common stock. In 2022, all shares of Class B common stock were converted into shares of Class A common stock.

In December 2021, we entered into the Amplyx Agreement, pursuant to which we paid $5.0 million to Amplyx to purchase assets relating to MAU868. In September 2022, we entered into an amendment to the Novartis License to modify the terms of potential

development milestone payments. Pursuant to this amendment, we 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 we accrued in December 2021. The value of the shares issued was $5.7 million based on the closing market value of our Class A common stock as of the effective date of the amendment, and as a result of the amendment we recognized $3.7 million of research and development expense.

In December 2021, we entered into the Loan Agreement with Oxford, which was amended in November 2022, pursuant to which we may borrow up to an aggregate maximum principal amount of $50.0 million, of which $5.0 million was funded on December 17, 2021, and $20.0 million was funded on November 4, 2022, and the balance of which is available to be drawn between January 3, 2022, and December 29, 2023. See "—Loan and security agreement" below.

In February 2022, we completed a follow-on public offering and issued 5,742,026 shares of Class A common stock for net proceeds of approximately $80.0 million, after deducting underwriting discounts and commissions and offering related expenses.

In February 2023, we completed a follow-on public offering and issued 16,428,572 shares of Class A common stock for net proceeds of approximately $107.6 million, after deducting underwriting discounts and commissions and offering related expenses.

We have incurred significant operating losses since the commencement of our operations. Our net losses were $89.1 million and $32.6 million for the years ended December 31, 2022 and 2021, respectively, and we expect to incur significant and increasing losses for the foreseeable future as we continue to advance our product candidates, atacicept and MAU868, to 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, 2022, we had an accumulated deficit of $213.1 million. Our primary use of cash is to fund operating expenses, which consist of research and development expenditures 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 near- and long-term activities as we:

- continue our ongoing and planned development of our product candidates, atacicept for the treatment of IgAN and LN, and MAU868 for the treatment of BK viremia;
- conduct clinical trials and nonclinical studies for atacicept and MAU868;
- 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;
- attract, develop and retain additional clinical, scientific, quality control, manufacturing management and administrative personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

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

The coronavirus (including its variants, COVID-19) pandemic has had a significant economic impact across the global marketplace presenting challenges to maintaining business continuity and dramatically changing the ways in which we live and interact with others. While vaccines have become widely available in certain countries, and businesses and economies have reopened, the status of global economic recovery remains uncertain and unpredictable, and will continue to be impacted by developments in the pandemic including any subsequent waves of outbreak or new variant strains of COVID-19 which may require re-closures or other preventative measures. As public health directives surrounding the pandemic have relaxed, our office has reopened and we are permitting travel and in-person events, taking into consideration government restrictions, employee safety, and health risks. Our approach may vary among geographies depending on appropriate health protocols, and may change at any time. Additionally, our efforts to reopen our office safely may not be successful, could expose our employees to health risks, and could involve additional costs or liability.

Due to the ongoing military conflict between Ukraine and Russia, 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. In connection with the military conflict, the United States, United Kingdom and European Union (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 and related sanctions, 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 and supply chain continuity in both Europe and globally, and has introduced significant uncertainty into global markets. As a result, our business and results of operations may be adversely affected by the ongoing military 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.

Although we did not see a significant financial impact to our business operations as a result of recent geopolitical and macroeconomic developments, such as the COVID-19 pandemic and the ongoing Ukraine-Russia conflict for the year ended December 31, 2022, 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, the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic or adverse geopolitical and macroeconomic concerns, interruptions or delays in the operations of the FDA or other regulatory authorities, continued increases in inflation and interest rates, changes in availability and cost of credit and 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 revenue and the way we conduct our business, is highly uncertain and subject to continued change, and we recognize that they may continue to present unique challenges for us.

We continue to believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the issuance date of the financial statements included in this Annual Report. However, should adverse geopolitical and macroeconomic events, such as the COVID-19 pandemic, the ongoing Ukraine-Russia conflict and related sanctions, and any associated recession or depression 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, 2022 and 2021

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

(dollars in thousands)	Year Ended December 31, 2022	2021	CHANGE AMOUNT	%
Operating expenses:				
Research and development	$ 68,993	$ 22,484	$ 46,509	207%
General and administrative	21,910	11,918	9,992	84%
Total operating expenses	90,903	34,402	56,501	164%
Loss from operations	(90,903)	(34,402)	(56,501)	164%
Other income (expense):				
Interest income	1,750	15	1,735	*
Interest expense	(992)	(20)	(972)	*
Other income	1,899	—	1,899	*
Change in fair value of non-marketable equity securities	(809)	(892)	83	*
Gain on sale of PNAi technology	—	2,691	(2,691)	*
Total other income, net	1,848	1,794	54	3%
Loss before provision of income taxes	$ (89,055)	$ (32,608)	$ (56,447)	173%

* Not meaningful

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, laboratory supplies and costs of lab studies, 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 for research and development personnel and activities and other expenses. From October 2020 until December 2021, we have been engaged in the development of atacicept as our sole product candidate. In December 2021, we entered into the Amplyx Agreement and acquired our second product candidate, MAU868.

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.

(dollars in thousands)	Year Ended December 31, 2022	2021	CHANGE AMOUNT	%
Direct research and development expenses				
Contract drug manufacturing	$ 27,587	$ 2,236	$ 25,351	1134%
Clinical trial expenses	20,534	6,754	13,780	204%
Consulting and professional services	5,431	2,508	2,923	117%
License and milestone obligations	3,661	7,000	(3,339)	(48)%
Indirect research and development expenses				
Compensation and related benefits	10,987	3,870	7,117	184%
Facilities and other	793	116	677	584%
Research and development expenses	$ 68,993	$ 22,484	$ 46,509	207%

Research and development expenses increased by $46.5 million, or 207%, to $69.0 million in the year ended December 31, 2022, from $22.5 million in the year ended December 31, 2021. The increase was primarily due to progressing clinical development of

atacicept in IgAN and LN, including expenses incurred in manufacturing drug supply for clinical trials. Contract drug manufacturing increased by $25.4 million primarily due to production of atacicept drug supply for clinical trials. Clinical trial expenses increased by $13.8 million primarily due to startup of the COMPASS trial, as well as increased expenses for the ORIGIN trial as enrollment rates increased in 2022. Compensation and related benefits for research and development employees, including stock-based compensation, increased by $7.1 million, and consulting and professional research and development services increased by $2.9 million, due to increased headcount and resources required to support clinical development of our product candidates during 2022. Facilities, depreciation and other expenses related to research and development increased by $0.7 million primarily due to our office lease that commenced in December 2021, and was amended to expand our leased space in September 2022, and other expenses related to the support of increased research and development headcount. These increases were partially offset by a decrease of $3.3 million in license and milestone expense. In September 2022, we recorded license and milestone expense of $3.7 million as a result of an amendment to the Novartis License that was assigned to us in connection with our purchase of MAU868 and certain related assets from Amplyx. In December 2021, we paid $5.0 million to Amplyx for the purchase of MAU868 and accrued $2.0 million of milestone expense in connection with the purchase.

We expect our research and development expenses to increase in future periods as we initiate our ORIGIN-3 Phase 3 trial of atacicept in IgAN, continue our COMPASS Phase 3 trial of atacicept in LN and develop other product candidates.

General and administrative

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 incurred, and payments we make prior to the receipt of goods or services to be used for general and administrative purposes efforts are deferred as prepaid expenses until the goods or services are received and used.

	Year Ended December 31,		CHANGE	
(dollars in thousands)	2022	2021	AMOUNT	%
General and administrative	$ 21,910	$ 11,918	$ 9,992	84%

General and administrative expenses increased by $10.0 million, or 84%, to $21.9 million in the year ended December 31, 2022, from $11.9 million in the year ended December 31, 2021, due primarily to an increase of $3.8 million of payroll and related expenses including stock-based compensation, an increase of $2.3 million of rent and facilities expense primarily due to a change in lease accounting under which rent expense is recorded related to our previous headquarters facility in South San Francisco, California, which is subleased to another party, an increase of $1.6 million in insurance premium expenses, an increase of $0.8 million in consulting and non-employee director compensation expense, including stock-based compensation, an increase of $0.6 million in legal expenses, and an increase of $0.4 million in recruiting and placement fees.

Other income

	Year Ended December 31,		CHANGE	
(dollars in thousands)	2022	2021	AMOUNT	%
Other income, net	$ 1,848	$ 1,794	$ 54	(3)%

Other income, net was $1.8 million in each of the years ended December 31, 2022 and 2021. In the year ended December 31, 2022, interest income increased by $1.7 million due to higher yields on marketable securities investments and we recognized $1.9 million of other income from a sublease due to changes in lease accounting. These increases were partly offset by a $1.0 million increase in interest expense related to loans payable to Oxford. In the year ended December 31, 2021, we recognized other income of $2.7 million recognized in 2021 from the sale of assets to NeuBase.

Liquidity and Capital Resources

Overview

To date, we have funded our operations primarily through proceeds from the sale of shares of our Class A common stock, redeemable convertible preferred stock, debt financing and convertible notes. From our inception through December 31, 2022, we have raised aggregate net cash proceeds of $295.0 million from the issuance and sale of redeemable convertible preferred stock, convertible notes, Class A common stock and our Loan Agreement with Oxford. 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.

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 atacicept and MAU868, hire additional staff, including clinical, operational, financial 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. We expect that our research and development and general and administrative costs will increase substantially in connection with conducting additional clinical trials and 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, 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.

