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DELTA REPORT

10-K

VERA THERAPEUTICS, INC.

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	4806
CHANGES	240
DELETIONS	1628
ADDITIONS	2938

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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 2023

OR

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

Commission file number 001-40407

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

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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 June 30, 2023, the last business day of the Registrant’s most recently completed second fiscal quarter, was approximately $163.2 449.2 million based on the closing price of the Registrant’s Class A common stock on the Nasdaq Global Select Market of $13.61 $16.05 per share.

As of March 23, 2023 March 20, 2024, the registrant had 44,261,109 54,452,029 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.

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DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2023 2024 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 December 31, 2023, 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

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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 potential commercial markets who suffer from the diseases we target and the number of subjects that will enroll in our clinical trials;
- the progress and focus of our current and future clinical trials, and the reporting of data from those trials;
- our ability to advance product candidates into and successfully complete clinical trials;
- the ability of our clinical trials to demonstrate the safety and efficacy of our product candidates, and other positive results;
- the success of competing therapies that are or may become available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;

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- 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 c 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 qualifi 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.

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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 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 a 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 futu In addition, we may be unable to continue as a going concern over the long-term.
- The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.
- We are substantially dependent on the success of our product candidates, atacicept and MAU868, which are curre 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 participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with immunoglobulin A nephropathy (IgAN), the availability of competitive products, and signific competition for recruiting patients participants in clinical trials.
- The incidence and prevalence for target patient populations of atacicept in specific indications are based on estima 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 narrow 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 r change as more patient participant data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than us.
- Changes in methods of manufacturing or formulation of our product candidates may result in additional costs or

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- Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when use 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 signifi 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 an results of operations.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies. If we or ou 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 key consultants.
- We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- If we breach our license agreement (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, ou ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

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- 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 me 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 prospec could be significantly harmed.
- The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If 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 commor stock.
- Our principal stockholders and management own a significant percentage of our outstanding voting stock and will b 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 Delawa 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. IgA nephropathy (IgAN) is a B cell disorder with a kidney

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pathology. Our lead product candidate, atacicept, is a an at home, self-administered transmembrane activator and CAML interactor (TACI)-Fc fusion protein that blocks both B lymphocyte stimulator (BLyS) B-cell activating factor (BAFF) and a proliferation-inducing ligand (APRIL) with best-in-class potential for the treatment of IgA nephropathy (IgAN). IgAN. The Phase 2b ORIGIN clinical trial evaluating the safety and efficacy of atacicept in patients participants with IgAN completed enrollment in mid-2022 and reported positive results at three timepoints: 24-week topline results in January 2023. Atacicept 2023, 36-week results in June 2023, and 72-week results in January 2024. The trial remained blinded through 36 weeks, after which all participants were eligible for the open label extension portion of the study and received atacicept 150 mg through 96 weeks. At 24 and 36 weeks, respectively, atacicept met its primary endpoint at 24 weeks, achieved statistical significance with statistically significant reductions in the urine protein creatinine ratio (UPCR) on atacicept 150 mg, dose group, and showed a trend towards deeper stable estimated glomerular filtration rate (eGFR) was observed for participants on atacicept, with clinically meaningful and statistically significant difference versus placebo. Participants treated with atacicept demonstrated reductions in proteinuria galactose-deficient IgA1 (Gd-IgA1), the autoantigen produced by B cells in patients with available data at 36 weeks, for which full IgAN, and a reduction in hematuria. The improvements in Gd-IgA1, hematuria, UPCR and eGFR represent the quartet of findings consistent with IgAN disease modification. The 72-week open label extension results will read out showed consistent and sustained reductions in the second quarter of 2023. Gd-IgA1, hematuria, UPCR and continued eGFR stabilization. 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 advanced atacicept 150 mg in a pivotal Phase 3 clinical trial in IgAN in the second quarter of 2023. We also believe that atacicept has pipeline in a molecule potential, with potential application in additional indications including systemic lupus erythematosus (SLE) and lupus nephritis (LN), a severe renal manifestation of SLE. We have designed and are planning poised to conduct a Phase 3 clinical trial of atacicept in lupus nephritis (LN), a severe renal manifestation of systemic lupus erythematosus (SLE), LN, 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 We also hold worldwide, exclusive development and commercial rights to MAU868, a potentially first-in-class monoclonal antibody to treat reactivated BK virus (BKV) infections. MAU868 is infections, for which we completed 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 in 2022. In January 2023, we delayed enrollment in the pivotal Phase 3 trial for LN and commitment of resources to the 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. program. We believe that our current pipeline programs leverage the deep expertise of our team and have strong potential 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

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IgAN is a serious and progressive autoimmune disease of the kidney that is driven by the production of immunogenic galactose-deficient IgA1 (Gd-IgA1), Gd-IgA1, which is associated with increased risk of kidney-related morbidity and mortality. We estimate there are will be approximately 126,000 157,000 biopsy-confirmed IgAN patients in the United States, 136,000 in the European Union, Europe, and 130,000 in Japan. Japan, at estimated peak year of sales. 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 TARPEYO (budesonide, developed by Calliditas Therapeutics AB under the name Nefecon) AB), a recently approved reformulated steroid, and FILSPARI™ (developed FILSPARI (sparsentan, developed by Travere Therapeutics under the name sparsentan) Therapeutics), a recently approved dual endothelin angiotensin receptor antagonist. Neither of these agents are disease-modifying treatments in IgAN. 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. in some patients, sodium-glucose cotransporter-2 (SGLT2) inhibitors. We estimate the U.S. global market opportunity for novel, disease-modifying therapeutics in IgAN is approximately $4.0 billion $6.0 billion to $8.0 billion $10.0 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 TACI-Fc fusion protein self-administered at home as a subcutaneous injection once weekly that blocks both BLyS BAFF 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 generate clinical success by measures designed to assess efficacy in IgAN and other immunologic diseases. BLyS BAFF inhibition has been clinically and commercially validated through the approval of Benlysta (belimumab) in both SLE and LN. Preclinical and clinical evidence support that atacicept's mechanism of dual inhibition of BLyS BAFF 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 modulate B cell and plasma cell activity, with reductions in a Phase 2a clinical trial Gd-IgA1, hematuria, and proteinuria – and stabilization 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. eGFR.

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

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atacicept 25 mg and 75 mg weekly on serum Gd-IgA1, proteinuria, and key biomarkers, including serum Ig levels. As reported at the

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American Society of Nephrology (ASN) Kidney Week conference in 2022, atacicept is also the first known therapeutic candidate in IgAN to show reduction in all first three hits of disease pathogenesis—serum Gd-IgA1, anti-Gd-IgA1 autoantibody, and immune complex levels.

We are conducting a multinational, randomized, double-blind, placebo-controlled Phase 3 clinical trial in IgAN, which we refer to as ORIGIN 3, and completing the open label extension of our Phase 2b clinical trial in IgAN, which we refer to as ORIGIN. ORIGIN 2b. The ORIGIN 3 trial is evaluating atacicept 150 mg by weekly subcutaneous injection at home versus placebo through 104 weeks. The primary endpoint is reduction in UPCR in a 24-hour urine collection versus placebo at 36 weeks to support potential accelerated approval. A significant reduction in proteinuria, as measured by UPCR in a 24-hour urine collection, is associated with improved renal outcomes in patients with IgAN. UPCR is a surrogate endpoint accepted by the FDA for primary glomerular diseases associated with significant proteinuria, including IgAN. Given the FDA's recent approvals of TARPEYO and FILSPARI, we believe the use of proteinuria as a surrogate endpoint for accelerated approval has been validated. The key secondary endpoint is eGFR change up to week 104.

The ORIGIN 2b trial evaluated three subcutaneous weekly doses of atacicept (25 mg, 75 mg and 150 mg) and their impact on the reduction of proteinuria as measured by UPCR 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 endpoint, 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, secondary endpoints 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 participants as measured by estimated glomerular filtration rate (eGFR) eGFR and reduction in Gd-IgA1. We completed enrollment of the Phase 2b ORIGIN trial in mid-2022, enrolling a total of 116 patients participants 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 June 2023, we announced positive results at 36 weeks in a late-breaking presentation at the European Renal Association (ERA) Conference. In a prespecified per-protocol (PP) analysis in which a blinded third-party CRO identified patients and excluded participants with protocol deviations, that potentially confounded proteinuria measure. In the PP population excluding these patients, atacicept 150 mg achieved a 41% 43% mean reduction in proteinuria versus baseline, resulting placebo, and a 35% mean reduction in a statistically significant 34% placebo-adjusted reduction. Available data show a trend towards deeper reductions proteinuria versus placebo in proteinuria the intent-to-treat (ITT)

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population. Stable eGFR was observed for participants on atacicept 150 mg at 36 weeks, for patients on with an 11% mean eGFR change versus placebo, approximating to an absolute difference of 5.8 mL/min/1.73m2. Atacicept 150 mg reduced Gd-IgA1 64% from baseline. Hematuria was resolved in 80% of participants receiving atacicept for which full results will read out in the second quarter 150 mg compared to 5% of 2023. those receiving placebo. Furthermore, Atacicept was well tolerated, and its safety profile in IgAN patients was also comparable to placebo. The ORIGIN 2b trial will remain remained blinded through 36 weeks, after which all patients will participants were eligible to roll onto the open label portion of the trial and receive atacicept 150 mg once weekly through 96 weeks, allowing for the evaluation of long-term safety and durability of response of atacicept in IgAN. In January 2024, we announced positive results at 72 weeks at an R&D Day. Through 72 weeks, atacicept showed consistent and sustained UPCR reduction and eGFR stabilization. Atacicept also achieved consistent and sustained Gd-IgA1 reduction and reductions in percentage of participants with hematuria through 72 weeks. The open label extension adverse events profile was consistent with the randomized period. In aggregate, we believe these data provide evidence of long-term, comprehensive IgAN disease modification.

We plan to advance atacicept into a pivotal Phase anticipate full enrollment for the primary endpoint of ORIGIN 3 trial in the second quarter half 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. 2024. 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.

Pipeline

Beyond our lead indication in IgA nephropathy, we have several late-stage opportunities for potential patient benefit – consisting of both indication expansion opportunities for atacicept, and the development of MAU868 for BK viremia among kidney transplant recipients. We are currently evaluating these opportunities for future development.

For atacicept, we plan to evaluate the possibility of extended dosing intervals as part of our life cycle management strategy. There are also multiple indications in which blocking BAFF and APRIL may offer therapeutic benefit and offer an attractive commercial opportunity. Indications in which atacicept is Phase 3 ready based on feedback from regulators include LN and SLE. We have designed a Phase 3 clinical trial in LN. We believe that atacicept also has potential to initiate Phase 3 clinical trials in Sjogren's syndrome, myasthenia gravis, and membranous nephropathy, pending alignment with regulatory authorities.

Regarding MAU868 for BK viremia among kidney transplant recipients, 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. Following feedback from the FDA on the Phase 2 clinical trial, we are evaluating strategies for continued development, including a potential next clinical trial.

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 have designed a Phase 3 clinical trial of atacicept as a potential treatment for patients with LN, a severe

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renal manifestation of SLE. LN. We estimate that there are will be approximately 120,000 LN patients in the United States, 70,000 in the European Union, Europe , and 21,000 in Japan. Japan, at estimated peak year of sales. 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

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without a complete response, over half will have non-functioning kidneys within five years. Benlysta (belimumab), a BlyS-only BAFF-only inhibitor, is one of the two therapies approved for patients with LN. Both BLyS BAFF and APRIL levels are increased in patients with SLE, suggesting that dual inhibition by atacicept may be more potent than blocking BLyS BAFF 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 participants with active LN. However, this trial was terminated early due to three patients participants developing hypogammaglobulinemia with induction therapy (mycophenolate mofetil (MMF) and corticosteroids (CS)) which continued to worsen when initiating atacicept and subsequently two patients participants 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] ≥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 BAFF 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 currently designed Phase 3, randomized, parallel-group, double-blind, placebo-controlled, multicenter, multinational study will plans to evaluate the efficacy and safety of atacicept vs placebo in patients participants 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 have exclusive worldwide rights, pursuant to the Novartis license, to MAU868, as which is a potential treatment for reactivated BK infection in kidney transplant recipients. While up to 90% of healthy adults have been infected with BKV at some point in their lives, it remains latent except in everyone except severely immunocompromised

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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

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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 15 medicines from leading companies, including Gilead Sciences and Genentech. Amgen. We leverage our team's know-how with additional outsourced resources and enable focused clinical development of our product candidates with the goal of improving patients' lives.

These principles have guided us to the successful in-licensing of atacicept from Ares 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

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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 72-week results from the open label extension of the ORIGIN Phase 2b clinical trial in January 2023, 2024, and we will report 96-week results from 36-week data in the second quarter half of 2023, and plan to initiate a 2024. Our global pivotal Phase 3 clinical trial is currently ongoing and we expect to complete enrollment for the primary endpoint in the second quarter half of 2023.
- **Complete global development of atacicept in LN.** We are planning a Phase 3 clinical trial of atacicept as a potential treatmentfor 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

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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 inkidney

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transplant recipients in 2022. Pending alignment with regulatory authorities, we plan to initiate a Phase 2b or Phase 3 clinical trial. 2024.

- **Build and scale organizational capabilities to support commercialization of atacicept and MAU868.** **atacicept.**Under the leadership of ourexperienced management team, we have begun building a specialized commercial organization with deep launch experience in nephrology, B-cell, B cell, and 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 BAFF and APRIL,atacicept's ability to reduce disease-causing autoantibodies may provide clinical benefit. We intend to explore additional immunologic diseases where BLyS BAFF and APRIL are abnormally elevated, or where autoantibodies play an important role. We have designed a global Phase 3 clinical trial of atacicept as a potential treatment for patients with LN, a frequent and devastating complication of SLE.
- **Identify next clinical trial for MAU868 in BK viremia in kidney transplant recipients and align with regulatory authorities.** We reported final results from our Phase 2 clinical trial in kidney transplant recipients in 2022.
- **Expand our pipeline by acquiring or in-licensing product candidates for immunologic diseases with unmet needs.** Webelieve our expertise and track record will enable us to identify and acquire or in-license additional product candidates that represent opportunities to expand the potential value of our pipeline. We will leverage our lean clinical development operation to bring to market additional product candidates to address kidney and immunologic diseases.

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

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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, increasingly includes the use of SGLT2 inhibitors, and potentially includes 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 24-week results in January 2023, 36-week results in June 2023, and we plan to initiate 72-week results in January 2024 from the Phase 2b ORIGIN trial. We initiated a pivotal Phase 3 clinical trial in the second quarter of 2023. 2023, which we refer to as ORIGIN 3, that is currently ongoing. 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

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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 pathophysiology

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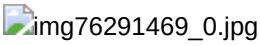

(1) B cells, which mature into plasma cells, are abnormally primed in the Peyer's patch region of the ileum of the intestines, potentially due to a combination of genetic predisposition and environmental, bacterial or dietary factors BLyS promotes BAFF and APRIL are upregulated, leading to B cell maturation and survival, increasing the number 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 c production from one immunoglobulin to another, causing an increase in the production of immunogenic Gd-IgA1.

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

(5) **(3)**Autoantibodies against Gd-IgA1 lead and anti-Gd-IgA1 autoantibodies combine to the formation of form pathogenic immune complexes, or clusters of antibodies.

(6) **(4)**Pathogenic immune complexes are deposited and become trapped in the kidney's glomeruli, and initiate glomeruli.

(5) This initiates an inflammatory response that damages the membranes, resulting in protein and blood leaking into th urine. membranes.

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(7) **(6)**As the glomeruli are destroyed, the kidney's ability to remove waste products from the blood is reduced, which and protein and blood leak into the urine. This can result in potentially life-threatening complications that lead to the nee 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. region. The hinge region is a stretch of amino acids in the IgA antibody.

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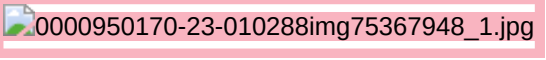
Circulating immune complex-containing Gd-IgA1 proteins antibodies have been shown to be the target antigens of autoantigens for IgG antibodies with specificity for the hinge region.