On May 18, 2021, we completed our IPO. In connection with our IPO, we issued and sold 5,002,500 shares of Class A common stock, including 652,500 shares associated with the full exercise on May 20, 2021, of the underwriters' option to purchase additional shares, at a price to the public of $11.00 per share, resulting in net proceeds to us of approximately $48.4 million, after deducting underwriting discounts and commissions and offering related expenses payable by us. Upon the closing of our IPO, all outstanding shares of our redeemable convertible preferred stock converted into 15,464,776 shares of our Class A common stock and 309,238 shares of our Class B common stock.

In December 2021, we entered into the Amplyx Agreement, pursuant to which we paid $5.0 million to Amplyx to purchase assets relating to MAU868. In September 2022, we entered into an amendment to the Novartis License to modify the terms of potential development milestone payments. Pursuant to this amendment, we 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 we accrued in December 2021. The value of the shares issued was $5.7 million based on the closing market value of our Class A common stock as of the effective date of the amendment, and as a result of the amendment we recognized $3.7 million of research and development expense.

In December 2021, we entered into the Loan Agreement with Oxford, which was amended in November 2022, pursuant to which we may borrow up to 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 balance of which is available to be drawn between January 3, 2022, and December 29, 2023. See "—Loan and security agreement" below.

In February 2022, we completed a follow-on public offering and issued 5,742,026 shares of Class A common stock for net proceeds of approximately $80.0 million, after deducting underwriting discounts and commissions and offering related expenses.

In February 2023, we completed a follow-on public offering and issued 16,428,572 shares of Class A common stock for net proceeds of approximately $107.6 million, after deducting underwriting discounts and commissions and offering related expenses.

As of December 31, 2022, we had cash, cash equivalents and marketable securities balances of $114.7 million, as compared to $79.7 million as of December 31, 2021. We expect that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements for at least 12 months subsequent to the issuance date of the financial statements appearing elsewhere in this Annual Report.

Contractual Obligations

We 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.

Our operating lease obligations reflect our lease obligations for our office space in Brisbane, California, and our office and life science research space in South San Francisco, California.

During 2020, we vacated the leased facilities in South San Francisco. In November 2020, we entered into a non-cancellable sublease agreement for the facility, under the terms of which we are entitled to receive $8.8 million in lease payments over the term of the sublease, which ends concurrently with the original lease in September 2025. As tenant, we remain responsible for the $6.7 million minimum lease commitment remaining on the facilities as of December 31, 2022, regardless of whether we are paid by the subtenant.

In November 2021, we entered into a lease agreement for approximately 5,000 square feet of office space in Brisbane, California. The term of the lease is three years, and rent will be approximately $0.3 million for the first year, with scheduled annual 3% increases.

In July 2022, we entered into an amendment to this lease to add approximately 5,000 square feet of office space in the same building adjacent to this location. The term of the lease amendment is 27 months from September 2022, and the base rent is approximately $0.3 million for the first 12 months with scheduled annual 3% increases. The lease includes renewal options.

Cash Flows

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

	Year Ended December 31,	
(dollars in thousands)	**2022**	**2021**
Net cash used in operating activities	$ (67,596)	$ (23,708)
Net cash used in investing activities	(70,552)	(4,204)
Net cash provided by financing activities	101,933	53,882
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (36,215)	$ 25,970

Operating Activities

For the year ended December 31, 2022, we used $67.6 million of cash in operating activities, attributable to a net loss of $89.1 million, a $8.2 million increase in prepaid expenses and other current assets and a $2.6 million decrease in operating lease liabilities, partially offset by a $10.6 million increase in accounts payable, $8.9 million of non-cash stock based compensation expense, a $7.0 million increase in accrued and other current liabilities, $3.7 million of non-cash license and milestone expenses and a $2.3 million reduction in the carrying amount of operating lease right-of-use assets.

For the year ended December 31, 2021, we used $23.7 million of cash in operating activities, attributable to a net loss of $32.6 million, a $2.7 million non-cash gain on sale of assets to NeuBase, and a $2.3 million increase in prepaid expenses and other current assets, partially offset by $5.0 million of the net loss related to the purchase of MAU868 classified as an investing activity, a $5.4 million increase in accrued and other current liabilities, and $3.0 million of non-cash stock-based compensation expense.

Investing Activities

For the year ended December 31, 2022, our investing activities used $70.6 million of cash, primarily resulting from the purchase of short-term marketable securities, less maturities of short-term marketable securities during the year.

For the year ended December 31, 2021, our investing activities used $4.2 million of cash, resulting from the $5.0 million cash payment for the purchase of MAU868 pursuant to the Amplyx Agreement, partially offset by $0.8 million of cash received resulting from the sale of assets to NeuBase.

Financing Activities

For the year ended December 31, 2022, our financing activities provided $101.9 million of cash resulting from $86.1 million gross proceeds received from our follow-on offering, $19.8 million of net cash proceeds from the issuance of debt to Oxford and $2.1 million proceeds from exercise of stock options and issuance of shares under our employee stock purchase plan, less $6.2 million offering costs related to our follow-on offering, including underwriting discounts and commissions.

For the year ended December 31, 2021, our financing activities provided $53.9 million of cash resulting from $51.2 million proceeds received from our IPO, net of underwriting discounts and commissions, partially offset by the payment of $2.8 million of related offering costs during the period, and $4.9 million of net cash proceeds from the issuance of debt to Oxford.

Loan and security agreement

On December 17, 2021, we entered into the Loan Agreement with Oxford, a Delaware limited liability company, as lender (Lender) and collateral agent. The Loan Agreement provides for a term loan (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 balance of which is available to be drawn between January 3, 2022 and December 31, 2023. The Loan is available in minimum draws of $5.0 million, entirely at our option and not contingent upon the completion of clinical, regulatory, financial or other related milestones.

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 Loan Agreement. We are required to make monthly interest-only payments for 60 months followed by full amortization through maturity.

Initially, through December 30, 2021, the Loan incurred interest at a per annum rate of 8.254%. Thereafter, the Loan bears 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 greater of (i) 8.25%

and (ii) the sum of (a) 1-Month CME Term SOFR as reported by CME Group Benchmark Administration Limited on the last business day of the month that immediately precedes the month in which the interest will accrue, and (b) 8.25%.

We are permitted to prepay the Loan in full or in part at any time upon 10 business days' written notice to the Lender, subject to the applicable Prepayment Fee (as defined below). Upon the earliest to occur of the maturity date, acceleration of the Loan or prepayment of the Loan, we are required to make a final payment equal to 7.0% of the aggregate principal amount of the Loan (the Final Fee). Any prepayments of the Loan, whether mandatory or voluntary, must include an amount equal to the sum of (a) the portion of the outstanding principal of the Loan being prepaid plus accrued and unpaid interest thereon through the prepayment date, (b) the Final Fee, (c) the Lender's expenses and all other obligations that are due and payable to the Lender, and (d) a prepayment fee of (i) 3.0% of the portion of the Loan being prepaid if the repayment is on or before the first anniversary of the funding date of such term loan or (ii) 2.0% of the portion of the Loan being prepaid if the repayment is after the first anniversary of the funding date but on or before the second anniversary of the funding date of such term loan (the Prepayment Fee). There is no Prepayment Fee for any prepayments occurring after the second anniversary of the funding date of such term loan.

Our obligations under the Loan Agreement are secured by a security interest in all of our assets, other than our intellectual property, which is subject to a negative pledge. The Loan Agreement does not contain any financial related covenants. Included in the 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 5.0% may be applied to the outstanding loan balances, and the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. Events of default under the Loan Agreement include customary events of default, including, but not limited to: (i) failure to (a) make any payment of principal or interest on its due date, or (b) pay any other obligations within three business days after such obligations are due and payable; (ii) failure to perform any obligation under specified covenants; (iii) the occurrence of a material adverse change; (iv) we or any of our subsidiaries being or becoming insolvent, beginning an insolvency proceeding, or becoming subject to an insolvency proceeding that is not dismissed or stayed within 45 days; (v) a default under any agreement with a third party resulting in a right by such third party to accelerate the maturity of any indebtedness in an amount in excess of $500,000 or that could reasonably be expected to have a material adverse change; (vi) the rendering of judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least $500,000 that remain unsatisfied, unvacated, or unstayed for a period of 10 days after the entry thereof; (vii) revocation, rescission, suspension or adverse modification of any governmental approval, or non-renewal of a governmental approval in the ordinary course for a full term, that could reasonably be expected to result in a material adverse change; and (viii) failure of a lien created under the Loan Agreement or any other loan document to constitute a valid and perfected lien on any of the collateral purported to be secured thereby, subject to no prior or equal lien, other than permitted liens.

At-the-Market Offering

In June 2022, we entered into a sales agreement with Cowen and Company LLC (Cowen) as sales agent, pursuant to which we may issue and sell shares of our Class A common stock for an aggregate maximum offering price of $150.0 million under an at-the-market offering program (ATM). We will pay Cowen up to 3.0% of gross proceeds of the Class A common stock sold through the ATM. As of December 31, 2022, no shares of Class A common stock had been issued or sold under the ATM.

Emerging growth company status

We are an emerging growth company, as defined in the JOBS Act. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company under the JOBS Act until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenue of $1.235 billion or more, (ii) the date on which we have issued more than $1.0 billion of non-convertible debt instruments during the previous three fiscal years, (iii) the date on which we are deemed a "large accelerated filer" under the rules of the SEC with at least $700.0 million of outstanding equity securities held by non-affiliates, or (iv) December 31, 2026.

Critical Accounting Policies and Significant Judgments and 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 United States generally accepted accounting principles. 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 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. We record accruals for estimated ongoing research and development costs. 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. Significant judgments and estimates are made in determining the prepaid and accrued balances at the end of any reporting period. Actual results could differ materially from our estimates.

Fair value of common stock

Historically, for all periods prior to our IPO, the fair values of the shares of our common stock underlying our share-based awards were determined on each grant date by our board of directors with input from management and the assistance of an independent third-party valuation specialist. Given the absence of a public trading market of our common stock, and in accordance with the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation (Practice Aid), our board of directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of our common stock at each grant date. These factors include:

- external market conditions affecting the proteomics and genomics biotechnology industry and trends within the industry;
- our stage of development;
- the rights, preferences and privileges of our redeemable convertible preferred stock relative to those of our common stock;
- the prices at which we sold shares of our redeemable convertible preferred stock;
- actual operating results and projected financial performance, including our levels of available capital resources;
- the progress of our research and development efforts and business strategy;
- equity market conditions affecting comparable public companies;
- general U.S. market conditions; and
- the lack of marketability of our common stock.

In valuing our common stock, the fair value of our business, or enterprise value, was determined using various valuation methods, including combinations of income, market and asset approaches with input from management. The income approach determines value by using one or more methods that convert anticipated economic benefits into a present single amount. The application of the income approach establishes value by methods that discount or capitalize earnings or cash flow, by a discount or capitalization rate that reflects investors' rate of return expectations, market conditions, and the relative risk of the subject investment. The market approach involves identifying and evaluating comparable public companies and acquisition targets that operate in the same industry or which have similar operating characteristics as the subject company. From the comparable companies, publicly available information is used to extrapolate market-based valuation multiples that are applied to historical or prospective financial information in order to derive an indication of value. The asset approach determines the value of the underlying assets and liabilities of a business as a means of determining the value of the business in aggregate. This approach can include the value of both tangible and intangible assets.

- **Option Pricing Method (OPM).** Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the redeemable convertible preferred stock and common stock are inferred by analyzing these options. This method is appropriate to use when the range of possible future outcomes is difficult to predict and thus creates highly speculative forecasts.
- **Probability-Weighted Expected Return Method (PWERM).** The PWERM is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class. This method is

generally most appropriate to use when the time to a liquidity event is short, making the range of possible future outcomes relatively easy to predict.

Based on our early stage of development and other relevant factors, we determined that the OPM was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock for valuations during early 2020.

Beginning in March 2020, we used a hybrid method to determine the estimated fair value of our common stock, which included both the OPM and PWERM models.

Application of these approaches involves the use of estimates, judgment, and assumptions that are highly complex and subjective, such as those regarding our expected future revenue, expenses, and cash flows, discount rates, market multiples, the selection of comparable companies, and the probability of future events. Changes in any or all of these estimates and assumptions, or the relationships between those assumptions, impact our valuations as of each valuation date and may have a material impact on the valuation of common stock.

The assumptions underlying these valuations represent our management's best estimate, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

After the completion of our IPO, the fair value of each share of the underlying common stock has been determined based on the closing price as reported on the date of grant on the primary stock exchange on which our Class A common stock is traded.

Recent accounting pronouncements

See Note 2 to our audited financial statements included elsewhere in this Annual Report on Form 10-K for more information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition of results of operations.

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

Not required.

Item 8. Financial Statements and Supplementary Data.

VERA THERAPEUTICS, INC.
Index to Financial Statements and Supplementary Data
Years ended December 31, 2022 and 2021

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Vera Therapeutics, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Vera Therapeutics, Inc. (the Company) as of December 31, 2022 and December 31, 2021, the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2022, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and December 31, 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement of the 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. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2018.
San Francisco, California
March 28, 2023

VERA THERAPEUTICS, INC.
Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 43,459	$ 79,674
Marketable securities	71,194	—
Prepaid expenses and other current assets, current	11,045	2,863
Total current assets	125,698	82,537
Restricted cash, noncurrent	293	293
Property and equipment, net	51	—
Operating lease right-of-use assets	5,173	—
Prepaid expenses and other current assets, noncurrent	162	51
Non-marketable equity securities	58	867
Total assets	$ 131,435	$ 83,748
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,991	$ 1,385
Operating lease liabilities	2,645	—
Restructuring liability, current	—	377
Accrued expenses and other current liabilities	10,964	5,928
Total current liabilities	25,600	7,690
Long-term debt	24,810	4,923
Operating lease liabilities, noncurrent	3,831	—
Restructuring liability, noncurrent	—	1,257
Accrued and other noncurrent liabilities	286	286
Total liabilities	54,527	14,156
Stockholders' equity		
Preferred stock, $0.001 par value; 10,000,000 authorized as of December 30, 2022 and December 31, 2021; no shares issued and outstanding as of December 30, 2022 and December 31, 2021	—	—
Class A common stock, $0.001 par value; 500,000,000 shares authorized as of December 31, 2022 and December 31, 2021; 27,800,861 and 20,968,376 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	28	21
Class B non-voting common stock, $0.001 par value; 14,600,000 shares authorized as of December 31, 2022 and December 31, 2021; 0 and 309,238 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively.	—	—
Additional paid-in capital	290,216	193,627
Accumulated other comprehensive loss	(224)	—
Accumulated deficit	(213,112)	(124,056)
Total stockholders' equity	76,908	69,592
Total liabilities and stockholders' equity	$ 131,435	$ 83,748

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,	
	2022	2021
Operating expenses:		
Research and development	$ 68,993	$ 22,484
General and administrative	21,910	11,918
Total operating expenses	90,903	34,402
Loss from operations	(90,903)	(34,402)
Other income (expense):		
Interest income	1,750	15
Interest expense	(992)	(20)
Other income	1,899	—
Change in fair value of non-marketable equity securities	(809)	(892)
Gain on sale of PNAi technology	—	2,691
Total other income, net	1,848	1,794
Loss before provision for income taxes	(89,055)	(32,608)
Provision for income taxes	(1)	(1)
Net loss	$ (89,056)	$ (32,609)
Other comprehensive loss:		
Change in unrealized loss on marketable securities	$ (224)	$ —
Comprehensive loss	$ (89,280)	$ (32,609)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.35)	$ (2.43)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	26,570,676	13,435,706

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

VERA THERAPEUTICS, INC.
Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity
(in thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Class A Common Stock		Class B Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Equity
Balances as of December 31, 2020	**182,772,372**	**$ 139,576**	**355,296**	**$ —**	**—**	**$ —**	**$ 2,099**	**$ —**	**$ (91,447)**	**$ (89,348)**
Class A common stock issued pursuant to initial public offering, net of issuance costs	—	—	5,002,500	5	—	—	48,406	—	—	48,411
Conversion of preferred stock into common stock	(182,772,372)	(139,576)	15,464,775	16	309,238	—	139,560	—	—	139,576
Issuance of Class A common stock upon exercise of options	—	—	145,805	—	—	—	550	—	—	550
Stock-based compensation	—	—	—	—	—	—	3,012	—	—	3,012
Net loss	—	—	—	—	—	—	—	—	(32,609)	(32,609)
Balances as of December 31, 2021	**—**	**—**	**20,968,376**	**21**	**309,238**	**—**	**193,627**	**—**	**(124,056)**	**69,592**
Issuance of Class A common stock from underwritten follow-on offering, net of offering costs	—	—	5,742,026	6	—	—	80,028	—	—	80,034
Issuance of Class A common stock upon exercise of options	—	—	405,140	1	—	—	1,791	—	—	1,792
Issuance of Class A common stock pursuant to employee stock purchase plan	—	—	15,328	—	—	—	291	—	—	291
Issuance of Class A common stock upon vesting of restricted stock units	—	—	77,719	—	—	—	—	—	—	—
Conversion of Class B common stock into Class A common stock	—	—	309,238	—	(309,238)	—	—	—	—	—
Issuance of Class A common stock for payment of licensing fees, net of offering costs	—	—	283,034	—	—	—	5,592	—	—	5,592
Stock-based compensation	—	—	—	—	—	—	8,887	—	—	8,887
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(224)	—	(224)
Net loss	—	—	—	—	—	—	—	—	(89,056)	(89,056)
Balances as of December 31, 2022	**—**	**$ —**	**27,800,861**	**$ 28**	**—**	**$ —**	**$ 290,216**	**$ (224)**	**$ (213,112)**	**$ 76,908**

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

VERA THERAPEUTICS, INC.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (89,056)	$ (32,609)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and accretion	(846)	176
Reduction in the carrying amount of operating lease right-of-use assets	2,271	—
Stock-based compensation	8,887	3,012
Issuance of Class A common stock for licensing payment, net of costs	3,592	—
Payment for MAU868 asset purchase	—	5,000
Restructuring payments	—	(999)
Gain on sale of PNAi technology	—	(2,691)
Change in fair value of non-marketable equity securities	809	892
Changes in operating assets and liabilities:		
Prepaid expense and other current assets	(8,182)	(2,306)
Other assets	(111)	(51)
Accounts payable	10,606	475
Accrued and other current liabilities	7,036	5,393
Operating lease liabilities	(2,602)	—
Net cash used in operating activities	(67,596)	(23,708)
Cash flows from investing activities		
Proceeds from sale of PNAi technology	—	796
Payment for MAU868 asset purchase	—	(5,000)
Purchase of property and equipment	(62)	—
Purchase of marketable securities	(148,490)	—
Proceeds from maturities of marketable securities	78,000	—
Net cash used in investing activities	(70,552)	(4,204)
Cash flows from financing activities		
Proceeds from exercise of stock options and employee stock purchase plan	2,083	550
Proceeds from issuance of Class A common stock upon initial public offering, net of underwriting discounts and commissions	—	51,176
Proceeds from borrowings, net of costs	19,816	4,921
Payment of offering costs related to initial public offering	—	(2,765)
Proceeds from issuance of Class A common stock in follow-on offering	86,131	—
Payment of costs and underwriting discounts and commissions related to follow-on offering	(6,097)	—
Net cash provided by financing activities	101,933	53,882
Net (decrease) increase in cash and cash equivalents and restricted cash	(36,215)	25,970
Cash, cash equivalents and restricted cash, beginning of year	79,967	53,997
Cash, cash equivalents and restricted cash, end of year	$ 43,752	$ 79,967
Reconciliation of cash and cash equivalents and restricted cash to the balance sheets		
Cash and cash equivalents	43,459	$ 79,674
Restricted cash	293	293
Total cash and cash equivalents and restricted cash	$ 43,752	$ 79,967
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 895	$ 17
Cash paid for operating leases	$ 2,734	$ —
Issuance of Class A common stock in payment of licensing fees	$ 2,000	$ —
Reclassification of redeemable convertible preferred stock into common stock upon initial public offering	$ —	$ 139,576
Non-marketable equity securities received as partial proceeds from sale of PNAi technology	$ —	$ 1,759
Lease assignment	$ —	$ 136
Liability assumed in connection with MAU868 asset purchase	$ —	$ 2,000

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 and operations are located in Brisbane, California. The Company operates in one segment.