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 complexes 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 2 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: 2: Renal survival by serum Gd-IgA1 quartiles in IgAN patients

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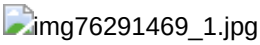

In addition, high serum APRIL levels correlate with increased expression of serum Gd-IgA1 in IgAN patients and high serum BLyS BAFF levels are associated with more severe clinical features, as well as more severe histopathological features. For these reasons, we believe a fusion protein that blocks both BLyS BAFF and APRIL, which has the potential to reduce serum Gd-IgA1, would address the upstream source of IgAN, and represent the first disease-modifying approach for IgAN.

Disease burden, diagnosis, and predictors of disease progression

IgAN is a rare disease in the United States and European Union Europe 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

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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 will be approximately 126,000 157,000 biopsy-confirmed IgAN patients in the United States, 136,000 in the European Union, Europe, and 130,000 in Japan, at estimated peak year of sales, and that growth in the diagnosed prevalent population is due to overall population growth. Underlying genetic differences may contribute to the significantly higher rate in Japan. As therapies become commercially available, however, an increase in diagnosis rate or longer time to progression, due to better treatments, may increase the diagnosed population over time.

We estimate the U.S. market opportunity for novel therapeutics in Figure 3: Estimated IgAN is approximately $4.0 billion to $8.0 billion annually, based on the prevalence epidemiology at estimated peak year 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. sales

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Current standard of care for IgAN patients

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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, RAA inhibitors including (including ACE inhibitors or ARBs. ARBs) and SGLT2 inhibitors.
- 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

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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% 64% reduction of Gd-IgA1, the upstream source of IgAN pathogenesis. pathogenesis, after 36 weeks of treatment.

These agents can be grouped mechanistically into the following categories: glucocorticoid receptor agonists, endothelin receptor antagonists (ERAs), complement inhibitors, B-cell 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 B cell activity and reducing systemic steroid toxicity. Currently Reformulated budesonide is currently approved by the FDA and European Commission for reducing the loss of kidney function in a Phase 3 clinical trial in adults with IgAN reformulated budesonide has demonstrated statistically meaningful reduction of proteinuria, who are at risk for disease progression, though systemic steroid side effects have been observed in prior clinical trials and the ongoing Phase 3 clinical trial. trials.

ERAs. Aberrant endothelin signaling is implicated in structural podocyte changes and increased mesangial proliferation in chronic kidney diseases, including IgAN. ERAs block endothelin-induced cell proliferation and hence may reduce renal perfusion pressure and proteinuria. Since this mechanism of action works downstream of disease-related immune activities, it is not expected to reduce Gd-IgA1 or the resulting immune complexes that cause the disease. 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 effect. One ERA that is currently in approved by the FDA has a boxed warning for hepatotoxicity and embryo-fetal toxicity and a REMS for liver toxicity, and another ERA is completing Phase 3 development

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and have been shown to reduce proteinuria in patients with IgAN. However, development. 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 B cell modulators. B-cell 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 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 BAFF and APRIL offers improved suppression of B-cell B cell activities than over blocking BLyS BAFF or APRIL alone. Atacicept blocks both BLyS BAFF and APRIL and has shown substantial reduction (60%) (64% at 36 weeks) 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 BAFF and APRIL, which play key roles in the upstream pathway that causes IgAN, and is dosed once weekly via a 1-mL subcutaneous injection. injection, self-administered at home. 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 participants to date, atacicept has a well-characterized clinical safety profile. In a Phase 2a clinical trial in patients participants with IgAN, atacicept substantially reduced Gd-IgA1 and demonstrated a clinically meaningful reduction in proteinuria

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and stable eGFR parameters at week 24. We completed enrollment of patients participants in the Phase 2b ORIGIN trial in 2022, and we reported positive topline results at 24 weeks in January 2023. 2023, 36 weeks in June 2023, and 72 weeks in January 2024.

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

Atacicept is a fully humanized fusion protein that impacts is designed to modulate the B-cell B cell and plasma cell pathway, which has well characterized implications in immunologic diseases. Specifically, as shown in Figure 4 below, atacicept contains the soluble transmembrane activator extracellular domain of the TACI receptor fused with the inactivated Fc domain of IgG1. TACI is a native receptor for BAFF and CAML interactor (TACI) receptor that binds to the cytokines BLyS and APRIL. These cytokines are APRIL, members of the tumor necrosis factor family that promote B-cell B cell survival and autoantibody production associated with IgAN and other immunologic diseases. Dual blockade of BLyS BAFF and APRIL by TACI has been shown to be more potent than blocking BLyS BAFF alone or APRIL alone and has the benefit of targeting long-lived plasma cells, in addition to B cells, thus reducing autoantibody production including of Gd-IgA1 IgA,

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IgG and IgM. its autoantibodies. Therefore, atacicept's atacicept is designed to modulate B cell and plasma cell activity by binding both BAFF and APRIL, and follows a long history of impactful agents that are logically designed Fc fusion proteins. This mechanism acts directly on the source of IgAN, which we believe will significantly mitigate the downstream effects of the disease.

Figure 4: Atacicept blocks both BLyS and APRIL is the result of rational drug design

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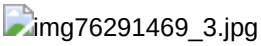

Atacicept: Potential to address the core processes underlying IgAN pathogenesis

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

Figure 5: Atacicept impact on IgAN pathogenesis

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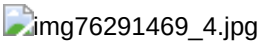

(1) Atacicept blocks BLyS, a factor important for B cell survival inhibits BAFF and maturation, resulting in reduced numbers of disease-causing APRIL, leading to decreased Gd-IgA1 production by B cells.

(2) Atacicept blocks APRIL, This leads to a factor important for plasma cell survival, resulting reduction 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 the autoantibodies that bind Gd-IgA1.

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

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

(7) **(5)**Glomerular inflammation is reduced.

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

Atacicept's 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

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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 participants 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. extension (Figure 6). The ORIGIN Phase 2b trial was designed to evaluate the efficacy and safety of atacicept in participants with IgAN who continue to have persistent proteinuria and remain at high risk of disease progression despite being on a stable prescribed regimen of a RAAS inhibitor for at least 12 weeks that is at the maximum labeled or tolerated dose. The clinical trial consisted of a 36-week double-blind treatment period, followed by a 60-week open-label treatment period — which is currently ongoing — and a 26-week safety follow-up period. The trial assessed three doses (25 mg, 75 mg and 150 mg) of once weekly 1-mL subcutaneous injections of atacicept versus placebo on impact of renal function as measured by proteinuria. The primary endpoint was change from baseline in UPCR at 24 weeks based on 24-hour urine collection, with a secondary endpoint of UPCR at 36 weeks. Other 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, 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.

On January 3, 2023, and January 30, 2023, Figure 6: Phase 2b ORIGIN trial design

Vera reported positive week 24 primary results and shared from the randomized phase of the Phase 2b ORIGIN clinical trial, which showed the following results: at 36 weeks:

- Atacicept met its primary endpoint Gd-IgA1 reduction of 64% from baseline with a statistically significant reduction atacicept 150 mg.
- Hematuria resolution in proteinuria in the pooled 75/ 80% of participants on atacicept 150 mg arms versus placebo on placebo.

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- In a prespecified per-protocol (PP) PP analysis, a blinded third-party CRO identified patients participants with proto deviations that potentially confounded proteinuria measure. In the PP population excluding these patients, participa atacicept 150 mg achieved a 41%

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43% mean reduction in proteinuria versus baseline, resulting placebo (p<0.05); in the ITT population, atacicept 150 mg achieved a statistically significant 34% placebo-adjusted reduction (p=0.025) at an early week 24 timepoint35% delta versus placebo.

- There was a trend towards deepening reductions in proteinuria at week 36 Stable eGFR observed for participants o atacicept, with available data in patients on atacicept. clinically meaningful and statistically significant difference ver placebo.
- eGFR was stable through week 24 for all patients on atacicept
- Atacicept was well tolerated, and its Clinical safety profile in IgAN patients was comparable to placebo
- There was a 60% reduction in Gd-IgA1 at week 24 with similar between atacicept 150 mg and placebo.

Based on In January 2024, Vera reported positive results from the open label phase of the Ph2b ORIGIN clinical trial at 72 weeks, which demonstrated consistent and sustained reductions in Gd-IgA1, hematuria and UPCR and consistent and stable eGFR (Figure 7 below). In aggregate, we believe these data provide evidence of long-term, comprehensive IgAN disease modification.

Figure 7: Phase 2b ORIGIN clinical trial 72-week results the with atacicept 150 mg dose was selected for a forthcoming

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We initiated our ORIGIN 3 Phase 3 clinical trial which we expect to initiate in the second quarter of June 2023. We will use are using the same formulation as the Phase 2b trial, while incorporating and have incorporated learnings from Phase 2b subgroup analyses to into the design a de-risked of our Phase 3 trial that aims to accurately assesses assess treatment efficacy while minimizing potential confounders for proteinuria measure.

Atacicept safety and tolerability profile: Integrated analysis profile

Though there In the randomized phase of the ORIGIN Phase 2b clinical trial, the clinical safety profile was a limited number of patients similar between atacicept and placebo – and in the JANUS week 72 results, the safety profile observed

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was consistent with that of the randomized phase (Figure 8 below).

Figure 8: Phase 2b ORIGIN clinical trial in an adverse events profile

An integrated safety analysis of clinical trials in multiple indications with over 1,500 patients participants in a number of indications, atacicept was well tolerated, shown in Figure 6 9 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. 9: Integrated safety analysis: Summary of treatment-emergent adverse events > 5% in any arm, by dose

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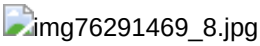

The safety profile of atacicept 25 mg, 75 mg and 150 mg has been characterized in healthy subjects and patients with RA, multiple sclerosis, optic neuritis, SLE, and B-cell B cell malignancies, and is considered acceptable in IgAN. Over 1,940 individuals have been enrolled in 22 clinical trials, of which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

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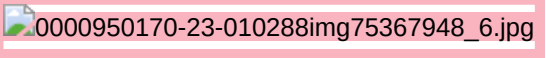
12, 48, and 96 weeks, change from baseline in eGFR at 12, 24, 36, 48, and 96 weeks, change from baseline in IgA, IgG, IgM, C3, C4, and Gd-IgA1 levels at 12, 24, 36, 48, and 96 weeks, number of

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 potentially 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, European Medicines Agency (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

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

Figure 10: Phase 3 ORIGIN 3 trial design

ORIGIN 3 is a Phase 3 global, multicenter, 104-week randomized, placebo-controlled, double-blind trial, with a 52-week open label extension and a 26-week safety follow-up period (Figure 10), in participants with IgAN who continue to

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have persistent proteinuria and remain at high risk of disease progression despite being on a stable prescribed regimen of renin-angiotensin system inhibitors (ACE inhibitors or ARBs) for at least 12 weeks that is the maximum labeled or tolerated dose. The clinical trial consists of a 104-week double-blind treatment period which is currently ongoing, followed by a 52-week open-label treatment period and a 26-week safety follow-up period. The trial will assess once weekly 1-mL subcutaneous injections of atacicept 150 mg versus placebo on impact of renal function as measured by proteinuria and eGFR. The primary endpoint is change from baseline in UPCR at 36 weeks based on 24-hour urine collection and the key secondary endpoint is eGFR up to 104 weeks. Additional secondary endpoints are change in Gd-IgA1, change in eGFR up to 52 weeks, and time from randomization to first occurrence of composite kidney failure endpoint event.

With the ongoing data from the Phase 2b trial expected 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 have designed 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 will be approximately 120,000 LN patients in the United States, 70,000 in the European Union, Europe, and 21,000 in Japan. Japan, at estimated peak year of sales. 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 BAFF-only inhibitor, is one of the two therapies approved for patients with LN. Both BLyS BAFF and APRIL levels are increased in patients with SLE, suggesting that dual inhibition by atacicept may be more potent than blocking BLyS BAFF 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 participants developing hypogammaglobulinemia with induction therapy (MMF and CS) which continued to worsen when initiating atacicept and subsequently two patients participants developed pneumonia. In prior Phase 2 clinical

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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

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believe supports atacicept's applicability in LN. Because both preclinical and clinical evidence suggests atacicept's dual inhibition of BLyS BAFF 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, Europe, 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 11 below, LN typically develops early in the disease course, though the rate of SLE patients who develop LN increases over time.

Figure 8: 11: LN progression

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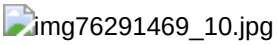

LN market opportunity

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

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Approximately half of individuals living with SLE develop LN within 15 years of their initial diagnosis, as shown in Figure 8 11 above.

We estimate that there are will be approximately 120,000 LN patients in the United States, 70,000 in the European Union, Europe, and 21,000 in Japan, at present. estimated peak year of sales. 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 cyclophosphamide (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

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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 relatively recently, there were no approved therapies for the treatment of LN. In December 2020, the FDA approved Benlysta (belimumab), an anti-BLyS anti-BAFF 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

B cell Modulators. Benlysta (belimumab) is an anti-BLyS anti-BAFF antibody, belonging to the class of B-cell B cell modulators. Within the B-cell 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. Other B cell modulatory approaches under late-stage investigation include blocking the BAFF receptor and binding CD20.

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 (Type 1 IFNs) IFNs, IL17A, IL23) involved in the pathogenesis of LN, however, they are early in their development. LN.

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 BAFF 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.

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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. BAFF. Therefore, B cell blocking agents such as Rituxan (rituximab; anti-CD20) and Benlysta (belimumab; anti-BLyS) anti-BAFF) can reduce short-lived plasma cells and the resulting autoantibody production.

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Long-lived plasma cells are in bone marrow and inflammatory tissue niches, and form antibodies in the absence of B-cell B cell activation. Inflammatory tissue has high levels of BLyS BAFF 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 BAFF and APRIL and prevents their interaction with TACI, BCMA and BLyS BAFF receptors (BLyS-R (BAFF-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 BAFF and APRIL is superior to either BLyS BAFF or APRIL alone. Animal models of kidney disease have confirmed that atacicept reduces plasma cell numbers and reduces autoantibodies more effectively than BLyS BAFF 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) 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 BAFF-only inhibitor did not. Atacicept also decreased established plasma cells in an immunization model better than single inhibitors of BLyS BAFF or APRIL.

In patients with active SLE, targeting BLyS BAFF and APRIL with atacicept appears to have improved clinical outcomes, measured by endpoints designed to assess efficacy, compared to BLyS BAFF alone (Benlysta [belimumab] (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 participants 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: 12: Evidence for atacicept performance in SLE

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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 participants 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 participants developed severe hypogammaglobulinemia, defined as IgG <3 g/L, and pneumonia. These two patients participants 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

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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.

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Phase 2 clinical trial in patients with SLE for 24 weeks

ADDRESS II, a Phase 2b SLE trial of 306 patients, participants, 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 13 below.

Figure 10: 13: Atacicept impact on key biomarkers in the phase 2 ADDRESS II trial

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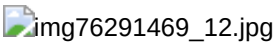

Though atacicept missed its primary endpoint of SRI-6 reduction versus placebo in all comers, in a prespecified analysis of HDA patients, which comprised approximately half of those enrolled, atacicept 150 mg showed improved clinical outcomes, measured by multiple endpoints designed to assess efficacy, 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

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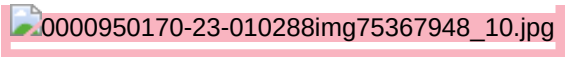

Also, among this HDA patient segment, significantly more patients participants on the atacicept 150 mg arm reached LDA, as measured by SLEDAI-2K ≤2, as shown in Figure 12 14 below.

Figure 12: 14: SRI-6 response and LDA attainment among HDA patients reaching LDA in the phase 2 ADDRESS II trial

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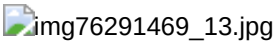

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Furthermore, Figure 13 15 below demonstrates the durable clinical outcomes observed in the HDA segment: more patients participants reached LDA by multiple measures at both week 24 and week 48. Significantly more patients participants treated with atacicept 150 mg once weekly versus placebo demonstrated clinical improvement (as shown by SRI-6), achieved LDA, and remission.