Reverse Stock Split

On May 7, 2021, the Company filed a certificate of amendment to its fourth amended and restated certificate of incorporation to effect a 11.5869-for-one reverse stock split of its issued and outstanding Class A common stock. Adjustments corresponding to the reverse stock split were made to the ratio at which the Company's redeemable convertible preferred stock converted into Class A common stock. Accordingly, all share and per share amounts related to Class A common stock, stock options and restricted stock awards for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable to reflect the reverse stock split.

Initial Public Offering

On May 13, 2021, the Company's registration statement on Form S-1 for its initial public offering (the IPO) was declared effective by the Securities and Exchange Commission (the SEC), and the shares of its Class A common stock commenced trading on the Nasdaq Global Select Market on May 14, 2021. The IPO closed on May 18, 2021, pursuant to which the Company issued and sold 4,350,000 shares of its Class A common stock at a public offering price of $11.00 per share. On May 20, 2021, the Company issued 652,500 shares of its Class A common stock to the underwriters of the IPO pursuant to the exercise of the underwriters' option to purchase additional shares. The Company received total net proceeds of $48.4 million from the IPO, after deducting underwriting discounts and commissions of $3.9 million, and offering costs of $2.8 million. Prior to the completion of the IPO, all shares of redeemable convertible preferred stock then outstanding were converted into 15,464,776 shares of Class A common stock and 309,238 shares of Class B common stock.

Follow-on Public Offering

On February 14, 2022, the Company completed a follow-on public offering pursuant to which the Company issued and sold 5,742,026 shares of its Class A common stock at a public offering price of $15.00 per share, including 748,959 shares of Class A common stock pursuant to the full exercise of the underwriters' option to purchase additional shares. The Company received total net proceeds of approximately $80.0 million, after deducting underwriting discounts and commissions of $5.2 million, and offering costs of approximately $0.9 million.

Liquidity

Since inception, the Company devoted substantially all of its resources to its research and development efforts, pre-clinical studies and clinical trials, 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 flow from operations since its inception, and had an accumulated deficit of $213.1 million as of December 31, 2022. The Company had cash, cash equivalents and marketable securities of $114.7 million as of December 31, 2022 and has access to additional debt financing under a credit facility (see Note 8). 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, 2022 will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months subsequent to the issuance date of these financial statements. The Company intends to raise additional capital through public or private equity offerings or 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 SEC regarding financial reporting. The U.S. dollar is the Company's functional and reporting currency.

Emerging Growth Company Status

The Company is an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (1) is no longer an emerging growth company or (2) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

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 research contract costs and accruals, fair value of common stock and stock-based compensation expense, and the valuation allowance for deferred tax assets. The Company evaluates and adjusts its estimates and assumptions on an ongoing basis using historical experience and other factors. Actual results could differ materially 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 a federally insured financial institution 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 agencies 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

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. Cash equivalents consist of money market funds and are stated at fair value.

Restricted Cash

Restricted cash represents cash held by a financial institution as collateral for a letter of credit securing its operating lease for office and laboratory space, which is classified as a non-current asset on the balance sheets based on the maturity of the lease.

Marketable Securities

The Company holds investments in marketable securities, consisting of U.S. government securities and are classified as available-for-sale securities and are carried at estimated fair values as determined based on quoted prices in active markets. Management

determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designation periodically. Short-term marketable securities have maturities less than one year as of the balance sheet date. Long-term marketable securities have maturities greater than one year as of the balance sheet date. Unrealized gains and losses are reported as a component of other comprehensive loss. Interest, amortization and accretion of purchase premiums and discounts on marketable debt securities are included in other 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 income, net in the statements of operations and comprehensive loss.

The Company regularly reviews all of the marketable securities for decline in fair value to determine whether unrealized losses have resulted from credit loss or other factors. The review includes considerations for the cause of the impairment but is not limited to (i) the consideration of the cause of the decline, (ii) any currently recorded expected credit losses and (iii) the creditworthiness of the respective security issuers. A decline of fair value below cost basis is considered an other-than-temporary impairment if the Company has the intent to sell the 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. Regardless of the Company's intent or requirement to sell the security, an impairment is considered other-than-temporary if the Company does not expect to recover the entire cost basis. In those instances, an impairment charge equal to the difference between fair value and the cost basis is recorded in other income (expense), on the statements of operations and comprehensive loss. No impairment loss was recognized for the fiscal years ended December 31, 2022 and 2021.

The amortized or accreted cost basis of the marketable securities approximates its fair value.

Deferred Offering Costs

Deferred offering costs consisting of legal, accounting and filing fees relating to equity offerings. Deferred offering costs are included in other long-term assets on the Company's balance sheets. Upon completion of the offering, these amounts are offset against the proceeds of the offering.

Leases

The Company leases office space under operating leases and determines if the arrangement is a lease at inception. These leases contain lease and non-lease components. Non-lease components include payments for maintenance, utilities, real estate taxes, and management fees. The lease and non-lease components are combined and accounted as a single lease component. Payments made under operating leases (net of any incentive received from the lessors) are recorded on a straight-line basis over the term of the lease.

These leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on information available at commencement date in determining the present value of lease payments. The incremental borrowing rate is a hypothetical rate based on the Company's understanding of what the credit rating would be in a similar economic environment. Operating leases are included in operating lease right-of-use assets and operating lease liabilities, current and non-current, on the balance sheets.

Leases may include one or more options to renew. The Company does not assume renewals in determination of the lease term unless the renewals are deemed to be reasonably assured. The lease agreements generally do not contain any material residual value guarantees or material restrictive covenants.

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 observable inputs and significant 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, restricted cash, marketable securities, prepaid expenses and other current assets, non-marketable equity securities, accounts payable and accrued expenses and long-term debt. Cash, restricted cash, and marketable securities and non-marketable securities are reported at their respective fair values on the Company's balance sheets. The remaining financial instruments are reported on the Company's balance sheets at cost, which approximate 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 are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

The Company's non-marketable equity securities (see Note 6) are measured at fair value using an option pricing valuation methodology. The option pricing methodology relies on risk-neutral valuation which calculates the value of an asset by discounting the expected value of its future payoffs at the risk-free rate of return. The fair value of the non-marketable equity securities is derived from quoted prices for similar instruments and observable inputs in active markets. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

There were no transfers between Levels 1, 2, or 3 for any of the periods presented. As of December 31, 2022, and December 31, 2021, the Company held $42.5 million and $73.8 million, respectively, in money market funds.

Restructuring Costs

Restructuring costs primarily consist of contract termination costs related to leases and employee termination costs. The Company recognizes restructuring charges when the liability has been incurred. Key assumptions in determining the restructuring costs include the terms and payments that may be negotiated to terminate certain contractual obligations, cease use date of leased property and equipment, and the timing of employees leaving the Company.

Accretion expenses related to restructuring costs are included in general and administrative expenses.

Comprehensive Loss

Comprehensive loss consists of two components: net loss and other comprehensive loss. Other comprehensive loss refers to unrealized gains and losses that are recorded as an element of stockholder's equity and are excluded from net loss. For the twelve months ended December 31, 2022, other comprehensive loss 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 and termination expenses 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.

Research Contract Costs and Accruals

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. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially 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 judgements 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) for "plain vanilla" stock option awards, 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.

Prior to the IPO, the fair value of the shares of common stock underlying the stock options was determined by the board of directors with the assistance of management and input from an independent third-party valuation firm, as there was no public market for the common stock. The board of directors determined the fair value of the Company's common stock by considering a number of objective and subjective factors, including the valuation of comparable companies, sales of redeemable convertible preferred stock, the Company's operating and financial performance, the lack of liquidity of common stock, and general and industry specific economic outlook, amongst other factors. Subsequent to the IPO, the Company determines the fair value using the market closing price of its Class A common stock 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

Net loss per share of common stock is computed using the two-class method required for multiple classes of common stock and participating securities based upon their respective rights to receive dividends as if all income for the period has been distributed. The rights, including the liquidation and dividend rights and sharing of losses, of the Class A and Class B common stock are identical, other than voting rights. As the liquidation and dividend rights and sharing of losses are identical, the undistributed earnings are allocated on a proportionate basis and the resulting net loss per share attributed to common stockholders is therefore the same for Class A and Class B common stock on an individual or combined basis.

Prior to the IPO, the Company's participating securities included the Company's redeemable convertible preferred stock, as the holders were entitled to receive noncumulative dividends on a pari passu basis in the event that a dividend is paid on common stock. The Company also considers any shares issued on the early exercise of stock options subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of redeemable convertible preferred stock, as well as the holders of early exercised shares subject to repurchase, did not and do not have a contractual obligation to share in losses of the Company, and therefore during periods of loss there is no allocation required under the two-class method.

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 2019, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) No. 2019-12, Income Taxes *(Topic 740)*, *Simplifying the Accounting for Income Taxes*, related to simplifying the accounting for income taxes. The guidance eliminates certain exceptions from Accounting Standards Codification (ASC) 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The guidance also clarifies and simplifies other aspects of the accounting for income taxes. The guidance became effective for the Company beginning on the first quarter of 2021 on a prospective basis. The Company adopted this standard on January 1, 2021, and it did not have a material impact on the Company's financial statements or related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, subsequently amended by ASU 2018-10, ASU 2018-11, ASU 2018-20, ASU 2019-01 and ASU 2019-10, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both lessors and lessees of a contract. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification on the balance sheets. Leases with a term of 12 months or less may be accounted for similar to historical guidance for operating leases. The Company adopted this standard on January 1, 2022, using the optional transition method, which allows for the prospective application of the standard. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the standard, which allowed the Company to carry forward historical lease classification, to not reassess prior conclusions related to initial direct costs, and to not reassess whether any expired or existing contracts are or contain leases. The Company also elected the practical expedient to not separate lease and non-lease components for all leases. In connection with the adoption of the new guidance, the Company recognized $6.8 million of operating lease right-of-use assets and $8.5 million of operating lease liabilities and derecognized $1.6 million of restructuring lease liability, with immaterial effect to the statements of operations and comprehensive loss and cash flows.

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848)*: Facilitation of the Effects of Reference Rate Reform on Financial Reporting. In response to concerns about structural risks of the cessation of London Interbank Offered Rate (LIBOR), the amendments in this ASU provide optional guidance for a limited time to ease the potential burden in accounting for (or recognizing the effect of) reference rate reform on financial reporting. The amendments in this ASU provide optional expedients and exceptions for applying GAAP to contracts, hedging relationships and other transactions affected by reference rate reform if certain criteria are met. The expedients and exceptions provided by this amendment do not apply to contract modifications made and hedge relationships entered into or evaluated after December 31, 2022. The amendments in this ASU are elective and are effective for all entities as of March 12, 2020 through December 31, 2022. The Company amended its Loan Agreement with Oxford in November 2022, which among other things, changed the interest rate index that the Company uses to accrue interest on outstanding borrowings from LIBOR to the Secured Overnight Financing Rate ("SOFR") as published by the Chicago Merchantile Exchange ("CME") Term SOFR Administrator. The Company no longer has any contracts that reference LIBOR as of December 31, 2022. The Company adjusted the effective interest rate on outstanding borrowings on a prospective basis, which did not have a material impact on the financial statements for the fiscal year ending December 31, 2022.

Recently Issued Accounting Pronouncements

In June 2022, the FASB issued ASU2022-03, *Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*. The standard clarifies the guidance in Topic 210, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security and introduces new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value in accordance with Topic 820. The guidance is effective for the Company beginning December 15, 2023, with early adoption permitted. The Company is currently evaluating the impact the standard may have on its financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The objective of the standard is to provide information about expected credit losses on financial instruments at each reporting date and to change how other-than temporary impairments on investment securities are recorded. The guidance became

effective for the Company beginning on January 1, 2023. The Company does not anticipate the implementation will have a material impact on its financial statements upon adoption.

3. OTHER FINANCIAL STATEMENT INFORMATION

Prepaid Expense and Other Current Assets

Prepaid expenses and other current assets consist of the following *(in thousands)*.

	December 31, 2022	December 31, 2021
Prepaid clinical trial and drug manufacturing costs	$ 8,487	$ 320
Prepaid insurance	998	1,193
Prepaid equity financing costs	490	275
Prepaid rent	247	219
Prepaid audit fees	—	123
Prepaid recruiting fees	—	253
Other	823	480
Total prepaid expenses and other current assets	$ 11,045	$ 2,863

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following *(in thousands)*.

	December 31, 2022	December 31, 2021
Accrued clinical and drug manufacturing expenses	$ 4,334	$ 364
Accrued payroll	3,217	1,458
Related party payable	2,780	1,022
Accrued legal fees	338	457
Accrued expenses and other	295	627
Accrued development milestone	—	2,000
Total accrued expenses and other current liabilities	$ 10,964	$ 5,928

Related party payable represents amounts due to Ares Trading S.A. (Ares), an affiliate of Merck KGaA, Darmstadt, Germany, related to manufacturing technology and know-how transfer services performed for atacicept pursuant to the license agreement between the Company and Ares (see Note 12).

4. NEUBASE ASSET SALE

On January 27, 2021, the Company entered into an asset purchase agreement with NeuBase Therapeutics, Inc. (NeuBase), whereby the Company agreed to sell all assets relating to its investment in PNA Innovations, Inc. (PNAi), including all inventory, machinery, intellectual property, goodwill, and licenses, and NeuBase agreed to assume certain related liabilities. The sale closed on April 26, 2021. A gain of $2.7 million was recognized on the sale to NeuBase. The Company received $0.8 million in cash and 308,635 shares of NeuBase common stock, with a fair market value of $1.8 million based on the closing price reported on the Nasdaq Capital Market on the date the sale closed. Of the total NeuBase shares issued to the Company, 162,260 shares were placed in escrow to secure certain obligations under the asset purchase agreement; of which, 54,070 shares were released from escrow in March 2022.

5. MARKETABLE SECURITIES

Marketable securities are debt securities measured at fair value on a recurring basis and accounted for as available-for-sale. These securities are classified within Level 2 in the fair value hierarchy because the Company uses quoted market prices to the extent available

or alternative pricing sources to determine fair value. The Company's marketable securities have maturities of less than one year as of the balance sheet date.

Unrealized gains and losses are reported as a component of other comprehensive loss. Fair value of the debt securities totaled $71.2 million as of December 31, 2022. The Company did not hold marketable debt securities as of December 31, 2021.

The following table summarizes the unrealized gains and losses in the Company's investments in marketable securities *(in thousands)*:

	As of December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Level 2:				
US Government bonds	$ 71,418	$ 1	$ (225)	$ 71,194
Total marketable securities	$ 71,418	$ 1	$ (225)	$ 71,194

6. NON-MARKETABLE EQUITY SECURITIES

The Company has an investment in NeuBase common stock with restrictions on the sale or transfer of the shares. Fair value is determined using alternative pricing sources and models utilizing market observable inputs. The Company reports the restricted equity securities as non-marketable equity securities on the balance sheet, and determines current or non-current classification based on the expected duration of the restriction.

The Company recorded a net unrealized loss of $0.8 million in other expense for the year ended December 31, 2022. The carrying value is measured as the total initial cost, less the cumulative net unrealized loss. The carrying value of the non-marketable equity securities as of December 31, 2022, is summarized below *(in thousands)*.

Balance as of December 31, 2021	$ 867
Change in fair value	(809)
Balance as of December 31, 2022	$ 58

7. LEASES

Net lease cost recognized for 2022 is summarized as follows *(in thousands)*:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Operating lease cost	$ 2,378	$ 24
Sublease income	(1,928)	—
Net lease cost	$ 450	$ 24

As of December 31, 2022, the maturities of the lease liabilities based on minimum lease commitment amount are as follows *(in thousands)*:

As of December 31:	**(in thousands)**
2023	2,999
2024	3,022
2025	1,880
2026	-
2027	-
Total minimum lease payments	7,901
Less: Imputed interest	(1,425)
Present value of operating lease liabilities	6,476
Less: Current portion of operating lease liabilities	(2,645)
Non-current operating lease liabilities	$ 3,831

In November 2020, the Company entered into a non-cancellable sublease agreement for the leased facilities in South San Francisco, California, which ends concurrently with the original lease in September 2025.
As of December 31, 2022, under the terms of the sublease agreement, the Company is entitled to receive future annual sublease payments as follows (in thousands):

2023	$ 1,910
2024	1,954
2025	1,496
Total sublease payments	$ 5,360

As tenant, the Company remains responsible for minimum lease commitments of $6.7 million as of December 31, 2022, on the South San Francisco facilities.

In July 2022, the Company entered into a lease amendment to increase the amount of leased office space in its Brisbane, California, headquarters. The lease includes renewal options for the Company. As of December 31, 2022, the Company had not executed any finance leases that were yet to commence.

As of December 31, 2022, the weighted-average remaining operating lease term was 2.5 years and the weighted-average discount rate was 9.0% for operating leases recognized in the financial statements.

In accordance with ASC 840, Leases, the aggregate minimum non-cancellable annual lease payments for operating leases in effect as of December 31, 2021, were as follows *(in thousands)*:

	Operating Leases [1]	Sublease Income
2022	$ 2,669	$ 1,901
2023	2,755	1,964
2024	2,818	2,029
2025	1,954	1,569
Total minimum lease payments	$ 10,196	$ 7,463

(1) Future minimum lease payments include repayment of outstanding restructuring liabilities.

8. NOTE PAYABLE

Note payable consists of the following *($ in thousands)*:

		December 31, 2022		December 31, 2021	
	Maturity	Effective Interest Rate	Amount	Effective Interest Rate	Amount
Collateralized note 2021-12	2026	13.57%	$ 5,000	9.53%	$ 5,000
Collateralized note 2022-11	2026	13.74%	20,000		—
Total borrowings			25,000		5,000
Less: Debt issuance costs			(190)		(77)
Net carrying amount of debt			$ 24,810		$ 4,923

The carrying amount of debt approximates fair value due to its variable interest rate.