Figure 13: 15: Durable clinical outcomes observed in HDA patients in the phase 2 ADDRESS II trial

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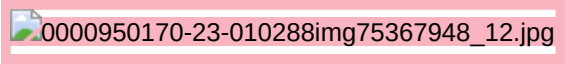

We believe that the clinical outcomes, measured by multiple endpoints designed to assess efficacy within the HDA segment of the SLE population in the ADDRESS II trial—and a favorable tolerability profile observed in ADDRESS II, as well as the integrated safety analysis in over 1,500 patients— participants—provide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

Planned phase Phase 3 clinical trial design

Our currently designed 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

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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 16 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 16: Phase 3 clinical trial design

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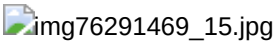
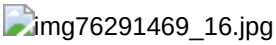


MAU868 in reactivated BK infection among kidney transplant recipients

We are developing have exclusive worldwide rights, pursuant to the Novartis license, to MAU868, as which is a potential treatment for reactivated BK infection in kidney transplant recipients. While up to 90% of healthy adults have been infected with BKV at some point in their lives, it remains latent in everyone except severely immunocompromised populations such as kidney transplant recipients. There are approximately 80,000 kidney transplants annually worldwide, with approximately 20,000 in the United States. Approximately 225,000 kidney allograft recipients are living in the United States. Waitlists to receive kidneys are long: approximately 3–5 years and 75,000 people long in the United States. Up to 12% of transplants per year are re-transplants, which further limits organ availability for new patients. BKV is a polyoma virus that is tropic to the kidney and bladder tissue and can reactivate with the immunosuppression required for kidney transplant. This reactivation can cause BKVN, a condition in which BK infection, typically first identified as BK viremia, triggers inflammation, which then progresses to renal fibrosis and tubular injury; as shown in Figure 15, 17, BKVN is a leading cause of allograft loss, a devastating outcome for kidney transplant recipients.

Figure 15: 17: 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 Amplyx. Following feedback from the FDA on the Phase 2b or Phase 3 2 clinical trial, pending alignment with regulatory authorities. we are evaluating strategies for continued clinical development, including a potential next clinical trial. We believe that MAU868 has the potential to become standard of care for the treatment of BK viremia in order to prevent devastating consequences such as BKVN.

Pathophysiology of 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

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adverse effects from either primary or persistent infection. Control of infection is dependent on CD4+ and CD8+ T cell immunity, which immunosuppressants can displace. be displaced by immunosuppressants. In the setting of kidney transplant and related immunosuppression, latent virus can be reactivated or new virus can be transmitted via the donor kidney. BKV reactivation is marked first by viruria—or detection of virus in the urine, and then viremia—detection of viral DNA in the blood, and most commonly occurs within the first year of transplant.

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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

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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.

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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 has paused in its development following 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. Memo Therapeutics is also developing a BKV neutralizing monoclonal antibody, though limited supporting data is available.

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. 18. 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 hematopoietic stem cell transplant (HSCT) recipients (BKV-associated hemorrhagic cystitis). MAU868 also has neutralizing activity in vitro against the closely related JC virus, the cause of progressive multifocal leukoencephalopathy.

Figure 16: 18: MAU868 blocks BK virion binding

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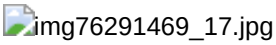


Clinical development of MAU868

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.

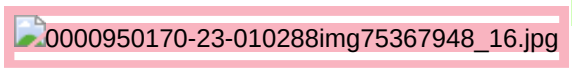
Ongoing phase Phase 2

A We completed a Phase 2 randomized, double-blind, placebo-controlled clinical trial designed to assess the safety, tolerability, and efficacy of MAU868 for the treatment of allograft-threatening BKV infection in kidney (or kidney-pancreas) transplant recipients is ongoing. Up to 36 patients in 2022. Two sequential cohorts enrolled a total of 28 participants with BK viremia will participate in 1 of 3 sequential cohorts. viremia. As shown in Figure 17, 19, each cohort was designed to randomize approximately 12 patients participants (8 to MAU868 and 4 to placebo), for which Cohort 1 (1350 mg IV approximately every 28 days for a total of 4 doses) and Cohort 2 (6750 mg IV on Day 1, 1350 mg IV every 28 days for 3 additional doses) have completed dosing.

The primary objective of the clinical trial is was to assess the safety and tolerability of MAU868, with secondary objectives to assess the impact of MAU868 on BKV related outcomes. MAU868 has been shown in an interim analysis of week 12 data from Cohorts 1 and 2 to be well-tolerated and showed a greater proportion of patients participants 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: 19: MAU868 phase 2 clinical trial design



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Future clinical trials

We plan to initiate Following feedback from the FDA on the Phase 2 clinical trial, we are evaluating strategies for continued development, including a Phase 2b or Phase 3 potential next 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.

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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

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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

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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 December 31, 2023, 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 six 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.

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There is also a pending U.S. application as well as certain foreign counterparts directed to treatment of IgAN and proteinuria. Patents The 20-year expiration date for patents that issue in this family are is expected to expire be 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 December 31, 2023, 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 countries within the European Patent Convention, Australia, China, Japan, India, Israel, Mexico, Macau and Taiwan, and pending in other jurisdictions such as Canada, Mexico, Europe, Israel and Japan. Canada. The foreign 20-year expiration date for patents are expected to expire in this family is 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 The 20-year expiration date for patents in this family are expected to expire is 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.”

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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 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

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We estimate the market opportunity for novel therapeutics in IgAN across to be approximately 157,000 patients in the United States, 136,000 patients in Europe and 130,000 in Japan, to be approximately $5.6 billion to $9.6 billion annually, at estimated peak year of sales, based on our assumptions, secondary research, and primary market research with physicians and payors. In order to capitalize on this opportunity, we 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 will be approximately 120,000 LN patients in the United States, 70,000 in Europe, and 21,000 in Japan, to be $2.8 billion to $5.8 billion annually, based on a similar methodology. at estimated peak year of sales. 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.

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MAU868

We plan to develop MAU868 for the treatment of BK viremia in kidney transplant as an initial indication, which we believe has strong potential 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.

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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) SGLT2 inhibitors, including AstraZeneca plc's (AstraZeneca) Farxiga, which is approved for chronic kidney disease, is are 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.; Roche/Ionis; and the following companies with programs in Phase 2 of clinical development: Chinook Therapeutics Inc., Reata

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Pharmaceuticals, Inc., RemeGen Co., Ltd., Ionis Pharmaceuticals, AstraZeneca, HI-Bio, Inc., AstraZeneca, Eladon Pharmaceuticals, and DiaMedica Therapeutics, Inc.

Atacicept in LN

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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

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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, and AstraZeneca, 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, Amgen Inc., 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 competitors to be Allovir's multi-virus specific T-cell therapy, posoleucel, which is in currently paused after a Phase 2 clinical trial for BK viremia in kidney transplant recipients, and Memo Therapeutics AG's AntiBKV, a neutralizing monoclonal antibody in a Phase 2/3 clinical trial for treatment of virus-associated cystitis, and a Phase 2 clinical trial in multi-virus prevention following allogeneic HSCT. trial.

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

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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, includi 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 hum 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, G 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 fi 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;

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- 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 ass 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,

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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

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clinical trials is to assess the metabolism, pharmacokinetics, pharmacologic action, side effect tolerability, safety of 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 pharmacokine 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 establis the overall benefit/risk relationship of the product and provide an adequate basis for product labeling. In most case 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 voluntarily pursue, post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

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

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

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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

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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

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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

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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.

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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

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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

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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

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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.

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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,

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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.

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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, (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 authorities do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional

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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 t 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

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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 Good Laboratory Practice regulations;
- submission of a single clinical trial application (CTA) through the Clinical Trials Information System (CTIS) to the

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relevant national competent authorities of EU Member States in which a clinical trial application (CTA) for each tria humans, is planned to be conducted, which must be approved by such national authorities and the subject of a pos opinion from at least one independent ethics committee before the trial may begin in each country where patient enrollment the clinical trial is planned;

- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for eac 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 prod in clinical development and proposed labelling;
- satisfactory completion of an inspection by the relevant competent national authorities of EU Member States of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced 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 In the European Economic Area (EEA), comprising the European Union Member States plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after a related marketing authorization (MA), has been granted. To obtain an MA for a product in the EEA, an applicant must submit a MAA under one of four procedures: the centralized authorization procedure, based on administer by the EMA, or one of the procedures administered by the competent authorities of EEA countries, the mutual recognition procedure, the 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.

The centralized procedure provides for the grant of a single submission MA by the European Commission that is valid throughout the EEA. Pursuant to Regulation (EC) No 726/2004, 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 single E.U. portal, an assessment 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 leading to is optional for products containing a single decision, as well as transparency requirements (the proactive publication of clinical trial data new active substance not yet authorized in the E.U. database). EEA, and indicated for the treatment of

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other diseases, or for products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval

Manufacturing 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 import into the E.U. quality of investigational 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 use the co-ordination of the evaluation with the possible assistance of a further member of the CHMP acting as a Co-Rapporteur. The CHMP is required to issue an opinion within 210 days of receipt of a valid application, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in clinical trials response to questions of the CHMP Once the procedure is subject 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 holding 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 appropriate authorizations receipt of the CHMP's opinion. If the opinion is negative, information is given as to the grounds on

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which this conclusion was reached. The CHMP is also responsible for several post-authorization and must be carried out in accordance with cGMP. maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization.

Review and approval

Authorization to market a product in the European Economic Area (EEA), 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 Member

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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

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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 Alternative approvals, accelerated assessment and accelerated assessment PRIME

As per In the EU, in accordance with Article 14(7) of Regulation (EC) 726/2004, a medicine that would fulfill an unmet medical need "conditional" marketing authorization may if its immediate availability is be granted in cases where all the interest of public health, be granted required safety and efficacy data are not yet available. The European Commission may grant 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 medicinal

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product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicine medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicine medicinal product fulfils an unmet medical need; and (iv) the benefit of the medicine's immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. Such an The conditional marketing authorization shall is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year on and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional marketing authorization can be converted into a renewable basis.traditional marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the marketing authorization will cease to be renewed.

When A marketing authorization may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data

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may be contrary to generally accepted ethical principles. Like a conditional marketing authorization, a marketing authorization granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard marketing authorization. However, unlike the conditional marketing authorization, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the marketing authorization "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the marketing authorization will be withdrawn if the risk-benefit ratio is no longer favorable.

Accelerated assessment may be granted by the CHMP in exceptional cases, when an application is submitted for a marketing authorization in respect of a drug for human use targeting an unmet medical need which is expected to be of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, innovation. In these circumstances, the applicant may request an accelerated assessment procedure pursuant to Article 14(9) of Regulation (EC) 726/2004. Under 2004, which must be substantiated. If the CHMP accepts the request for accelerated assessment, procedure, the CHMP time limit of 210 days for the CHMP's opinion is required reduced to issue an opinion within 150 days of receipt of a valid application, subject to excluding clock stops, but it is possible that the stops. The CHMP may, however, revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment. We believe that some of the disease indications in which our product candidates are currently being or may be developed in the future may qualify for this provision, and in which

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case, we will take advantage of this provision intend to submit related applications for accelerated assessment as appropriate.

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines scheme (PRIME), which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

Period

Validity of authorization and renewals marketing authorizations

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 consolidated version of the file Common Technical Document providing up-to-date data in respect of quality, safety and efficacy, including all variants variations introduced since the marketing authorization was granted, at least six nine 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. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. 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

Pediatric development

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

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for a six-month extension to the law Supplementary Protection Certificate (SPC), if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Manufacturing regulation in the EU

In addition to a marketing authorization, various other requirements apply to the manufacturing and placing on the protection EU market of industrial medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization and commercial property, import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including EU cGMP standards. Similarly, the

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distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU Member States. Marketing authorization holders and/or manufacturing and import authorization, or marketing authorizations authorization holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

Data and market exclusivity

The EU provides opportunities for data and market exclusivity related to marketing authorizations. Upon receiving a marketing authorization, innovative medicinal products benefit from an 8+2+1 year period of regulatory protection. This regime consists of a regulatory data protection period of are generally entitled to receive eight years plus of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a concurrent generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity of period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years plus an additional market exclusivity have elapsed from the initial marketing authorization of one the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those 10 ten years, the marketing approval authorization holder obtains an approval authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their approval, authorization, are determined held to bring a significant clinical benefit in comparison with existing therapies. Under However, there is no guarantee that a product will be considered by the current rules, EU's regulatory authorities to be a third party making new chemical/biological entity, and products may not qualify for data exclusivity.

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In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or biosimilar clinical trials must be provided in support of an application may not reference for marketing authorization. Guidelines from the preclinical and clinical EMA detail the type of quantity of supplementary data to be provided for different types 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 biological product.

Orphan drug designation

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Regulation (EC) 141/2000, as implemented by Regulation (EC) 847/2000 states that a drug shall can 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 submission of an application MAA. A marketing authorization for approval an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to market be sought. Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the product. centralized marketing authorization procedure.. Marketing authorization for an orphan drug leads to a 10-year period of market exclusivity for the approved therapeutic indication, which means that no the EMA cannot accept another marketing authorization application or accept an application to extend for a similar medicinal product can be authorized in and the European Commission cannot grant a marketing authorization for the same indication. indication for a period of ten years. A “similar medicinal product” is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. 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 a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period of market exclusivity on an individual basis in very select cases, such as with consent from the marketing authorization holder, inability if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities of the authorized product or demonstration of “clinically

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relevant superiority" by a if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. Medicinal A company may voluntarily remove a product from the register of orphan products.

Post-authorization requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products designated as orphan drugs pursuant are subject to Regulation (EC) 141/2000 are eligible for incentives made available comprehensive regulatory oversight by the EMA, the European Union Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must

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establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (PSURs).

All new MAAs must include a risk management plan (RMP) describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk- minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

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

If the MAA

Combination products

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The EU regulates medical devices and medicinal products separately, and through different legislative instruments. Products that are a combination of a medicinal product designated and a medical device may be regulated as either a medicinal product, a medical device or, subject to certain requirements, on the basis of both sets of rules. The applicable requirements governing placing a drug-device combination on the EU market will vary depending on the type of drug-device combination product and on which of the components of the combination has the primary mode of action. Drug-device combination products that form a single integral product that is not reusable and for which the action of the medicinal product is principal to that of the medical device are governed by the regulatory framework applicable to medicinal products. However, the General Safety and Performance Requirements (GSPRs) of Annex I to Regulation (EU) 2017/745 on Medical Devices (MDR) will be applicable to the safety and performance of the medical device part of the product in the context of its use with the medicinal product. Drug-device combination products that form a single integral product that is not reusable and for which the action of the medicinal products is ancillary to that of the medical device are governed by the regulatory framework applicable to medical devices in accordance with the MDR. Where a medical device incorporates a medicinal product as an orphan integral part as a single use drug pursuant delivery system, which is intended exclusively for use in the given combination and which is not reusable, it is regulated as a medicinal product. In this case, the relevant GSPRs of the MDR will apply to Regulation (EC) 141/2000 includes the results safety and performance of all studies conducted in compliance with an agreed pediatric investigation plan, the device element. By contrast, drug-device combination products which do not form a single integral product will be regulated separately. This may include, for example a drug-device combination product where a medical device and a corresponding statement medicinal product are co-packaged and the medical device is subsequently included intended solely to be used for the administration of the co-packaged medicinal product.

Brexit

The United Kingdom's (UK) withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The MHRA is now the UK's standalone regulator for medicinal products and medical devices. Great Britain (England, Scotland and Wales) is now a third country to the EU. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules for now.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the Clinical Trials Directive (EU) 2001/20 (CTD), as implemented into UK national law through secondary legislation. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials, and which aimed to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments will determine how closely the UK regulations will align with the EU Clinical Trials Regulation (CTR). In October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established

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in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1,

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2021, unless the marketing authorization granted, holder opted-out of this possibility. Northern Ireland currently remains within the 10-year period scope of EU authorizations in relation to centrally authorized medicinal products. Accordingly, until the Windsor Framework is implemented in Northern Ireland on January 1, 2025, products falling within the scope of the EU centralized procedure can only be authorized through UK national authorization procedures in Great Britain.

The MHRA has also introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, a rolling review procedure and the International Recognition Procedure. Since January 1, 2024, the MHRA may rely on the International Recognition Procedure (IRP) when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the EMA and CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures are considered to be authorizations for the purposes of the IRP.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in Great Britain, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be extended to 12 years. set from the date of first approval of the product in Great Britain.