In December 2021, the Company entered into a non-revolving loan and security agreement (the "Loan Facility") with borrowing capacity of up to $50.0 million, which was scheduled to expire in December 2022. In November 2022, the Company entered into an amendment of the Loan Facility. Among other changes, the amendment extended the scheduled expiration of the Loan Facility to December 2023 and modified the reference rate from the London Interbank Offered Rate ("LIBOR") to the Secured Overnight Financial Rate ("SOFR"). In conjunction with the amendment, the Company borrowed an additional $20.0 million from the Loan Facility with $25.0 million remaining capacity available in minimum draws of $5.0 million.

As of December 31, 2022, the Company's outstanding borrowing under the Loan Facility was $25.0 million. The variable interest rate on the drawn amount is adjusted SOFR plus 825 basis points, subject to a per annum floor rate of 8.25%. The loan matures in December 2026, which may be extended by 12 months subject to certain clinical data milestones. The Loan Facility provides for interest-only payments to December 2025, which may be extended by 12 months to 2026 if the final maturity date is extended. The Company is permitted to prepay the loan, subject to certain conditions. Upon the maturity date or prepayment of the loan, the Company is required to make a final payment equal to 5.0% (or 7.0% if the maturity date is extended) of the aggregate principal amount of the loan. The Loan Facility contains a subjective acceleration clause in the case of an event of default. If such a matter occurs and is continuing, the lender may legally demand the outstanding principal and interest immediately due and payable. There are no financial covenants associated with the Loan Facility and the loan is secured by the Company's assets. The Loan Facility is available for working capital, capital expenditures, and other general corporate purposes.

Principal installments due on the note subsequent to December 31, 2022, are as follows *(in thousands)*:

2023	—
2024	—
2025	—
2026	25,000
Total accrued expenses and other current liabilities	$ 25,000

9. COMMON STOCK

As of December 31, 2022, the Company's amended and restated certificate of incorporation authorized the Company to issue 500,000,000 shares of Class A common stock and 14,600,000 shares of Class B common 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. Class B common stock is non-voting. The holders of Class A common stock, voting exclusively and as a separate class, have the exclusive right to vote for the election of one director of the Company. Class A common stockholders and holders of Class B common stock are entitled to receive dividends, as may be declared by the board of directors. Through December 31, 2022, no cash dividends have been declared or paid.

In May 2022, 210,000 shares of Class B common stock were converted into 210,000 shares of Class A common stock. In September 2022, the remaining 99,238 shares of Class B common stock were converted into 99,238 shares of Class A common stock. The shares of Class B common stock that were converted into shares of Class A common stock have been retired and cancelled, and therefore will not be available for reissuance. As of December 31, 2022, the Company had no shares of Class B common stock outstanding.

In June 2022, the Company filed a shelf registration statement on Form S-3 (File No. 333-265408) with the Securities and Exchange Commission, which permits the offering, issuance, and sale of up to a maximum aggregate offering price of $400.0 million of the Company's common stock, preferred stock, debt securities and warrants. (See Note 18). Up to a maximum of $150.0 million of the maximum aggregate offering price of $400.0 million may be issued and sold pursuant to an at-the-market financing facility under a sales agreement dated June 3, 2022, between the Company and Cowen and Company, LLC (Sales Agreement). As of December 31, 2022, all $150.0 million remains available for issuance and sale under the Sales Agreement.

In September 2022, the Company issued 283,034 shares of Class A common stock, registered pursuant to a shelf registration statement, to Novartis Pharma AG pursuant to an amendment to a license agreement between the two parties.

10. STOCK COMPENSATION

In April 2021, the Company adopted the 2021 Employee Stock Purchase Plan (ESPP) and the 2021 Equity Incentive Plan (2021 EIP), each of which became effective in connection with the IPO. The Company has reserved 429,934 and 3,260,753 shares of Class A common stock for issuance under the ESPP and 2021 EIP, respectively.

The Company may not grant any additional awards under the 2017 Equity Incentive Plan (2017 EIP). The 2017 EIP will continue to govern outstanding equity awards granted thereunder. As of December 31, 2022, there were 945,108 shares available for issuance under the 2021 EIP.

2017 EIP and 2021 EIP

Stock option activity under the 2017 EIP and 2021 EIP was 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, 2021	2,924,521	$ 5.62	9.11	$ 61,712
Granted	1,319,802	18.98		
Exercised	(405,140)	4.42		
Cancelled and forfeited	(17,396)	17.52		
Outstanding as of December 31, 2022	3,821,787	10.30	8.51	35,872
Options exercisable as of December 31, 2022	1,150,982	7.07	8.17	14,363
Vested and expected to vest as of December 31, 2022	3,821,787	10.30	8.51	35,872

The aggregate intrinsic value of stock options exercised during the year ended December 31, 2022 was $5.8 million. The weighted-average grant date fair value of options granted during the year ended twelve months ended December 31, 2022 and 2021, was $13.63 per share and $9.36 per share, respectively.

ESPP

The ESPP enables eligible employees to purchase shares of the Company's Class A common stock at the end of each offering period at a price equal to 85% of the fair market value of the shares on the first trading day or the last trading day of the offering period, whichever is lower. Eligible employees generally include all employees. Share purchases are funded through payroll deductions of at least 1% and up to 15% of an employee's eligible compensation for each payroll period. The number of shares reserved for issuance under the ESPP increase automatically on the first day of each fiscal year, beginning on January 1, 2022, by a number equal to the lesser of 440,502 shares, 1% of the total number of shares of the Company's capital stock (including all classes of the Company's common stock) outstanding on the last day of the calendar month prior to the date of the increase, or such lower number of shares (including no shares) approved by the Company's board of directors. As of December 31, 2022, 15,328 shares have been issued pursuant to the ESPP. The ESPP generally provides for six-month consecutive offering periods beginning on September 14, 2021. The ESPP is a compensatory plan as defined by the authoritative guidance for stock compensation. As such, stock-based compensation expense has been recorded for the twelve months ended December 31, 2022.

Stock-Based Compensation Expense

The following tables summarize the stock-based compensation expense for stock options, restricted stock awards, 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 twelve months ended December 31, 2022 and 2021 *(in thousands)*.

	Year Ended December 31,	
	2022	2021
Research and development	$ 4,592	$ 915
General and administrative	4,295	2,097
Total stock-based compensation expense	$ 8,887	$ 3,012

	Year Ended December 31,	
	2022	2021
Employees	$ 5,975	$ 2,605
Nonemployees	2,912	407
Total stock-based compensation expense	$ 8,887	$ 3,012

As of December 31, 2022, the Company had $20.3 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.

The fair value of stock options granted during the year ended December 31, 2022 and 2021 was estimated using the Black-Scholes option pricing model based on the following weighted average assumptions.

	Year Ended December 31,	
	2022	2021
Expected term (in years)	5.5 – 6.1	5.5 – 6.1
Expected volatility	75.8% – 77.6%	75.4% – 76.8%
Risk-free rate	1.76% – 4.2%	0.6% – 1.3%
Dividend yield	—	—

Restricted Stock Units

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, 2022.

	NUMBER OF SHARES	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE PER SHARE
Unvested balance at December 31, 2021	77,719	$ 23.99
Granted	215,750	18.38
Vested	(77,719)	23.99
Cancelled and forfeited	(11,750)	18.60
Unvested balance at December 31, 2022	204,000	18.37

For the twelve months ended December 31, 2022, the Company recognized $2.3 million of stock-based compensation for RSUs.

As of December 31, 2022, the Company had $3.3 million of unrecognized stock-based compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 1.77 years.

Restricted Stock Awards

In October 2020, in conjunction with the Company's issuance of Series C redeemable convertible preferred stock (which subsequently converted into Class A and Class B common stock), the Company restricted 49,636 shares of fully issued and outstanding Class A common stock held by the Company's Chief Executive Officer and founder. The restriction allowed the Company to repurchase shares that had not vested. The vesting term of restricted stock was one year. These restricted stock awards fully vested in October 2021. The grant date fair value of the restricted stock was $6.37 per share.

No stock-based compensation expense related to restricted stock awards was recognized in 2022.

11. EMPLOYEE BENEFIT PLANS

The Company sponsors a qualified 401(k) defined contribution plan covering eligible employees. Participants may contribute a portion of their annual compensation limited to a maximum annual amount set by the Internal Revenue Service. The Company contributed $95,000 to the plan for the twelve months ended December 31, 2022. There were no employer contributions under this plan during 2021.

12. LICENSES AND COLLABORATIONS

Ares Trading S.A.

In October 2020, the Company entered into a license agreement with Ares (the Ares Agreement), 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 issued to Ares a non-refundable license issue fee of 22,171,553 shares of Series C redeemable convertible preferred stock resulting in Ares becoming a related party to the Company. The Series C redeemable convertible preferred stock had a deemed issuance price of $0.5918 per share, or $13.1 million in the aggregate.

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 Company is obligated to pay Ares aggregate milestone payments of up to $176.5 million upon the achievement of specified BLA filing or regulatory approval milestones and up to $515.0 million upon the achievement of specified commercial milestones.

The non-refundable license issue fee and milestone payment were recorded to research and development expense in the period incurred.

Subsequent to the effective date of the Ares Agreement, Ares is performing manufacturing technology and know-how transfer to the Company. The Company recorded related party expense of $4.5 million and $1.7 million to Ares for these services during the twelve months ended December 31, 2022, and December 31, 2021, 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 is 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 (the 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-BKV monoclonal antibody referred to as MAU868 for the treatment of 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 transaction was treated as an asset acquisition, as the assets acquired did not meet the definition of a business. ASC 805-10-55 states that if substantially all the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the set is not considered a business. Since the gross assets acquired are concentrated on a single identifiable asset, MAU868, the transaction was accounted for as an asset acquisition. In accordance with accounting guidance, costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future use. The assets purchased from Amplyx require substantial completion of research and development, regulatory and marketing approval efforts in order to reach technological feasibility. Accordingly, 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 (the 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, and as a result of the amendment the Company recognized $3.7 million of research and development expense in the twelve months ended December 31, 2022.

As of December 31, 2022, the Company is obligated to make future milestone payments of up to $7.0 million and $62.0 million to Amplyx and Novartis, respectively, 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.

13. INCOME TAXES

For financial reporting purposes, income (loss) before provision for income taxes, includes the following components *(in thousands)*:

	December 31,	
	2022	2021
Domestic	$ (89,055)	$ (32,608)
Foreign	—	—
Loss before income taxes	$ (89,055)	$ (32,608)

Provision for Income Taxes

The provision for income taxes consisted of the following *(in thousands)*.

	December 31,	
	2022	2021
Current:		
Federal	$ —	$ —
State	1	1
Total current	1	1
Total deferred	—	—
Provision for income taxes	$ 1	$ 1

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)*.

	December 31,	
	2022	2021
Tax on U.S. statutory rate on income before income taxes	$ (18,702)	$ (6,847)
State taxes	3,583	(5,405)
State valuation allowance	(3,582)	5,405
Federal valuation allowance	19,643	6,600
Tax credits	(710)	(209)
Other	(231)	457
Provision for income taxes	$ 1	$ 1

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,	
	2022	2021
Deferred tax assets:		
Federal and state NOL carryforward	$ 21,945	$ 17,469
Research and other credits	3,762	2,671
Capitalized R&D	12,731	—
Fixed assets	2	15
Reserves and accruals	519	947
Stock based compensation	1,430	535
Other intangibles	8,583	12,589
Other DTA	402	266
Lease liability	1,360	—
Total gross DTA	50,734	34,492
Less: valuation allowance	(49,648)	(34,492)
Total deferred tax assets	1,086	—
Deferred tax liabilities:		
Right of use	(1,086)	—
Total gross DTL	(1,086)	—
Net deferred tax assets	$ —	$ —

As of December 31, 2022, the Company has federal and state net operating loss carryforwards of $92.3 million and $35.7 million, respectively, of which $0.1 million of federal net operating loss carryforwards and $0.3 million of state net operating carryforwards will begin expiring in the year 2032 and 2036, respectively, if not utilized. The Company also has $82.1 million of federal net operating loss carryforwards as of December 31, 2022 that does not expire as a result of recent tax law changes. The Company has $3.3 million of federal research and development tax credit carryforwards, which begin to expire in the year 2037. The Company has $1.4 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 $49.6 million and $34.5 million for the year ended December 31, 2022 and 2021 has been established to offset the deferred tax assets as realization of such assets is uncertain.

Uncertain Tax Benefits

The Company has the following activity relating to the gross amount of unrecognized tax benefits *(in thousands)*:

	Year Ended December 31,	
	2022	2021
Beginning balance	$ 668	$ 663
Additions based on tax positions related to prior year	19	—
Decreases based on tax positions related to prior year	(11)	(97)
Additions based on tax positions related to current year	265	102
Ending balance	$ 941	$ 668

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 had no interest or penalty accruals associated with uncertain tax benefits in its balance sheet and statement of operations for the years ended December 31, 2022 and 2021. The Company files income tax returns in the U.S. and California. 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.

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. As of December 31, 2022 and 2021, the Company had no material unrecognized tax benefits. No significant interest or penalties were recorded during the years ended December 31, 2022 and 2021.We are currently unaware of any uncertain tax positions that could result in significant additional payments, accruals, or other material deviation in this estimate over the next 12 months.

14. COMMITMENTS AND CONTINGENCIES

Facilities Leases

In November 2020, the Company entered into a non-cancellable sublease agreement for the facilities in South San Francisco, California, under the terms of which the Company is entitled to receive $7.9 million in sublease payments over the term of the sublease, which ends concurrently with the original lease in September 2025. As tenant, the Company remains responsible for the minimum lease commitment on the facilities.

In November 2021, the Company entered a lease for approximately 4,900 square feet of office space for a term of 36 months in Brisbane, California. The base rent is approximately $0.3 million for the first year with scheduled annual 3% increases. The lease includes renewal options for the Company.

In July 2022, the Company entered into an amendment to this lease to add approximately 5,000 square feet of office space in Brisbane, California, adjacent to its current offices. The term of the lease is 27 months beginning September 2022, and the base rent is approximately $0.3 million for the first 12 months with scheduled annual 3% increases. The lease includes renewal options for the Company.

15. RESTRUCTURING AND RELATED ACTIVITIES

In July 2020, the Company initiated a restructuring plan to reduce operating expense as a result of the disposal of PNAi technology. The restructuring plan included reducing the number of employees, vacating leased facilities, and ceasing use of leased equipment. As a result of this restructuring plan, the Company completely vacated its leased facilities in South San Francisco, California, which was subleased to a third party in November 2020, and returned certain leased equipment to the lessor. The Company recorded a discounted lease-related restructuring liability of $2.2 million and $0.8 million for the abandonment of the leased facilities and equipment, which was calculated as the present value of the estimated future lease costs for which the Company would obtain no future economic benefit over the term of the leases. In addition, the Company recognized restructuring liability of $0.3 million related to severance and other employee termination costs related to the reduction in the number of employees.

The lease related restructuring liability of $1.6 million as of December 31, 2021, was derecognized upon the adoption of ASC 842 on January 1, 2022, and included in operating lease liabilities.

16. 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,	
	2022	2021
Class A common stock options issued and outstanding	3,821,787	2,924,521
Unvested restricted stock units	204,000	—
Total	4,025,787	2,924,521

17. RELATED PARTY TRANSACTIONS

In October 2020, the Company entered into the Ares Agreement with 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. Related party transactions and balances in the current periods presented are described in Note 3 and Note 12.

18. SUBSEQUENT EVENTS

On February 6, 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 an offering price of $7.00 per share, including the exercise in full by the underwriters of their option to purchase an additional 2,142,857 shares of Class A common stock. The Company received total net proceeds of approximately $107.6 million, after deducting underwriting discounts and commissions of $6.9 million, and offering costs of approximately $0.5 million, of which $0.2 million was incurred as of December 31, 2022.

In March 2023, upon achievement of a clinical data milestone, the Company elected to extend the Loan Facility maturity by 12 months, from December 2026 to December 2027. The interest-only payment period was also extended by 12 months to December 2026. With this election, the maturity date of the loan was also extended from December 2026 to December 2027 and the final payment increased from 5% to 7% of the aggregate principal balance of the loan, to be paid upon the maturity date or prepayment of the loan.

The Company has a banking relationship with Silicon Valley Bank (“SVB”). On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. On March 12, 2023, the Federal Reserve Board approved actions enabling the FDIC to complete its resolution of SVB in a manner that fully protects all depositors. Based on the foregoing and the Company’s analysis of the components of its relationship with SVB, the Company does not expect these events to have a material impact on the Company’s financial statements.

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, 2022, 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). We maintain internal control over financial reporting 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.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, in designing and evaluating the disclosure controls and procedures, management recognizes that any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Moreover, 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. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

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 based on the criteria set forth in "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this assessment, our management concluded that our internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2022.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies" and because we qualify as a "non-accelerated filer" (i.e., we do not qualify as either an "accelerated filer" or a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act).

Changes in Internal Control over Financial Reporting

There has been no change 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, 2022, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained under the captions "Proposal 1 – Election of Directors," "Information Regarding the Board of Directors and Corporate Governance," "Executive Officers," and "Delinquent Section 16(a) Reports," if any, in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with our 2023 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, 2022 and is incorporated herein by reference.

Code of Business Conduct and Ethics

We maintain a Code of Conduct that applies to all our employees, officers and directors. 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 www.veratx.com. 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 set forth under the caption "Executive Compensation" 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 set forth under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" 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 set forth under the captions "Transactions With Related Persons and Indemnification" and "Information Regarding the Board of Directors and Corporate Governance" 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 set forth under the caption "Proposal 2 – Ratification of Selection of Independent Registered Public Accounting Firm" in our Definitive Proxy Statement and is incorporated here 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 III, 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
1.1	Sales Agreement, by and between the Registrant and Cowen and Company, LLC, dated June 3, 2022 (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3, filed with the SEC on June 3, 2022).
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
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. 2021 Non-employee Director Compensation Policy, as amended on March 28, 2023.
10.8†	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, file with the SEC on May 10, 2021).
10.9†¥	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).
10.10†¥	Amended and Restated Offer Letter by and between the Registrant and Joanne Curley, Ph.D., dated May 7, 2021 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021).
10.11†¥	Amended and Restated Offer Letter by and between the Registrant and Celia Lin, M.D., dated May 7, 2021 (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021).
10.12†¥	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).
10.13^	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).
10.14¥	Loan and Security Agreement between the Registrant and Oxford Finance LLC, dated December 17, 2021 (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1, filed with the SEC on February 7, 2022).
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¥	First Amendment to Loan and Security Agreement, by and between the Registrant and Oxford Finance, LLC, dated November 4, 2022 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 9, 2022).
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included on signature page).
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.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File – 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: March 28, 2023