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 data about clinical trials participants and other individuals in Europe is governed by the European Union's General Data Protection Regulation (GDPR (EU GDPR), and in the UK, is governed by the European Union (Withdrawal) Act 2018 and the UK Data Protection Act 2018 (UK GDPR)). The EU GDPR and UK GDPR require companies to, among other things,

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give detailed disclosures about how they are processing personal information; data; ensure any consents relied on to process personal information data (including special categories of personal information, data, such as health information) meet the stricter strict EU GDPR requirements; contractually impose data protection measures on vendors entrusted with personal information; data; maintain adequate data security measures; notify regulators and affected individuals of certain data breaches; meet extensive privacy governance and documentation requirements; honor individuals' data protection rights, including their rights to access, correct and delete their personal information; data; and refrain from transferring personal information data from Europe or the UK to most other countries unless specific safeguards can be implemented. Companies that violate the EU GDPR or UK GDPR can face private litigation, prohibitions on data processing and heavy fines. Complying with the EU GDPR and UK GDPR may be costly and require us to limit our activities in Europe. If our efforts to comply are not successful, we may face litigation, reputational harm, significant penalties and other liabilities.

Marketing

Much like the Anti-Kickback Statute prohibition in the United States, as described below, the provision of benefits or advantages to physicians and other health care professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the E.U. The provision of benefits or advantages to induce or reward improper performance generally is Interactions between pharmaceutical companies and health care professionals are governed by the strict laws, such as national anti-bribery laws of European Union member states countries, national sunshine rules, regulations, industry self-regulation codes of conduct and the Bribery Act 2010 physicians' codes of professional conduct. Failure to comply with these requirements could result in the UK. reputational risk, public reprimands, administrative penalties, fines or imprisonment. Infringement of these related 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 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. Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union member states. 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

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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 kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an iter 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 th 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 ar 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, amended by the Health Care and Education Reconciliation Act of 2010 (collectively, Affordable Care Act), to a stric standard such that a person or entity does not need to have actual knowledge of the statute or specific intent to vio

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it in order to have committed a violation. Further, the Affordable Care Act codified case law that a claim including ite 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 citizen through civil qui tam actions, and civil monetary penalty laws prohibit individuals or entities from, among other thing 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-la promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the governme for government price reporting purposes, and allegedly providing free product to customers with the expectation tha the customers would bill federal healthcare programs for the product. In addition, a claim including items or service resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of 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, manufactu can be held liable under the False Claims Act even when they do not submit claims directly to government payors i 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 crim liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including priva 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 knowingl and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudule 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, item 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 respe 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 associa and subcontractors that perform services for them that involve individually identifiable health information. HITECH a created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicab business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions 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 a 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 supp reimbursed under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the Center for Medicare & Medicaid Services (CMS) information related to payments and other transfers of value provided to physicians (defined to

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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 ar 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 no 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 t federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare providers; professionals; state and foreign laws that require the reporting of marketing expenditure drug pricing, including information pertaining to and justifying price increases; state and local laws that require the registration of pharmaceutical sales representatives; state and foreign laws that prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals; state and foreign laws that require the posting of information relating to clinical trials and their outcomes; and other federal, state and foreign laws that govern the privacy and security of health information or personal information data in certain circumstances, including state hea information privacy and data breach notification laws which govern the processing of health-related and other pers information, data, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

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

Legislative reform

We operate in a highly regulated industry, and new laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, related to healthcare availability, the method of delivery and payment for healthcare

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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 The Affordable Care Act, which included changes to the coverage and reimbursement of drug products under government healthcare programs such as:

- among other things, increased the minimum level of Medicaid rebates owed payable by manufacturers under the of brand name drugs; required collection of rebates for drugs paid by Medicaid Drug Rebate Program;
- established a branded prescription drug fee that pharmaceutical managed care organizations; required manufactur 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 the program;
- established a new Medicare Part D coverage gap discount program, in under which manufacturers they must now agree to offer 70% point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) 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 imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid specified federal government 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 implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Reba Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted, or injected;
- established injected expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- and 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
- spending.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

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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, 2032, 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

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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, 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although they may be the Medicare drug price negotiation program is currently 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, In response to the Biden administration released an additional administration’s October 2022 executive order, on October 14, 2022 February 14, 2023, directing HHS to submit released a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test outlining three new models for lowering drug costs for Medicare testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and Medicaid beneficiaries. improve quality of care. It is unclear whether this executive order or similar policy initiatives the models will be implemented utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access 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

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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,

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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 authorities 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 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 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 market. Other EU Member States allow companies to fix their own prices for product but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies.

Reference pricing used by various European Union member states Member States and parallel distribution, or arbitrage between low-priced and high-priced member states, 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

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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 December 31, 2023, we had a total of 46 51 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

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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.

Company information

We were incorporated as a Delaware corporation in May 2016. Our principal executive offices are located at 8000 Marina Boulevard, Suite 120, Brisbane, California 94005.

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 An investment in shares of our Class A common stock (common stock) involves significant risks, some a high degree of which are described below. risk. You should carefully consider the risks and uncertainties described below, together with all of as well as the other information contained in this Annual Report, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the related notes. If before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks actually occur, it described below could harm our business, prospects, operating results and financial condition, and future prospects. In such event, the market results of operations, growth prospects, and/or stock price of or cause 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 to differ materially from those anticipated contained in the forward-looking statements

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as a result of factors that are described below and elsewhere we have made in this Annual Report. Report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

Risks related to our financial position and need for additional capital

We have 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 to our research and development efforts, to organizing pre-clinical studies and staffing clinical trials, establishing and maintaining our company, business planning, executing partnerships, intellectual property portfolio, hiring personnel, raising capital acquiring, developing and securing our technology providing general 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. administrative support for these operations. 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

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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 December 31, 2023, we had $114.7 million $160.7 million in cash, cash equivalents and marketable securities. In December 2021, we the Company entered into the a non-revolving loan and security agreement (the Loan Agreement Agreement) with Oxford, as amended in November 2022, providing us with borrowing capacity of up to $25.0 million of borrowing capacity, after $5.0 million was funded at $50.0 million. At the closing of the Loan Agreement in December 2021, $5.0 million was funded, and an additional $20.0 million was funded in November 2022. In December 2023, the Company borrowed the remaining $25.0 million from the Loan Agreement. As of December 31, 2023, the Company's outstanding borrowing under the Loan Agreement was $50.0 million. We expect that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations and capital expenditure requirements for at least the next 12 months subsequent to from 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 candidate that we may pursue in the future;
- continue our ongoing and planned research and development of MAU868 for the treatment of BKV BK 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 capa 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, a know-how;

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- 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; and
- add clinical, operational, financial and management information systems and personnel, including personnel to sup 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. efforts.

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 delayed 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 conflicts, 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 $96.0 million and $32.6 million $89.1 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. We had an accumulated deficit of $213.1 million $309.1 million as of December 31, 2022 December 31, 2023. 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. development. 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 or more indications, we

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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.

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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 commercializati partner;
- achieving adequate access and reimbursement by government and third-party payors for product candidates that v develop;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, i

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both amount and quality, products and services to support clinical development and the market demand for produc 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 ma 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 $50.0 million of borrowing capacity, after $5.0 million was funded at capacity. At the closing of the Loan Agreement in December 2021, $5.0 million was funded and an additional $20.0 million was funded in November 2022. In December 2023, the Company borrowed the remaining $25.0 million from the Loan Agreement. As of December 31, 2023, the Company's outstanding borrowing under the Loan Agreement was $50.0 million. Our overall leverage and certain obligations and affirmative and negative covenants contained in the related documentation could adversely affect our financial health and business and future operations by limiting our ability to, among other things, satisfy our obligations under the 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

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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 our pivotal Phase 3 trial of atacicept in IgAN into a pivotal Phase 3 trial. IgAN. 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, regulatory authorities, and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote our product candidates before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. 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

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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

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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, participants, 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 t

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extensive negotiation and may vary significantly among different CROs and trial sites;

- obtaining approval from one or more institutional review boards (IRBs); or positive Ethics Committee opinions;
- IRBs refusing to approve or Ethics Committees issuing negative opinions, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial 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 candidate 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 curr 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 performin our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices (GC 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 o regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute

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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 participants in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

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

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

Any delays in our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize 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 participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with IgAN, and LN, the availability of competitive products, and significant competition for recruiting patients participants in clinical trials.

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

Factors that may generally affect patient participant enrollment include:

- the size and nature of the patient population;
- the number and location of clinical sites we enroll;
- competition with other companies for clinical sites or patients;
- the drug background and clinical experience (e.g., safety profile, risk/benefit assessment, mechanism of action, kn

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proof of concept);

- the eligibility and exclusion criteria for the trial;

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- the design of the clinical trial;
- inability to obtain and maintain patient participant consents;

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- 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 w 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 participants may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Our inability to enroll a sufficient number of patients participants for our clinical trials would result in significant delays, which would increase our costs and have an adverse effect on our company.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and human resources. In resources, which has in the past and may in the future cause us to make prioritization and resource allocation decisions. For example, in January 2023, we announced our plan to prioritize and focus our current resources on the advancement of atacicept in IgAN into a our pivotal Phase 3 trial. trial of atacicept in IgAN. As a result, we are delaying delayed 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.

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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 or modify approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate 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.

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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 participant data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our nonclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient participant data become available or as patients participants from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our Class A common stock.

Further, others, including regulatory agencies, authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of our particular program, the approvability or commercialization of our particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

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

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

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The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. The current standard-of-care for IgAN consists of treatment with off-label use of RAAS inhibitors, (ACE including ACE inhibitors or ARBs), and ARBs, to control blood pressure, or steroids with or without other immunosuppressive agents to non-specifically reduce inflammation. SGLT2 inhibitors, including AztraZeneca's AstraZeneca's Farxiga, which is approved for chronic kidney disease, is becoming the standard-of-care in some geographies including the United States. Among emerging therapies, we consider our most direct competitors with respect to atacicept in IgAN to be approved products: the reformulated steroid from 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, Alnylam Pharmaceuticals Corporation, Omeros Corporation, Inc. and Chinook Therapeutics Inc.; Roche/Ionis; and the following companies with programs in Phase 2 of clinical development: Chinook Therapeutics Inc., Reata Pharmaceuticals, Inc., RemeGen Co., Ltd., Ionis Pharmaceuticals, AstraZeneca, HI-Bio. Inc., AstraZeneca, Eladon Pharmaceuticals 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., AstraZeneca, 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, Amgen Inc. 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 is in Phase I 1 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

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products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA or comparable approval for superior products. Many of our competitors have established 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 participant registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

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

Risks related to regulatory approval and other legal compliance matters

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

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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 ou 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 safe 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 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 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

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- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly chang 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

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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 or comparable foreign restriction, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- our pricing and the availability of coverage and adequate reimbursement by third-party payors, including governme 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, professionals, government agencies, regulatory authorities or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from such product candidate and may not be able to achieve or sustain profitability.

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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

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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

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MMF and high-dose CS, and persisted upon initiation of atacicept, which led to trial termination. The drug-related side effects could affect patient participant recruitment or the ability of enrolled patients participants to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

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

Patients Participants in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our nonclinical studies or previous clinical trials. Our product candidates may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory agencies. authorities. 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 participants to the clinical trials, patients participants may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB or Ethics Committee may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could significantly harm our business, financial condition, results of operations and prospects.

Further, toxicities associated with our products not seen during clinical testing may also develop after any approval, if obtained, and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict

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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.

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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,

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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 authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

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

The occurrence of any event or penalty described above may inhibit our ability to commercialize 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

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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. EU. 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, the EU, 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

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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 Orphan medicinal products are eligible for financial product designation entitles an applicant to incentives such as reduction of fees fee reductions or fee waivers, and applicants can benefit from specific regulatory protocol assistance, and scientific advice. Products receiving access to the centralized marketing authorization procedure. Marketing authorization for an orphan designation in the EU can receive 10 years drug leads to a 10-year period of market exclusivity during for the approved therapeutic indication, which time no "similar medicinal product" means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication may be placed on the market. for a period of ten years. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan product can also obtain an additional two years The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the EU for pediatric studies. However, duration of, the 10-year market exclusivity regulatory review and approval process. 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 designation— drug designation, for example if because the product is sufficiently profitable not to justify maintenance of continued market exclusivity. Additionally, In addition, a marketing authorization may be granted to a similar medicinal product for with the same orphan indication at any time if: during the 10 year period of market exclusivity on an individual basis in very select cases, such as with consent from the marketing authorization holder, if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities of the authorized product or if the

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the

second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;

- superior to the first marketing authorization holder for the authorized product consents to a second original orphan medicinal product. A company may voluntarily remove a product application; or
- from the marketing authorization holder for the authorized product cannot supply enough register of orphan medicir product.

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products.

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.

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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). eGFR. 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

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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.

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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.

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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.

In the European Union, upon receiving a marketing authorization, innovative medicinal products are generally entitled to receive eight years of data exclusivity and ten years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the European Union until ten years have elapsed from the initial marketing authorization of the reference product in the European Union. The overall ten-year period may, occasionally, be extended for a further year to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity. In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

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.

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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;

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- 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 study that compares the cost-effectiveness of atacicept, MAU868 or any future product candidates we may develop to other available therapies. The Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 will apply as of January 2025. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In

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general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix

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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

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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 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 and the Consolidated Appropriations Act of 2023, will remain in effect until 2031, 2032, 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

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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 the Medicare drug price negation program is currently subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but it is likely to have a significant impact on the pharmaceutical industry. Further, On February 14, 2023, in response to the Biden administration released an additional administration’s October 2022 executive order, on October 14, 2022, directing HHS to submit released a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test outlining three new models for lowering drug costs for Medicare testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility and Medicaid beneficiaries. improve quality of care. It is unclear whether this executive order or similar policy initiatives the models will be implemented utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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, the IRA, 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

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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 and comparable foreign regulations and guidance may be revised or reinterpreted by the FDA competent authorities in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen 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.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of the Clinical Trials Directive before January 31, 2023, the Clinical Trials Directive will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier

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date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans. In light of the entry into application of the CTR on January 31, 2022, we may be required to transition clinical trials for which we have obtained regulatory approvals in accordance with the CTD to the regulatory framework of the CTR. Transition of clinical trials governed by the CTD to the CTR will be required for clinical trials which will have at least one site active in the E.U. on January 30, 2025. A transitioning application would need to be submitted to the competent authorities of E.U. Member States through the Clinical Trials Information Systems and related regulatory approval obtained to continue the clinical trial past January 30, 2025. This would require financial, technical and human resources. If we are unable to transition our clinical trials in time, the conduct of those clinical trials may be negatively impacted. It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments will determine how closely the UK regulations will align with the CTR. Failure of the UK to closely align its regulations with the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization for the Company's product candidates on the basis of clinical trials conducted in the United Kingdom.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

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

Healthcare providers professionals and third-party payors play a primary role in the recommendation and prescription of our product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare

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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, in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or servic 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 purpos 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 false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the fed 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 statement relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their implementing regulations, also imposes obligations, including mandatory contractual terms, upon certain covered

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healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates a 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, biologi 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 o value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health c professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback and false claims laws, apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by

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governmental third-party payors, including private insurers.

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

related to payments and other transfers of value to physicians and other healthcare providers professionals or marketing expenditures. Some state and foreign laws require biotechnology companies to report information on the pricing of certain drug products. Some state and local laws require the registration of pharmaceutical sales representatives.

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

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians and other healthcare professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to induce or reward improper performance generally is Interactions between pharmaceutical companies and health care professionals are governed by the strict laws, such as national anti-bribery laws of EU Member States, European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and the Bribery Act 2010 physicians' codes of professional conduct. Failure to comply with these requirements could result in the United Kingdom (UK). reputational risk, public reprimands, administrative penalties, fines or imprisonment. Infringement of these related 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 and other healthcare professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of and other healthcare professionals may require prior notification and or approval by the physician's or other health care professional's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. 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

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

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

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) process) personal data and other sensitive information, including proprietary and

confidential business information, trade secrets, intellectual property, information we collect about trial participants in connection with clinical trials, 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 relating to data privacy and on our behalf.security.

Outside the United States, an increasing number of laws, regulations and industry standards apply to govern data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR and United Kingdom's UK GDPR collectively GDRP, (collectively, GDPR), Canada's Personal Information Protection and Electronic Documents Act or PIPEDA, (PIPEDA), Australia's Privacy Act, India's Information Technology Act, and South Korea's Personal Information Protection Act impose strict requirements to the for processing of personal information, data, including clinical trials participants and other individuals. For instance, companies that violate the GDPR can face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests, temporary or definitive prohibitions on data processing and other corrective actions, fines

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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 generally 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

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United States in compliance with law, such as the EEA and UK's standard contractual clauses, these the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework). These mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as the EEA and/or UK) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data to recipients outside Europe out of the EEA for allegedly violating the EU GDPR's cross-border data transfer limitations. Additionally, companies that transfer personal data to recipients outside out of the EEA and/or UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators individual litigants and activist groups.

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

Additionally, in the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements

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for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, or CCPA, as amended by the California Privacy Rights Act (CPRA,=), (collectively, the CCPA), applies to personal information data of consumers, business representatives, and employees who are California residents, and requires covered businesses to provide specific disclosures in privacy notices and honor requests of California residents such individuals to exercise certain privacy rights. The CCPA also provides for civil penalties for noncompliance fines 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 Similar laws are being considered in several other states, as well as at the federal and local levels. These levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Our employees and personnel use generative artificial intelligence (AI) technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

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 Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. All of these

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

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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 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

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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.

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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 global economic 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

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Russia and ongoing military conflicts, related sanctions, changes in U.S.-China relations, 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.

Tensions between the United States and China have increased over the past few years as a result of disputes in areas including trade policy, intellectual property, cybersecurity and data privacy, as well as due to geopolitical conflicts such as the war between Ukraine and Russia. We conduct manufacturing and clinical development activities in China. Any

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unfavorable government policies on cross-border relations or international trade, changes to law, executive orders, tariffs, treaties or trade agreements, or deterioration in U.S.-China relations or international trade may adversely affect the import or export of our drug candidates and materials required for manufacturing or otherwise delay our product development activities, which could in turn have a material adverse effect on our business, financial condition and results of operations.

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

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

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

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we

have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize 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.

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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

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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 educating adequate numbers of physicians to prescribe on the benefits of our current or any future product candidates we may develop and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of 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.

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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 December 31, 2023, we had 46 51 full-time employees, including 31 34 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' authorities' 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;
- improving our operational, financial and management controls, reporting systems and procedures.

In addition, we expect plan to be conducting conduct 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

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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 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

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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, in a region 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) and the Coronavirus Aid, Relief and Economic Security Act of 2020 (CARES 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

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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 December 31, 2023, we had federal and state net operating loss (NOL) carryforwards of $92.3 million $118.9 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 $109.0 million of federal NOL carryforwards as of December 31, 2022 December 31, 2023, 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 taxable 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 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 is limited to 80% of current year taxable income for tax years beginning after December 31, 2020. In addition, at income. At the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. It is generally uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. federal tax laws.

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

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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 nc 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;
- 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 si staff;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals servin 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 impos 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;

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- 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 deliver our instruments and consumables;
- interruption of, or delays in receiving, supplies of atacicept or MAU868 from our contract manufacturing organizatio (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 cont 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

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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

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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 third-party filings, certain sales or off for sale, or other activities that might be legally deemed to be public disclosures) and we might not be aware of suc 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 resu 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 not provide any competitive advantage;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope 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 candidat

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.

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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.

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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 i 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

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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,

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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

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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.

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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 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 pate
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents, for whi 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 fil 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

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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,

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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.

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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

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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.

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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.

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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.

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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

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circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future. For example, recent decisions raise questions regarding the award of patent term adjustment ("PTA") for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in the future and whether patent expiration dates may be impacted.An inability to obtain, enforce, and defend patents covering our proprietary technologies (including 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, took effect on June 1, 2023, which would will 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

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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

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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

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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.

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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

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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

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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.

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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,

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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 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 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

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license rights that are important to our business.

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

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- 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 i 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.***

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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.

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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

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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

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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.

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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
third-party contractors give greater priority to the supply of other products over our product candidates or otherwise
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 term
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly
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
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); epidemics; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have limited 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, other regulatory authorities, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates, or if it withdraws any such approval in the future, we may need to find alternative

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manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. We, or our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or other drugs necessary for the development or commercialization of our product candidates and significantly harm our business, financial condition, results of operations and prospects.

Furthermore, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the

cost of combination therapies 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

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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 associat 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 a 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.

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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 ma elect not to continue or renew development or commercialization programs based on clinical trial results, changes i 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 candid 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 rela 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 diver 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

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- 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.

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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 January 1, 2023 to March 24, 2023 March 20, 2024, has ranged from a low of $5.41 to a high of $28.06. $49.14. 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 ma 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 effor
- developments associated with our license with Ares, an affiliate of Merck KGaA, Darmstadt, Germany, including an 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 relationsh with Novartis or Amplyx;

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- 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;

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- 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

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- 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 ongoing military conflicts, related sanctions, economic slowdowns, recessions, inflation, rising interest rates, and tightening of credit markets and continuing effects of the COVID-19 pandemic. markets.

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

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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

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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 We have in the past and may in the future identify any additional material weaknesses in our internal control over financial reporting, reporting. If we identify any such material weaknesses, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or 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

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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.

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As of December 31, 2022 December 31, 2023, there were 27,800,861 44,452,161 shares of Class A common stock outstanding and held of record by 26 stockholders and no shares of Class B common stock outstanding. 23 stockholders. 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, 2024, 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 April 1, 2024, 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. For example, since our initial public offering, we have completed three follow-on public offerings of our common stock. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise

additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to 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.

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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 inte 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 Oversi Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional informati about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; an
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation ar 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. Based on our current public float, we anticipate that when we re-evaluate our filer status on June 30, 2024, we will determine that we qualify as a “large accelerated filer” for the year ending December 31, 2025.

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

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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. Based on our current public float, we anticipate that when we re-evaluate our smaller reporting company status on June 30, 2024, we will determine that we no longer qualify a smaller reporting company for the year ending December 31, 2025.

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

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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 instit a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential host 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 cas amend or repeal certain provisions of our amended and restated certificate of incorporations or amended and resta 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.

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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, c 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 ari out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our byl (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 resta certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, inclu 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 gover 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

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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), or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruption disruptions of our business operations; reputational harm; additional costs; loss of revenue or profits; and other adverse consequences.

In the ordinary course of business, we and our third-party partners (such as contract research organizations and clinical trial sites) may process proprietary, confidential and sensitive information, including personal information (such as health-related information), intellectual property and trade secrets (collectively, sensitive information).information.

As a result, we and our third party third-party partners (such as contract research organizations and clinical trial sites) are vulnerable to a variety of evolving threats. threats that could cause security incidents. 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 and 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 Some 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 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 and operations, supply chain, and ability to produce, sell and distribute our services.

We and our third party 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

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code (such as viruses and worms), software vulnerabilities, hacking, denial of service attacks, (such as credential stuffing), stuffing, social-engineering attacks (including deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods and other similar threats.

In particular, severe 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, ability to provide our products or services, loss of sensitive 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 risks 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

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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.

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

Any of the previously identified or similar threats could cause a security incident or other interruption 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. products or services. We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and 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, including affected individuals, customers, regulators and investors, of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. Security incidents affecting us If we or our third-party partners (such as contract research organizations and clinical trial sites) could result in experience a security incident or are perceived to have experienced a security incident, we may experience 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) data); substantial remediation costs; litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms.

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 to protect us from or mitigate liabilities arising out of our privacy and security liabilities actually incurred, practices, that such

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coverage will continue to be available to us on economically reasonable terms, or at all, or that any insurer such coverage will not deny coverage as to any pay 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. claims.

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. Additionally, sensitive data of the Company could be leaked, disclosed or revealed as a result of or in connection with our employees', personnel's or vendors' use of generative AI technologies.

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

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

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

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

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur

again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are

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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.

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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 1C. Cybersecurity

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third-party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and sensitive personal data, including of our employees, consultants and clinical trial participants (Information Systems and Data).

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The Chief Financial Officer, Chief Business Officer, Chief Accounting Officer, and Head of Legal form our Cybersecurity Risk Management Committee and help identify, assess and manage the Company's cybersecurity threats and risks. This Cybersecurity Risk Management Committee, which reports to our overall risk management committee, identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment and the Company's risk profile using various methods including, for example: manual and automated tools in certain environments and systems, subscribing to reports and services that identify certain cybersecurity threats, conducting scans of certain threat environments, analyzing reports of certain threats and actors, evaluating certain cybersecurity threats reported to us, and conducting internal and external audits of certain environments and systems.

Depending on the environment and system, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident response plan; incident detection and response tools; risk assessments of certain environments and systems; encryption of certain data; network security for certain environments and systems; access controls for certain environments and systems; data segregation of certain data; access controls; physical security; asset management; third-party systems monitoring; employee cybersecurity training; and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, our Cyber Security Risk Management Committee evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk.

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

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

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report, including the section titled "*Risk Factors—General risk factors—If our information technology systems or data, or those of any of our third-party partners (such as contract research organizations and clinical trial sites), or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; additional costs; loss of revenue or profits; and other adverse consequences.*"

Governance

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Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing the Company's cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our Chief Business Officer, Chief Accounting Officer, and Head of Legal, working closely with our third-party information technology team; the senior staff members of our third-party information technology team have been in business providing services to similarly situated companies in our industry for more than 27 years, including extensive experience addressing complex information technology and cybersecurity matters.

In particular, the Chief Business Officer is responsible for hiring appropriate personnel and third-party vendors, communicating key priorities to relevant personnel, and, in concert with members of the Cybersecurity Risk Management Committee, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy. Our Chief Business Officer, Chief Accounting Officer, and Head of Legal, in consultation with our third-party information technology team, is responsible for maintaining cybersecurity-related budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

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

The audit committee receives regular reports concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them, including during audit committee meetings and other periodic updates. These reports are provided by members of the Company's management team responsible for such reporting, including the Cybersecurity Risk Management Committee. The audit committee also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

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.

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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 March 20, 2024, there were approximately 26 21 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.

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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 As of December 31, 2023, all of the use of net proceeds from our IPO initial public offering have been applied 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.

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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. Report.

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. IgAN is a B cell disorder with a kidney pathology. Our lead product candidate, atacicept, is a an at home, self-administered TACI-Fc fusion protein that blocks both BLyS BAFF and APRIL with best-in-class potential for the treatment of IgAN. The Phase 2b ORIGIN clinical trial evaluating the safety and efficacy of atacicept in patients participants with IgAN completed enrollment in mid-2022 and reported positive results at three timepoints: 24-week topline results in January 2023. Atacicept 2023, 36-week results in June 2023, and 72-week results in January 2024. The trial remained blinded through 36 weeks, after which all participants were eligible for the open label extension portion of the study and received atacicept 150 mg through 96 weeks. At 24 and 36 weeks, respectively, atacicept met its primary endpoint at 24 weeks, achieved statistical significance with statistically significant reductions in the UPCR on atacicept 150 mg, dose group, and showed a trend towards deeper stable eGFR was observed for participants on atacicept, with clinically meaningful and statistically significant difference versus placebo. Participants treated with atacicept demonstrated reductions in proteinuria Gd-IgA1, the autoantigen produced by B cells in patients with available data at 36 weeks, for which full IgAN, and a reduction in hematuria. The improvements in Gd-IgA1, hematuria, UPCR and eGFR represent the quartet of findings consistent with IgAN disease modification. The 72-week open label extension results will read out showed consistent and sustained reductions in the second quarter of 2023. Gd-IgA1, hematuria, UPCR and continued eGFR stabilization. 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 advanced atacicept 150 mg in a pivotal Phase 3 clinical trial in IgAN in the second quarter of 2023. We also believe that atacicept has pipeline in a molecule potential, with potential application in additional indications including SLE and LN, a severe renal manifestation of SLE. We have designed and are planning poised to conduct a Phase 3 clinical trial of atacicept in LN) a severe renal manifestation of SLE, LN, 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 also hold worldwide, exclusive development and commercial rights to advance the development of MAU868, a potentially first-in-class monoclonal antibody to treat reactivated BKV infections. MAU868 is infections, for which we completed 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

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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.

2022. 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 delayed enrollment in the pivotal Phase 3 trial for LN and commitment of resources to the MAU868 program. We believe that our current pipeline programs leverage the deep expertise of our team and have strong potential commercial synergies. We hold global developmental and commercial rights to all of our pipeline molecule.

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. years. We also do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for nonclinical and clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing approval. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

To date, we have funded our operations primarily through proceeds from the sale of shares of our Class A common stock, redeemable convertible preferred stock, debt financing and convertible promissory notes. As of December 31, 2022 December 31, 2023, we had $114.7 million $160.7 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 securities, compared 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

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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 $114.7 million 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 December 31, 2022. 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 $96.0 million and $32.6 million $89.1 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, 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 December 31, 2023, we had an accumulated deficit of $309.1 million, compared to $213.1 million as of December 31, 2022. 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 and MAU868 for the treatment of BK viremia;

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- 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 capa 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 a know-how;
- attract, develop hire and retain additional clinical, scientific, quality control, and manufacturing management and administrative personnel; and
- add clinical, operational, financial and management information systems and personnel, including personnel to sup 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. efforts.

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

We will require substantial additional funding to develop our product candidates and support our continuing operations. Until such time that we can generate significant revenue from product sales or other sources, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which could include income from collaborations, strategic partnerships, or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. Our failure to obtain sufficient funds on acceptable terms when needed could have a

material adverse effect on our business, results of operations or financial condition, including requiring us to have to delay, reduce or eliminate our product development or future commercialization efforts. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts. We cannot provide assurance that we will ever be profitable or generate positive cash flow from operating activities.

Geopolitical and Macroeconomic Developments

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

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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 geopolitical and macroeconomic events, including ongoing military conflict between Ukraine conflicts, inflation and Russia, the actions taken by governments to address inflation and lingering effects of the COVID-19 pandemic, 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 of these factors and other geopolitical and macroeconomic developments described in this Annual Report, 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.affected.

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 during the year ended December 31, 2022 December 31, 2023, 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, or 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 macroeconomic and geopolitical factors may continue to present unique challenges for us.

We continue to believe that our existing cash, and cash equivalents and marketable securities held as of December 31, 2023, 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

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geopolitical and macroeconomic events, such as the COVID-19 pandemic, the ongoing Ukraine-Russia conflict and military conflicts, related sanctions, and any associated recession or depression associated with those events or other events described herein, continue for a prolonged period, our results of operations,

financial condition, liquidity and cash flows could be materially impacted as a result of a lower likelihood of effectively and efficiently developing and successfully commercializing our product candidates.

Results of operations Operations

Comparison of the years ended December 31, 2022 Years Ended December 31, 2023 and 2021 2022

The following table summarizes our results of operations for the years ended December 31, 2022 December 31, 2023 and 2021. 2022.

(dollars in thousands)	Year Ended December 31, 2022	2021	CHANGE AMOUNT	%	Year Ended December 31, 2023	2022	CHANGE AMOUNT	%
Operating expenses:								
Research and development	$ 68,399	$ 22,448	$ 46,950	207%	$ 78,225	$ 68,993	$ 9,232	13%
General and administrative	21,910	11,918	9,992	84%	23,787	21,910	1,877	9%
Total operating expenses	90,903	34,402	56,501	164%	102,012	90,903	11,109	12%
Loss from operations	(90,903)	(34,402)	(56,501)	164%	(102,012)	(90,903)	(11,109)	12%

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Other income (expense):								
Interest income	1,750	15	1,735	*	7,979	1,750	6,229	356%
Interest expense	(992)	(20)	(972)	*	(3,786)	(992)	(2,794)	282%
Other income	1,899	—	1,899	*	1,877	1,899	(22)	(1)%
Change in fair value of non-marketable equity securities	(809)	(892)	83	*	(47)	(809)	762	(94)%
Gain on sale of PNAi technology	—	2,691	(2,691)	*				
Total other income, net	1,848	1,794	54	3%	6,023	1,848	4,175	226%
Loss before provision of income taxes	(89,055)	(32,608)	(56,447)	173%				
	$ (5)	$ (8)	$ (7)	13%				
Loss before provision for income taxes					$ (95,989)	$ (89,055)	$ (6,934)	8%

* Not meaningful

Research and development expensesDevelopment 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 by 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.