By: /s/ Marshall Fordyce
Marshall Fordyce, M.D.
Chief Executive Officer and President
(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)	March 28, 2023
/s/ Sean Grant **Sean Grant**	Chief Financial Officer (Principal Financial Officer)	March 28, 2023
/s/ Joseph Young **Joseph Young**	Senior Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer)	March 28, 2023
/s/ Michael Morrissey **Michael Morrissey, Ph.D.**	Chairman of the Board	March 28, 2023
/s/ Andrew Cheng **Andrew Cheng, M.D., Ph.D.**	Director	March 28, 2023
/s/ Patrick Enright **Patrick Enright**	Director	March 28, 2023
/s/ Kimball Hall **Kimball Hall**	Director	March 28, 2023
/s/ Maha Katabi **Maha Katabi, Ph.D.**	Director	March 28, 2023
/s/ Scott Morrison **Scott Morrison**	Director	March 28, 2023
/s/ Beth Seidenberg **Beth Seidenberg, M.D.**	Director	March 28, 2023

Exhibit 4.3

DESCRIPTION OF COMMON STOCK

General

The following description summarizes the terms of the Class A common stock and Class B common stock of Vera Therapeutics, Inc., or we, our or us. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of the matters set forth in this "Description of Common Stock," you should refer to our amended and restated certificate of incorporation and amended and restated bylaws, which are included as exhibits to our Annual Report on Form 10-K, and to the applicable provisions of the Delaware General Corporation Law. Our amended and restated certificate of incorporation authorizes us to issue 500,000,000 shares of Class A common stock, par value $0.001 per share, 14,600,000 shares of Class B common stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share. Our board of directors is authorized, without stockholder approval except as required by the listing standards of The Nasdaq Stock Market LLC, to issue additional shares of our capital stock. In addition, under our amended and restated certificate of incorporation, our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding and not by more than the number of remaining authorized but designated shares of preferred stock. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the Class A common stock and Class B common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our Class A common stock and Class B common stock and may adversely affect the market price of our Class A common stock and the voting and other rights of the holders of our Class A common stock and Class B common stock.

Voting Rights and Conversion Rights

The holders of our Class A common stock are entitled to one vote per share of Class A common stock on any matter that is submitted to a vote of our stockholders and holders of our Class B common stock are not entitled to any votes per share of Class B common stock, including for the election of directors. Additionally, holders of our Class A common stock have no conversion rights, while holders of our Class B common stock shall have the right to convert each share of our Class B common stock into one share of Class A common stock at such holder's election, provided that as a result of such conversion, such holder would not beneficially own in excess of 9.9% of any class of our securities registered under the Securities Exchange Act of 1934, as amended (Exchange Act), unless otherwise as expressly provided for in our amended and restated certificate of incorporation. However, this ownership limitation may be increased to any other percentage designated by such holder of Class B common stock upon 61 days' notice to us or decreased at any time. Holders of our Class B common stock are also permitted to make certain transfers of Class B common stock to non-affiliates upon which, such transferred shares could be immediately converted into shares of our Class A common stock.

Our amended and restated certificate of incorporation does not provide for cumulative voting for the election of directors for our Class A common stock. Our amended and restated certificate of incorporation establishes a classified board of directors that is divided into three classes with staggered three-year terms. Only the directors in one class are subject to election by a plurality of the votes cast at each annual meeting of our stockholders holding shares of Class A common stock, with the directors in the other classes continuing for the remainder of their respective three-year terms. The affirmative vote of holders of at least 662⁄3% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, is required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified structure of our board of directors, the size of our board of directors, removal of directors, director liability, vacancies on our board of directors, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

Economic Rights

Except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law, and other than the voting rights and conversion rights stated above, all shares of Class A common

stock and Class B common stock have the same rights and privileges and rank equally, share ratably, and are identical in all respects for all matters, including those described below.

Dividends. Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our Class A common stock and Class B common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine.

Liquidation Rights. On our liquidation, dissolution, or winding-up, the holders of our Class A common stock and Class B common stock will be entitled to share equally, identically and ratably in all assets remaining after the payment of any liabilities, liquidation preferences and accrued or declared but unpaid dividends, if any, with respect to any outstanding preferred stock, unless a different treatment is approved by the affirmative vote of the holders of a majority of the outstanding shares of such affected class, voting separately as a class.

No Preemptive or Similar Rights

The holders of shares of our Class A common stock and Class B common stock are not entitled to preemptive rights, and are not subject to redemption or sinking fund provisions.

Anti-Takeover Provisions

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws, which are summarized below, may have the effect of delaying, deferring or discouraging another person from acquiring control of our company. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Certificate of Incorporation and Bylaws

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of Class A common stock are able to elect all of our directors. Our amended and restated certificate of incorporation and our amended and restated bylaws provide that stockholders may only take action at a duly called meeting of stockholders. A special meeting of stockholders may be called by a majority of our board of directors, the chair of our board of directors, or our chief executive officer or president. Our amended and restated bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors.

In accordance with our amended and restated certificate of incorporation, our board of directors is divided into three classes with staggered three-year terms.

The foregoing provisions will make it more difficult for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law (DGCL), which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, subject to certain exceptions.

Choice of Forum

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: (i) any derivative claim or cause of action brought on our behalf; (ii) 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; (iii) 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 amended and restated bylaws (as each may be amended from time to time); (iv) 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); (v) any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) 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 of 1933, as amended (Securities Act), the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America are 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 the offering. Additionally, our amended and restated certificate of incorporation provides that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

Exchange Listing

Our Class A common stock is listed on The Nasdaq Global Market under the symbol "VERA." We do not intend to list the Class B common stock on any securities exchange.

Transfer Agent and Registrar

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

EXHIBIT 10.7

VERA THERAPEUTICS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY
AMENDED AND RESTATED MARCH 28, 2023

Each member of the Board of Directors (the "***Board***") of Vera Therapeutics, Inc. (the "***Company***") who is not also serving as an employee of the Company or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy (this "***Policy***"). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be. This Policy shall be effective as of the date set forth above (the "***Effective Date***").

Annual Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, his or her first quarterly installment will be pro-rated based on days served in the applicable quarter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
   a. All Eligible Directors: $40,000
   b. Non-executive chairperson of the Board: $70,000 (inclusive of Annual Board Service Retainer)

2. Annual Committee Member (non-Chair) Service Retainer:
   a. Member of the Audit Committee: $7,500
   b. Member of the Compensation Committee: $5,000
   c. Member of the Nominating and Corporate Governance Committee: $4,000

3. Annual Committee Chair Service Retainer (inclusive of Committee Member Service Retainer):
   a. Chairperson of the Audit Committee: $15,000
   b. Chairperson of the Compensation Committee: $10,000
   c. Chairperson of the Nominating and Corporate Governance Committee: $8,000

The Company will also reimburse each of the Eligible Directors for his or her travel expenses incurred in connection with his or her attendance at Board and committee meetings. Such reimbursements shall be paid on the same date as the annual cash fees are paid.

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2021 Equity Incentive Plan, as the same may be amended or restated from time to time (the "***Plan***"). Capitalized terms used below not otherwise defined in this Policy shall have the meanings given to them in the Plan All stock options granted under this Policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock on the date of grant, a

term of 10 years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan), and subject to all the terms, conditions and limits set forth in the Plan and the applicable award agreement. For the avoidance of doubt, the share numbers in this Policy shall be subject to adjustment as provided in the Plan.

1. Initial Grant: For each Eligible Director who is first elected or appointed to the Board following the Effective Date, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase 40,000 shares (as adjusted for stock splits, combinations and the like) of the Company's common stock. The shares subject to each such stock option will vest monthly over a three-year period, subject to the Eligible Director's Continuous Service on each vesting date, and will vest in full upon a Change in Control, subject to the Eligible Director's Continuous Service through such date.

2. Annual Grant: On the date of each annual stockholders meeting of the Company, each Eligible Director who continues to serve as a member of the Board through and following such stockholders meeting (and who joined the Board no later than February 28 of the year in which the stockholders meeting is held) will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase 20,000 shares (as adjusted for stock splits, combinations and the like) of the Company's common stock (the "***Annual Grant***"). The shares subject to each such stock option will vest on the earlier of (a) the first anniversary of the date of grant and (b) the date of the Company's next annual stockholders meeting, subject to the Eligible Director's Continuous Service through such date. Such option will vest in full upon a Change in Control, subject to the Eligible Director's Continuous Service through such date.

Compensation Limits

Notwithstanding anything to the contrary in this Policy, all compensation payable under this Policy will be subject to any limits on the maximum amount of Eligible Director compensation set forth in the Plan, as in effect from time to time.

Approved by the Board of Directors: May 7, 2021
Most Recently Amended by the Compensation Committee of the Board: March 28, 2023

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (No. 333-265408) on Form S-3 and (Nos. 333-263899 and 333-256269) on Form S-8 of our report dated March 28, 2023, with respect to the financial statements of Vera Therapeutics, Inc.

/s/ KPMG LLP

San Francisco, California
March 28, 2023

Exhibit 31.1

CERTIFICATIONS

I, Marshall Fordyce, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vera Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability to financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2023

By: /s/ Marshall Fordyce

Marshall Fordyce, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Sean Grant, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vera Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability to financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2023

By: /s/ Sean Grant

Sean Grant
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Vera Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2023

By: **/s/ Marshall Fordyce**

Marshall Fordyce, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Vera Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2023

By: **/s/ Sean Grant**

Sean Grant
Chief Financial Officer
(Principal Financial Officer)