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

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

	Year Ended December 31,		CHANGE	
(dollars in thousands)	**2022**	**2021**	**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 %

	Year Ended December 31,		CHANGE	
(dollars in thousands)	**2023**	**2022**	**AMOUNT**	**%**
Direct research and development expenses				
Contract drug manufacturing	$ 35,049	$ 27,587	$ 7,462	27 %

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Clinical trial expenses	19,611	20,534	(923)	(4)%
Consulting and professional services	5,648	5,431	217	4%
License and milestone obligations	—	3,661	(3,661)	(100)%
Indirect research and development expenses				
Compensation and related benefits	16,623	10,987	5,636	51%
Facilities and other	1,294	793	501	63%
Research and development expenses	$ 78,225	$ 68,993	$ 9,232	13%

Research and development expenses increased by $46.5 million $9.2 million, or 207% 13%, to $78.2 million in the year ended December 31, 2023, from $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 related to manufacturing drug supply for clinical trials. Contract drug manufacturing expenses increased by $25.4 million $7.5 million primarily due to production of atacicept drug supply for our ORIGIN 3 clinical trials. Clinical trial expenses increased by $13.8 million primarily due to startup and development of the COMPASS trial, as well as increased expenses for the ORIGIN trial as enrollment rates increased in 2022. an atacicept auto-injector combination product. 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, $5.6 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 growth 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 Clinical trial expenses decreased by $0.9 million due to Amplyx a decrease in expenses for the purchase of MAU868 COMPASS trial in 2023 following our announcement to delay enrollment in this trial to prioritize and accrued $2.0 million of milestone expense in connection with the purchase.focus resources on our ORIGIN 3 clinical trial.

We expect our research and development expenses to increase in future periods as we initiate continue to support our ORIGIN-3 ongoing ORIGIN 3 Phase 3 clinical trial and prepare to seek regulatory approval of atacicept in IgAN, continue our COMPASS Phase 3 trial and if we resume development of atacicept in LN and develop other indications or product candidates.

General and administrativeAdministrative Expenses

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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		Year Ended December 31,		CHANGE	
(dollars in thousands)	2022	2021	AMOUNT	%	2023	2022	AMOUNT	%
General and administrative	$ 21,910	$ 11,918	$ 9,992	84%	$ 23,787	$ 21,910	$ 1,877	9%

General and administrative expenses increased by $10.0 million $1.9 million, or 84% 9%, to $23.8 million in the year ended December 31, 2023, from $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 $4.6 million of payroll and related expenses, including stock-based compensation, an increase as a result of $2.3 million increased general and administrative employee headcount, partially offset by a decrease of rent and facilities expense primarily due to $1.2 million in legal expenses, 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 decrease of $1.6 million $0.9 million in insurance premium expenses, an increase and a decrease 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 Income, Net

	Year Ended December 31,		CHANGE		Year Ended December 31,		CHANGE	
(dollars in thousands)	2022	2021	AMOUNT	%	2023	2022	AMOUNT	%
Other income, net	$ 1,848	$ 1,794	$ 54	(3)%	$ 6,023	$ 1,848	$ 4,175	226%

Other income, net, was increased by $4.2 million, or 226%, to $6.0 million in the year ended December 31, 2023, from $1.8 million in each of the years ended December 31, 2022 and 2021. In the year ended December 31, 2022, primarily due to an increase of $6.2 million in interest income increased by $1.7 million from investments in marketable securities. In addition, other expense recognized due to higher yields on marketable the change in fair value of non-marketable equity securities investments and we recognized $1.9 million of other was $0.8 million lower in the current year. The increase in

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interest income from a sublease due to changes in lease accounting. These increases were partly was partially offset by a $1.0 million $2.8 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.

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Oxford Loan Agreement, under which an additional $20.0 million and $25.0 million was funded in November 2022 and December 2023, respectively.

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 December 31, 2023, we have raised aggregate net cash proceeds of $295.0 million approximately $427.3 million from the issuance and sale of redeemable convertible preferred stock, convertible notes Class A and common stock, and proceeds from 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.

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In February 2024, we completed a follow-on public offering and issued 9,274,194 shares of common stock for net proceeds of approximately $269.6 million, after deducting underwriting discounts and commissions and offering related expenses.

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 administrative and management personnel, and incur additional expenses associated with operating as a public company. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our clinical development activities and our product candidate portfolio. 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

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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 December 31, 2023, we had cash, cash equivalents and marketable securities balances of $114.7 million $160.7 million, as compared to $79.7 million $114.7 million as of December 31, 2021 December 31, 2022. We expect believe, based on our current operating plan, that our existing cash, and cash equivalents and marketable securities as of December 31, 2023, and the net proceeds from our February 2024 follow-on public offering, will be sufficient to fund our operating expenses operations 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 Cash Flows

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

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(dollars in thousands)	Year Ended December 31, 2023	2022
Net cash used in operating activities	$ (92,181)	$ (67,596)
Net cash used in investing activities	(39,431)	(70,552)
Net cash provided by financing activities	133,541	101,933
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 1,929	$ (36,215)

Operating Activities

For the year ended December 31, 2023, we used $92.2 million of cash in operating activities, attributable to a net loss of $96.0 million, partially offset by non-cash charges of $9.7 million and a net change in our net operating assets and liabilities of $5.9 million. Non-cash charges primarily consisted of $11.5 million of stock-based compensation, $4.1 million of depreciation, amortization and accretion, and a $2.2 million reduction in the carrying amount of operating lease right-of-use assets. The change in our net operating assets and liabilities was primarily due to a decrease of $2.6 million in operating lease liabilities, a decrease of $2.2 million in accrued and other current liabilities and a decrease of $0.9 million in accounts payable.

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, partially offset by non-cash charges of $14.7 million and a net change in our net operating assets and liabilities of $6.7 million. Non-cash charges primarily consisted of $8.9 million of non-cash stock based compensation expense, $0.8 million of depreciation, amortization, and accretion, $2.3 million reduction in the carrying amount of operating lease right-of-use assets, and $3.7 million of

non-cash license and milestone expenses. The change in our net operating assets and liabilities was primarily due to 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, a $7.0 million increase in accrued and other current liabilities.

Investing Activities

For the year ended December 31, 2023, our investing activities used $39.4 million of cash, primarily resulting from the purchase of short-term marketable securities, less sales and maturities of short-term marketable securities during the year.

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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.

Financing Activities

For the year ended December 31, 2023, our financing activities provided $133.5 million of cash resulting from $115.0 million gross proceeds received from our February 2023 follow-on offering, $24.7 million of net cash proceeds from the issuance of debt to Oxford and $1.1 million proceeds from exercise of stock options and issuance of shares under our employee stock purchase plan, less $7.3 million offering costs related to our follow-on offering, including underwriting discounts and commissions.

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 February 2022 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.

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 our headquarters 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 California, which was amended 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

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(dollars in thousands)	December 31, 2022	December 31, 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.

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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 remaining $25.0 million was funded on December 22, 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%

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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

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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 Effective January 29, 2024, we suspended and terminated the prospectus related to the sale of December 31, 2022, no shares of Class A common stock had been issued or sold under the ATM. As a result, we will not make any sales of common stock pursuant to the ATM unless and until a new prospectus, prospectus supplement or registration statement is filed.

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.

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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. Based on our current public float, we anticipate that when we reevaluate our filer status on June 30, 2024, we will determine that we qualify as a “large accelerated filer” for the year ending December 31, 2025.

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. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent

assets and liabilities, at the date of the financial statements, as well as expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates.

While our significant accounting policies are described in the notes to our financial statements, we believe that the following critical accounting policies and estimates are most important to understanding and evaluating our reported financial results.

Research and development contract costs, and related prepaid and accrued balances

We enter into various research and development and other agreements with commercial firms, researchers and others for 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

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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 commo 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

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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.

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VERA THERAPEUTICS, INC.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the 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 December 31, 2023 and December 31, 2021 December 31, 2022, 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 December 31, 2023, 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 December 31, 2023 and December 31, 2021 December 31, 2022, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022 December 31, 2023, 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

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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 26, 2024

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	—

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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

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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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 45,681	$ 43,459
Marketable securities	115,035	71,194
Prepaid expenses and other assets, current	11,307	11,045
Total current assets	172,023	125,698
Restricted cash, noncurrent	—	293
Property and equipment, net	92	51
Operating lease right-of-use assets	2,949	5,173
Prepaid expenses and other assets, noncurrent	471	162
Non-marketable equity securities	11	58
Total assets	$ 175,546	$ 131,435
Liabilities and stockholders' equity		
Current liabilities:		

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Accounts payable	$ 11,118	$ 11,991
Operating lease liabilities	2,436	2,645
Accrued expenses and other liabilities, current	8,749	10,964
Total current liabilities	22,303	25,600
Long-term debt	49,877	24,810
Operating lease liabilities, noncurrent	1,395	3,831
Accrued expenses and other liabilities, noncurrent	286	286
Total liabilities	73,861	54,527
Stockholders' equity		
Preferred stock, $0.001 par value; 10,000,000 authorized as of December 31, 2023 and December 31, 2022; no shares issued and outstanding as of December 31, 2023 and December 31, 2022	—	—
Class A common stock, $0.001 par value; 500,000,000 shares authorized as of December 31, 2023 and December 31, 2022; 44,452,161 and 27,800,861 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	44	28
Additional paid-in capital	410,492	290,216
Accumulated other comprehensive gain (loss)	251	(224)
Accumulated deficit	(309,102)	(213,112)
Total stockholders' equity	101,685	76,908
Total liabilities and stockholders' equity	$ 175,546	$ 131,435

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

VERA THERAPEUTICS, INC.

Statements of Redeemable Convertible Preferred Stock Operations and Stockholders' Equity Comprehensive Loss

(in thousands, except share and per share amounts)

	Accumu	Total

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	Redeemable Convertible Preferred Stock		Class A Common Stock		Class B Common Stock		Additional Paid-in	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Capital			
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										

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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**

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 78,225	$ 68,993
General and administrative	23,787	21,910
Total operating expenses	102,012	90,903
Loss from operations	(102,012)	(90,903)
Other income (expense):		
Interest income	7,979	1,750
Interest expense	(3,786)	(992)
Other income	1,877	1,899
Change in fair value of non-marketable equity securities	(47)	(809)
Total other income	6,023	1,848
Loss before provision for income taxes	(95,989)	(89,055)
Provision for income taxes	(1)	(1)
Net loss	$ (95,990)	$ (89,056)
Other comprehensive loss:		
Change in unrealized gain (loss) on marketable securities	251	(224)

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Comprehensive loss	$ (95,739)	$ (89,280)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.25)	$ (3.35)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	42,707,072	26,570,676

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

VERA THERAPEUTICS, INC.

Statements of Cash FlowsStockholders' Equity

(in thousands)thousands, except share amounts)

	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

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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

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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

	Class A Common Stock		Class B Common Stock		Additional Paid-in	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital			
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**

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Issuance of common stock from underwritten follow-on offering, net of offering costs	16,428,572	16	—	—	107,727	—	—	107,743
Issuance of Class A common stock upon exercise of options	111,927	—	—	—	781	—	—	781
Issuance of Class A common stock upon vesting of restricted stock units	66,321	—	—	—	—	—	—	-
Issuance of Class A common stock pursuant to employee stock purchase plan	44,480	—	—	—	275	—	—	275
Stock-based compensation	-	—	—	—	11,493	—	—	11,493
Unrealized gain on marketable securities	—	—	—	—	—	475	—	475
Net loss	—	—	—	—	—	—	(95,990)	(95,990)
Balances as of December 31, 2023	**44,452,161**	**$ 44**	**—**	**$ —**	**$ 410,492**	**$ 251**	**$ (309,102)**	**$ 101,685**

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

VERA THERAPEUTICS, INC.

Statements of Cash Flows

(in thousands)

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (95,990)	$ (89,056)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and accretion	(4,086)	(846)
Reduction in the carrying amount of operating lease right-of-use assets	2,224	2,271

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Stock-based compensation	11,493	8,887
Issuance of Class A common stock for licensing payment, net of costs	—	3,592
Change in fair value of non-marketable equity securities	47	809
Changes in operating assets and liabilities:		
Prepaid expense and other current assets	173	(8,182)
Other assets	(309)	(111)
Accounts payable	(873)	10,606
Accrued and other current liabilities	(2,215)	7,036
Operating lease liabilities	(2,645)	(2,602)
Net cash used in operating activities	(92,181)	(67,596)
Cash flows from investing activities		
Purchase of property and equipment	(63)	(62)
Purchase of marketable securities	(224,930)	(148,490)
Proceeds from maturities of marketable securities	176,019	78,000
Proceeds from sale of marketable securities	9,543	—
Net cash used in investing activities	(39,431)	(70,552)
Cash flows from financing activities		
Proceeds from exercise of stock options and employee stock purchase plan	1,056	2,083
Proceeds from borrowings, net of costs	24,741	19,816
Proceeds from issuance of Class A common stock in follow-on offering	115,000	86,131
Payment of costs and underwriting discounts and commissions related to follow-on offering	(7,256)	(6,097)
Net cash provided by financing activities	133,541	101,933
Net increase (decrease) in cash and cash equivalents and restricted cash	1,929	(36,215)
Cash, cash equivalents and restricted cash, beginning of year	43,752	79,967
Cash, cash equivalents and restricted cash, end of year	$ 45,681	$ 43,752
Reconciliation of cash and cash equivalents and restricted cash to the balance sheets		
Cash and cash equivalents	45,681	43,459
Restricted cash	—	293
Total cash and cash equivalents and restricted cash	$ 45,681	$ 43,752
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 3,352	$ 895
Cash paid for operating leases	$ 3,000	$ 2,734
Issuance of Class A common stock in payment of licensing fees	$ —	$ 2,000

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

VERA THERAPEUTICS, INC.

Notes to 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 15,464,776shares of Class A common stock and309,238 shares of Class B common stock.

Follow-on Public Offering

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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 $213.1 309.1 million as of December 31, 2022 December 31, 2023. The Company had cash, cash equivalents and marketable securities of $114.7 160.7 million as of December 31, 2022 and has access to additional debt financing under a credit facility (see Note 8) December 31, 2023. 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 December 31, 2023 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.

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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

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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

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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 authorities prior to commercial sales in their respective jurisdictions. There can be no assurance

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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. Marketable debt securities and with stated maturities of three months or less from the date of purchase are classified as available-for-sale cash equivalents and those with stated maturities of greater than three months as marketable securities and are carried at estimated fair values as determined based on quoted prices in active markets. Management

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the balance sheet. The Company determines the appropriate classification of its marketable debt securities at the time of purchase and reevaluates such designation periodically. Short-term marketable securities have maturities less than one year as of purchase. The Company has the balance sheet date. Long-term marketable securities have ability, if necessary, to liquidate its investments to meet its liquidity needs in the next 12 months, without significant penalty. Accordingly, those investments with contractual maturities greater than one year from the date of purchase are classified as of current assets on the accompanying balance sheet date. Unrealized sheets. All marketable debt securities are classified as available-for-sale and are reported at estimated fair value, with unrealized gains and losses are reported as a component of recorded in accumulated other comprehensive loss. loss within stockholders' equity. Interest, amortization and accretion of purchase premiums and discounts on marketable debt securities are included in other income (expense), 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

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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

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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 December 31, 2023 and 2021. 2022.

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

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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 12 of the fair value hierarchy.

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The Company's non-marketable equity securities (see Note 6) 5) 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 December 31, 2023, and December 31, 2021 December 31, 2022, the Company held $42.5 44.7 million and $73.8 42.5 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 stockholders' equity and are excluded from net loss. For the twelve months year ended December 31, 2022 December 31, 2023, 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,

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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 judgments about the inputs used in the calculations, such as the fair value of the common stock, expected term, expected volatility of the Company's common stock, risk-free interest rate and expected dividend yield. The valuation of restricted stock awards is measured by the fair value of the Company's Class A common stock on the date of the grant.

For all stock options granted, the Company calculated the expected term using the simplified method (derived from the average midpoint between the weighted average vesting period and the contractual term of the award) 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 using the market closing price on the date of grant.

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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.

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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

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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 Not Yet Adopted

In June 2022, the FASB issued ASU2022-03, *ASU 2022-03, Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*. The Restrictions. This 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 annual periods beginning after December 15, 2023, with early adoption permitted. The Company is currently evaluating does not expect that the impact the adoption of this standard may will have a material impact on its financial statements and related disclosures.

In June 2016, December 2023, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses 2023-09, Improvements to Income Tax Disclosures (Topic 326): Measurement of Credit Losses on Financial Instruments*740). The objective of the standard is to provide ASU requires disaggregated information about expected credit losses a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is also permitted for annual financial instruments at each reporting date and to change how other-than temporary impairments on investment securities are recorded. The guidance became

effective statements that have not yet been issued or made available for issuance. This ASU will result in the Company beginning on January 1, 2023. The Company does not anticipate required additional disclosures being included in the implementation will have a material impact on its Company's financial statements upon adoption.

3. OTHER FINANCIAL STATEMENT INFORMATION

Prepaid Expense Expenses and Other Current Assets

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

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
Prepaid clinical trial and drug manufacturing costs	$ 8,487	$ 320	$ 6,480	$ 8,487

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Prepaid insurance	998	1,193	597	998
Prepaid equity financing costs	490	275	410	490
Prepaid rent	247	219	257	247
Prepaid audit fees	—	123		
Prepaid software costs			237	104
Prepaid recruiting fees	—	253	109	—
Other	823	480	3,217	719
Total prepaid expenses and other current assets	$ 11,045	$ 2,863	$ 11,307	$ 11,045

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

	December 31, 2023	December 31, 2022
Accrued payroll	$ 3,932	$ 3,217
Accrued clinical and drug manufacturing expenses	2,213	4,334
Related party payable	1,926	2,780
Accrued legal fees	59	338
Accrued expenses and other	619	295
Total accrued expenses and other current liabilities	$ 8,749	$ 10,964

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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) 11).

4. NEUBASE ASSET SALECASH EQUIVALENTS AND MARKETABLE SECURITIES

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 Cash equivalents are classified within Level 2 1 in the fair value hierarchy because the Company uses quoted market prices to the extent available

or alternative pricing sources to determine fair value. Marketable debt securities are classified as Level 2 because they are valued using fair value from an independent pricing service, which may use quoted market prices for identical or comparable instruments or valuations using observable market data. The Company's marketable debt securities have maturities of less than one year are accounted for as of the balance sheet date.available-for-sale securities.

Unrealized gains and losses are reported as a component of other comprehensive loss. Fair value of the debt securities totaled were $115.0 million and $71.2 million as of December 31, 2023 and December 31, 2022. The Company did not hold marketable debt securities as of December 31, 2021. , respectively.

The following table summarizes the unrealized gains and losses in presents the Company's investments in marketable securities financial assets measured at fair value on a recurring basis by level within the fair value hierarchy *(in thousands)*:

		December 31, 2023			
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	Level 1	$ 44,650	$ -	$ -	$ 44,650
U.S. Government bonds	Level 2	63,619	70	(6)	63,683

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U.S. Government agency securities	Level 2	19,665	7	(14)	19,658
Corporate debt securities	Level 2	31,500	194	-	31,694
Total cash equivalents and marketable securities		$ 159,434	$ 271	$ (20)	$ 159,685

		December 31, 2022			
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	Level 1	$ 42,495	$ -	$ -	$ 42,495
U.S. Government bonds	Level 2	71,418	1	(225)	71,194
Total cash equivalents and marketable securities		$ 113,913	$ 1	$ (225)	$ 113,689

	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

Marketable debt securities that had been in unrealized loss positions as of December 31, 2023 and December 31, 2022 were in an unrealized loss position for less than 12 months. Unrealized losses from marketable debt securities are primarily attributable to changes in interest rates. Management does not believe any remaining unrealized losses represent impairments based on evaluation of available evidence.

The following table classifies the estimated fair value of investments in available-for-sale marketable debt securities by effective contractual maturity dates *(in thousands)*:

	December 31, 2023
Due within one year	$ 93,845
Due after one year to two years	21,190
Total marketable securities	$ 115,035

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6. 5. NON-MARKETABLE EQUITY SECURITIES

The Company has an investment in NeuBase common stock with restrictions on the sale or transfer Fair value of the shares. Fair value non-marketable equity securities 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 following table summarizes the value of the non-marketable equity securities as of December 31, 2022, is summarized below using the measurement alternative *(in thousands)*. :

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

	December 31, 2023	December 31, 2022
Initial cost	$ 1,759	$ 1,759
Cumulative net fair value loss	(1,748)	(1,701)
Carrying value of non-marketable equity securities	$ 11	$ 58

7. 6. LEASES

Net lease cost recognized for 2022 2023 is summarized as follows *(in thousands)*:

	Year Ended December 31, 2022	Year Ended December 31, 2021	Year Ended December 31, 2023	Year Ended December 31, 2022
Operating lease cost	$ 2,378	$ 24	$ 2,577	$ 2,378
Sublease income	(1,928)	—	(1,928)	(1,928)
Net lease cost	$ 450	$ 24	$ 649	$ 450

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As of December 31, 2022 December 31, 2023, 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	$ 3,022
2025	1,880	1,880
2026	-	-
2027	-	-
Total minimum lease payments	7,901	4,902
Less: Imputed interest	(1,425)	(1,071)
Present value of operating lease liabilities	6,476	3,831
Less: Current portion of operating lease liabilities	(2,645)	(2,436)
Non-current operating lease liabilities	$ 3,831	$ 1,395

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 December 31, 2023, under the terms of the sublease agreement, the Company is entitled to receive future annual sublease payments as follows (in*(in thousands)*:

2023	$ 1,910	
2024	1,954	$ 1,954
2025	1,496	1,496
Total sublease payments	$ 5,360	$ 3,450

The subtenant of the leased facilities in South San Francisco, California, has disclosed in public filings that there is substantial doubt regarding its ability to continue as a going concern. As tenant, the Company remains responsible for minimum lease commitments of $6.7 4.3 million as of December 31, 2022 December 31, 2023, on the South San Francisco facilities.

In July 2022, November 2021, the Company entered into a lease amendment to increase the amount of leased agreement that was amended in July 2022 for its headquarters office space in its Brisbane, California,

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headquarters. California. The lease includes term is through November 2024 with renewal options for the Company.

As of December 31, 2022 December 31, 2023, the Company had not executed any finance leases that were yet to commence.

As of December 31, 2022 December 31, 2023, the weighted-average remaining operating lease term was 2.5 1.5 years and the weighted-average discount rate was 9.0 9.1% 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. 7. NOTE PAYABLE

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

December 31, 2022			December 31, 2021			December 31, 2023		December 31, 2022	
Maturity	Effective Interest Rate	Amount	Effective Interest Rate	Amount	Maturity	Effective Interest Rate	Amount	Effective Interest Rate	Amount

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Collateralized note 2021-12	2026	13.57%	$ 0	9.53%	$ 0	2027	14.73%	$ 5,000	13.57%	$ 5,000
Collateralized note 2022-11	2026	13.74%	0		—	2027	14.87%	20,000	13.74%	20,000
Collateralized note 2023-12						2027	15.37%	25,000		—
Total borrowings			0		0			50,000		25,000
Less: Debt issuance costs			(0)		(7)			(123)		(190)
Net carrying amount of debt			$ 0		$ 3			$ 49,877		$ 24,810

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") Loan Agreement) 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. Agreement. Among other changes, the amendment extended the scheduled expiration of the Loan Facility Agreement to December 2023 and modified the reference rate from the London Interbank Offered Rate ("LIBOR") (LIBOR) to the Secured Overnight Financial Rate ("SOFR") (SOFR). In conjunction with the amendment, the Company borrowed an additional $20.0 million from the Loan Facility with Agreement. In December 2023, the Company borrowed the remaining $25.0 million remaining capacity available in minimum draws of $5.0 million.

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from the Loan Agreement. As of December 31, 2022 December 31, 2023, the Company's outstanding borrowing under the Loan Facility Agreement was $25.0 50.0 million. The variable interest rate on

In March 2023, upon achievement of a clinical data milestone, the drawn amount is adjusted SOFR plus 825 basis points, subject Company elected to exercise a per annum floor rate borrower option to extend the maturity of 8.25%. The the outstanding loan matures in December 2026, which may be extended by 12 months, subject from December 2026 to certain clinical data milestones. December 2027. The Loan Facility provides for interest-only payments to December 2025, which may be payment period was also extended by 12 months to 2026 if the final maturity date is extended. December 2026. 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 7% (or 7.0% if the maturity date is extended) of the aggregate principal amount of the loan.

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 Facility Agreement 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 Agreement and the loan is secured by the Company's assets. The Loan Facility Agreement is available for working capital, capital expenditures, and other general corporate purposes.

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

2023	—	
2024	—	$ —
2025	—	—
2026	25,000	—
Total accrued expenses and other current liabilities	$ 25,000	
2027		50,000
Total long-term debt		$ 50,000

9. 8. COMMON STOCK

As of December 31, 2022 December 31, 2023, 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 December 31, 2023, no cash dividends have been declared or paid.

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In February 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.

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 December 31, 2023, 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. parties (see Note 11).

In February 2023, the Company completed a follow-on public offering pursuant to which the Company issued and sold 16,428,572 shares of its Class A common stock at a public offering price of $7.00 per share, including 2,142,857 shares of Class A common stock pursuant to the full exercise of the underwriters' option to purchase additional shares.

10. 9. 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 429,934 707,942 and 3,260,753 4,650,796 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 December 31, 2023, there were 945,108 288,775 shares available for issuance under the 2021 EIP.

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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)	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				
Outstanding as of December 31, 2022					3,821,787	$ 10.30	8.51	$ 35,872
Granted	1,319,802	18.98			2,291,000			
Exercised	(405,140)	4.42			(111,927)			
Cancelled and forfeited	(17,396)	17.52			(238,624)			
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				

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Vested and expected to vest as of December 31, 2022	3,821,787	10.30	8.51	35,872

Outstanding as of December 31, 2023	5,762,236	$	9.42	7.66	$	39,197
Options exercisable as of December 31, 2023	2,611,696	$	8.45	7.10	$	20,112
Vested and expected to vest as of December 31, 2023	5,762,236	$	9.42	7.66	$	39,197

The aggregate intrinsic value of stock options exercised during the year ended December 31, 2022 December 31, 2023 was $5.8 1.0 million. The weighted-average grant date fair value of options granted during the year years ended twelve months ended December 31, 2022 December 31, 2023 and 2021, 2022, was $13.63 5.92 per share and $9.36 13.63 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 December 31, 2023, 15,328 59,808 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 Stock-based compensation expense has been recorded for the twelve months year ended December 31, 2022. December 31, 2023, was $0.2 million.

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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 years ended December 31, 2022 December 31, 2023 and 2021 2022 *(in thousands)*.

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Research and development	$ 4,592	$ 915	$ 4,845	$ 4,592
General and administrative	4,295	2,097	6,648	4,295
Total stock-based compensation expense	$ 8,887	$ 3,012	$ 11,493	$ 8,887

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Employees	$ 5,975	$ 2,605	$ 10,494	$ 5,975
Nonemployees	2,912	407	999	2,912
Total stock-based compensation expense	$ 8,887	$ 3,012	$ 11,493	$ 8,887

As of December 31, 2022 December 31, 2023, the Company had $20.3 22.0 million of unrecognized stock-based compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.5 years.

The fair value of stock options granted during the year years ended December 31, 2022 December 31, 2023 and 2021 2022, was estimated using the Black-Scholes option pricing model based on the following weighted average assumptions.

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Expected term (in years)	5.5 – 6.1	5.5 – 6.1	5.5 – 6.1	5.5 – 6.1
Expected volatility	75.8% – 77.6%	75.4% – 76.8%	79.5% – 80.5%	75.8% – 77.6%
Risk-free rate	1.76% – 4.2%	0.6% – 1.3%	3.4% – 4.7%	1.76% – 4.2%
Dividend yield	—	—	—	—

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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 December 31, 2023.

	NUMBER OF SHARES	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE PER SHARE	NUMBER OF SHARES	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE PER SHARE
Unvested balance at December 31, 2021	77,719	$ 23.99		
Unvested balance at December 31, 2022			204,000	$ 18.37
Granted	215,750	18.38	—	—
Vested	(77,719)	23.99	(66,321)	18.36
Cancelled and forfeited	(11,750)	18.60	(6,000)	18.60
Unvested balance at December 31, 2022	204,000	18.37		
Unvested balance at December 31, 2023			131,679	$ 18.36

For the twelve months year ended December 31, 2022 December 31, 2023, the Company recognized $2.3 1.6 million of stock-based compensation for RSUs.

As of December 31, 2022 December 31, 2023, the Company had $3.3 1.5 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 0.8 years.

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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. 10. 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 $142,000 and $95,000 to the plan for the twelve months years ended December 31, 2022. There were no employer contributions under this plan during 2021. December 31, 2023 and 2022, respectively.

12. 11. 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 paid a non-refundable license issue fee to Ares in the form of 22,171,553 shares of Series C redeemable convertible preferred stock valued at $13.1 million, resulting in Ares becoming a related party to the Company. The Series C redeemable convertible preferred stock had a deemed issuance price subsequently converted into 1,913,501 shares of $0.5918 per share, or $13.1 million Class A common stock in connection with the aggregate.

IPO.

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.

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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 2.8 million and $1.7 4.5 million to Aresfor these services during the twelve months years ended December 31, 2022, December 31, 2023 and December 31, 2021, 2022, 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 would be obligated to pay Ares a percentage ranging from the mid-single-digit to the low double-digits of specified sublicensing income received.

Amplyx Pharmaceuticals, Inc.

In December 2021, the Company entered into an asset purchase agreement (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.

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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 year ended December 31, 2022.

As of December 31, 2022 December 31, 2023, 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. 12. INCOME TAXES

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

	December 31,		December 31,	
	2022	2021	2023	2022
Domestic	$ (89,055)	$ (32,608)	$ (95,989)	$ (89,055)
Foreign	—	—	—	—

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Loss before income taxes	$ (89,055)	$ (32,608)	$ (95,989)	$ (89,055)

Provision for Income Taxes

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

	December 31,		December 31,	
	2022	2021	2023	2022
Current:				
Federal	$ —	$ —	$ —	$ —
State	1	1	1	1
Total current	1	1	1	1
Total deferred	—	—	—	—
Provision for income taxes	$ 1	$ 1	$ 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,		December 31,	
	2022	2021	2023	2022
Tax on U.S. statutory rate on income before income taxes	$ (18,702)	$ (6,847)	$ (20,158)	$ (18,702)
State taxes	3,583	(5,405)	(489)	3,583
State valuation allowance	(3,582)	5,405	490	(3,582)
Federal valuation allowance	19,643	6,600	21,250	19,643
Tax credits	(710)	(209)	(1,598)	(710)
Other	(231)	457	506	(231)
Provision for income taxes	$ 1	$ 1	$ 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

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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	$ —	$ —

	December 31,	
	2023	2022
Deferred tax assets:		
Federal and state NOL carryforward	$ 27,539	$ 21,945
Research and other credits	6,051	3,762
Capitalized R&D	25,264	12,731

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Fixed assets	3	2
Reserves and accruals	755	519
Stock based compensation	2,978	1,430
Other intangibles	8,313	8,583
Other DTA	384	402
Lease liability	804	1,360
Total gross DTA	72,091	50,734
Less: valuation allowance	(71,372)	(49,648)
Total deferred tax assets	719	1,086
Deferred tax liabilities:		
Right of use	(619)	(1,086)
Other DTL	(100)	—
Total gross DTL	(719)	(1,086)
Net deferred tax assets	$ —	$ —

As of December 31, 2022 December 31, 2023, the Company has federal and state net operating loss carryforwards of $92.3 118.9 million and $35.7 million, respectively, of which $0.1 10.2 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 $82.1 109.0 million of federal net operating loss carryforwards as of December 31, 2022 December 31, 2023 that does not expire as a result of recent tax law changes. The Company has $ $53.3 .4 million of federal research and development tax credit carryforwards, which begin to expire in the year 2037. The Company has $1.4 2.2 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 71.4 million and $34.5 49.6 million for the year ended December 31, 2022 December 31, 2023 and 2021 2022 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)*:

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	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Beginning balance	$ 668	$ 663	$ 941	$ 668
Additions based on tax positions related to prior year	19	—	—	19
Decreases based on tax positions related to prior year	(11)	(97)	—	(11)
Additions based on tax positions related to current year	265	102	572	265
Ending balance	$ 941	$ 668	$ 1,513	$ 941

The Company accounts for income taxes in accordance with authoritative accounting guidance which states the impact of an uncertain income tax position is recognized at the largest amount that is “more likely than not” to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained. None of these uncertain tax positions will impact the Company’s effective tax rate if assessed. The Company’s policy is to classify interest and penalties associated with unrecognized tax benefits as income tax expense. The Company 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 December 31, 2023 and 2021. 2022. 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

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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. 13. COMMITMENTS AND CONTINGENCIES

Facilities LeasesLegal Proceedings

In November 2020, The Company believes that there are no actions pending which would have a material adverse effect on its results of operations, financial condition, or cash flows.

Indemnifications

As of December 31, 2023, the Company entered into did not have any material indemnification claims that were probable or reasonably possible, and consequently no related liabilities have been recorded.

Employee Agreements

The Company has signed employment agreements with certain key employees pursuant to which, if their employment is terminated following a non-cancellable sublease agreement for the facilities in South San Francisco, California, under the terms change of which control of the Company, is the employees are entitled to receive $ certain benefits, including severance and accelerated vesting of equity incentives.

7.9 Development and Manufacturing Services Agreements

million The Company enters into development and manufacturing contracts with vendors in sublease payments over the term conduct of our business. Contracts with these vendors may be terminated at the sublease, which ends concurrently Company's option, with the original lease in September 2025. As tenant, varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company remains responsible would be obligated to pay for the minimum lease commitment on products or services that had been provided or received at the facilities.

In November 2021, time the Company entered a lease for approximately 4,900 square feet termination became effective, and potentially additional compensation based upon lead time remaining between the date of office space for a term notice 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, cancellation 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. manufacturing run.

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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. 14. 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,		Year Ended December 31,	
	2022	2021	2023	2022
Class A common stock options issued and outstanding	3,821,787	2,924,521	5,762,236	3,821,787
Unvested restricted stock units	204,000	—	131,679	204,000
Total	4,025,787	2,924,521	5,893,915	4,025,787

17. 15. 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 12.11.

18. 16. SUBSEQUENT EVENTS

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Effective January 29, 2024, the Company suspended and terminated the prospectus (the ATM Prospectus) related to the sale of its Class A common stock in an “at-the-market” offering pursuant to the terms of the Sales Agreement (see Note 8). As a result, the Company will not make any sales of its Common Stock pursuant to the Sales Agreement unless and until a new prospectus, prospectus supplement or registration statement is filed. Deferred costs of $0.3 million were recognized as general and administrative expense upon termination of the ATM Prospectus.

On February 6, 2023 February 1, 2024, the Company completed a follow-on public offering pursuant to which the Company issued and sold 16,428,572 9,274,194 shares of its Class A common stock at an offering price of $7.00 31.00 per share, including the exercise in full by the underwriters of their option to purchase an additional 2,142,857 1,209,677 shares of Class A common stock. The Company received total net proceeds of approximately $107.6 269.6 million, after deducting underwriting discounts and commissions of $6.9 17.3 million, and offering costs of approximately $0.5 0.7 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. million.

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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 December 31, 2023, 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

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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 December 31, 2023.

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 December 31, 2023, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None. Trading Arrangements

During the quarter ended December 31, 2023, our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act adopted or terminated the contracts, instructions or written plans for the purchase or sale of the Company’s securities set forth in the table below.

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			Type of Trading Arrangement		

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Name and Position	Action	Adoption/ Termination Date	Rule 10b5-1*	Non-Rule 10b5-1**	Total Shares of Class A Common Stock to be Sold	Expiration Date
Celia Lin, Chief Medical Officer***	Adoption	October 10, 2023	X		Up to 134,401	December 19, 2024****
* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.						
** “Non-Rule 10b5-1 trading arrangement” as defined in Item 408(c) of Regulation S-K under the Exchange Act.						
***Dr. Lin separated from Vera effective January 3, 2024.						
****In connection with her separation from Vera, Dr. Lin terminated this 10b5-1 Plan effective January 19, 2024.						

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 2024 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 December 31, 2023 and is incorporated herein by reference.

Code of Business Conduct and Ethics

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We maintain a Code of Business Conduct and Ethics (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 herein by reference.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

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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).

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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).

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10.7†*	Vera Therapeutics, Inc. 2024 Inducement Plan.
10.7	
10.8†*	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Vera Therapeutics, Inc. 2024 Inducement Plan.
10.9†*	Form of Restricted Stock Unit Grant Notice and Award Agreement under the Vera Therapeutics, Inc. 2024 Inducement Plan.
10.10†*	Vera Therapeutics, Inc. 2021 Non-employee Director Compensation Policy, as amended on March 28, 2023. (incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 28, 2023).
10.8 10.11†*	Vera Therapeutics, Inc. Non-employee Director Compensation Policy, as amended December 6, 2023.
10.12†	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 10.13†¥	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 10.14†¥	Amended and Restated Offer Letter Separation Agreement by and between the Registrant and Joanne Curley, Ph.D. Celia Lin, M.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). January 3, 2024.
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 10.15†¥	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^ 10.16^	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¥ 10.17¥	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).

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10.15¥ 10.18¥ ^	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^ 10.19^	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^ 10.20^	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¥ 10.21¥	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.
97.1*	Vera Therapeutics, Inc. Incentive Compensation Recoupment Policy
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents

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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

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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 March 26, 2024

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 26, 2024
/s/ Sean Grant **Sean Grant**	Chief Financial Officer (Principal Financial Officer)	March 28, 2023 26, 2024
/s/ Joseph Young **Joseph Young**	Senior Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer)	March 28, 2023 26, 2024
/s/ Michael Morrissey **Michael Morrissey, Ph.D.**	Chairman of the Board	March 28, 2023 26, 2024
/s/ Andrew Cheng **Andrew Cheng, M.D., Ph.D.**	Director	March 26, 2024
/s/ Patrick Enright **Patrick Enright**	Director	March 26, 2024
/s/ Kimball Hall **Kimball Hall**	Director	March 26, 2024
/s/ Maha Katabi **Maha Katabi, Ph.D.**	Director	March 26, 2024
/s/ Scott Morrison	Director	March 26, 2024

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Scott Morrison		
/s/ Beth Seidenberg	Director	March 26, 2024
Beth Seidenberg, M.D.		
/s/ Andrew Cheng	Director	March 28, 2023
Andrew Cheng, M.D., Ph.D.		
/s/ Patrick Enright	Director	March 28, 2023
Patrick Enright		
/s/ Kimball Hall	Director	March 28, 2023
Kimball Hall		
/s/ Maha Katabi	Director	March 28, 2023
Maha Katabi, Ph.D.		
/s/ Scott Morrison	Director	March 28, 2023
Scott Morrison		
/s/ Beth Seidenberg	Director	March 28, 2023
Beth Seidenberg, M.D.		

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

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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.

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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

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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

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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

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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

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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

INDUCEMENT PLAN

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VERA THERAPEUTICS, INC. 2024 INDUCEMENT PLAN

ADOPTED BY THE BOARD OF DIRECTORS: FEBRUARY 2, 2024

1. GENERAL.

(a)Eligible Award Recipients. The only persons eligible to receive grants of Awards under this Plan are individuals who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) or 5635(c)(3), if applicable, and the related guidance under Nasdaq IM 5635-1. A person who previously served as an Employee or Director will not be eligible to receive Awards under the Plan, other than following a *bona fide* period of non-employment. Persons eligible to receive grants of Awards under this Plan are referred to in this Plan as "***Eligible Employees***." These Awards must be approved by either a majority of the Company's "Independent Directors" (as such term is defined in Nasdaq Marketplace Rule 5605(a)(2)) ("***Independent Directors***") or the Company's compensation committee, provided such committee is comprised solely of Independent Directors of the Company (the "***Independent Compensation Committee***") in order to comply with the exemption from the stockholder approval requirement for "inducement grants" provided under Rule 5635(c)(4) of the Nasdaq Marketplace Rules. Nasdaq Marketplace Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1 (together with any analogous rules or guidance effective after the date hereof, the "***Inducement Award Rules***").

(b)Plan Purpose. The Company, by means of the Plan, intends to provide (i) an inducement material for certain individuals to enter into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Marketplace Rules, (ii) incentives for Eligible Employees to exert maximum efforts for the success of the Company and any Affiliate and (iii) a means by which Eligible Employees may be given an opportunity to benefit from increases in value of the Common Stock through the granting of Awards.

(c)Available Awards. The Plan provides for the grant of the following Awards: (i) Nonstatutory Stock Options; (ii) SARs; (iii) Restricted Stock Awards; (iv) RSU Awards; (v) Performance Awards; and (vi) Other Awards.

(d) Effective Date. The Plan will come into existence on the Effective Date.

2. SHARES SUBJECT TO THE PLAN.

(a)Share Reserve. Subject to adjustment in accordance with Section 2(b) and any adjustments as necessary to implement any Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Awards will not exceed 500,000 shares of Common Stock.

(b) Share Reserve Operation.

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(i) Limit Applies to Common Stock Issued Pursuant to Awards. For clarity, the Share Reserve is a limit on the number of shares of Common Stock that may be issued pursuant to Awards and does not limit the granting of Awards, except that the Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy its obligations to issue shares pursuant to such Awards. Shares may be issued in connection with a merger or acquisition as permitted by, as applicable, Nasdaq Listing Rule 5635(c), NYSE Listed Company Manual Section 303A.08, NYSE American Company Guide Section 711 or other

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applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(ii) Actions that Do Not Constitute Issuance of Common Stock and Do Not Reduce Share Reserve. The following actions do not result in an issuance of shares under the Plan and accordingly do not reduce the number of shares subject to the Share Reserve and available for issuance under the Plan: (1) the expiration or termination of any portion of an Award without the shares covered by such portion of the Award having been issued; (2) the settlement of any portion of an Award in cash (*i.e.*, the Participant receives cash rather than Common Stock);

EXHIBIT 10.7

(3) the withholding of shares that would otherwise be issued by the Company to satisfy the exercise, strike or purchase price of an Award; or (4) the withholding of shares that would otherwise be issued by the Company to satisfy a tax withholding obligation in connection with an Award.

(iii) Reversion of Previously Issued Shares of Common Stock to Share Reserve. The following shares of Common Stock previously issued pursuant to an Award and accordingly initially deducted from the Share Reserve will be added back to the Share Reserve and again become available for issuance under the Plan: (1) any shares that are forfeited back to or repurchased by the Company because of a failure to meet a contingency or condition required for the vesting of such shares; (2) any shares that are reacquired by the Company to satisfy the

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exercise, strike or purchase price of an Award; and (3) any shares that are reacquired by the Company to satisfy a tax withholding obligation in connection with an Award.

3. Eligibility and Limitations.

(a)Eligible Award Recipients. Awards may only be granted to persons who are Eligible Employees described in Section 1(a) of the Plan, where the Award is an inducement material to the individual's entering into employment with the Company or an Affiliate within the meaning of Rule 5635(c)(4) of the Nasdaq Marketplace Rules or is otherwise permitted pursuant to Rule 5635(c) of the Nasdaq Marketplace Rules.

(b)Limitations on Nonstatutory Stock Options and SARs. Nonstatutory Stock Options and SARs may not be granted to Employees unless the stock underlying such Awards is treated as "service recipient stock" under Section 409A or unless such Awards otherwise comply with the requirements of Section 409A.

(c)Approval Requirements. All Awards must be granted either by a majority of the Company's Independent Directors or the Independent Compensation Committee.

Exhibit 10.7

4. Options and Stock Appreciation Rights.

Each Option and SAR will have such terms and conditions as determined by the Board. All Options will be Nonstatutory Stock Options. Each SAR will be denominated in shares of Common Stock equivalents. The terms and conditions of separate Options and SARs need not be identical; provided, however, that each Option Agreement and SAR Agreement will conform (through incorporation of provisions hereof by reference in the Award Agreement or otherwise) to the substance of each of the following provisions:

(a)Term. No Option or SAR will be exercisable after the expiration of ten years from the date of grant of such Award or such shorter period specified in the Award Agreement.

(b)Exercise or Strike Price. The exercise or strike price of each Option or SAR will not be less than 100% of the Fair Market Value on the date of grant of such Award. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value on the date of grant of such Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Section 409A of the Code.

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(c)Exercise Procedure and Payment of Exercise Price for Options. In order to exercise an Option, the Participant must provide notice of exercise to the Plan Administrator in accordance with the procedures specified in the Option Agreement or otherwise provided by the Company. The Board has the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to utilize a particular method of payment. The exercise price of an Option may be paid, to the extent permitted by Applicable Law and as determined by the Board, by one or more of the following methods of payment to the extent set forth in the Option Agreement:

(i) by cash or check, bank draft or money order payable to the Company;

(ii) pursuant to a "cashless exercise" program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the Common Stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock that are already owned by the Participant free and clear of any liens, claims, encumbrances or security interests, with a Fair Market Value on the date of exercise that does not exceed the exercise price, provided that (1) at the time of exercise the Common Stock is publicly traded, (2) any remaining balance of the exercise price not satisfied by such delivery is paid by the Participant in cash or other permitted form of payment, (3) such delivery would not violate any Applicable Law or agreement restricting the redemption of the Common Stock, (4) any certificated shares are endorsed or accompanied by an executed assignment separate from

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certificate, and (5) such shares have been held by the Participant for any minimum period necessary to avoid adverse accounting treatment as a result of such delivery;

(iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value on the date of exercise that does not exceed the exercise price, provided that (1) such shares used to pay the exercise price will not be exercisable thereafter and (2) any remaining balance of the exercise price not satisfied by such net exercise is paid by the Participant in cash or other permitted form of payment; or

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(v) in any other form of consideration that may be acceptable to the Board and permissible under Applicable Law.

(d)Exercise Procedure and Payment of Appreciation Distribution for SARs. In order to exercise any SAR, the Participant must provide notice of exercise to the Plan Administrator in accordance with the SAR Agreement. The appreciation distribution payable to a Participant upon the exercise of a SAR will not be greater than an amount equal to the excess of
(i) the aggregate Fair Market Value on the date of exercise of a number of shares of Common Stock equal to the number of Common Stock equivalents that are vested and being exercised under such SAR, over (ii) the strike price of such SAR. Such appreciation distribution may be paid to the Participant in the form of Common Stock or cash (or any combination of Common Stock and cash) or in any other form of payment, as determined by the Board and specified in the SAR Agreement.

(e)Transferability. Options and SARs may not be transferred to third party financial institutions for value. The Board may impose such additional limitations on the transferability of an Option or SAR as it determines. In the absence of any such determination by the Board, the following restrictions on the transferability of Options and SARs will apply, provided that except as explicitly provided herein, neither an Option nor a SAR may be transferred for consideration:

(i) Restrictions on Transfer. An Option or SAR will not be transferable, except by will or by the laws of descent and distribution, and will be exercisable during the lifetime of the Participant only by the Participant; provided, however, that the Board may permit transfer of an Option or SAR in a manner that is not prohibited by applicable tax and securities laws upon the Participant's request, including to a trust if the Participant is considered to be the sole beneficial owner of such trust (as determined under Section 671 of the Code and applicable state law) while such Option or SAR is held in such trust, provided that the Participant and the trustee enter into a transfer and other agreements required by the Company.

(ii) Domestic Relations Orders. Notwithstanding the foregoing, subject to the execution of transfer documentation in a format acceptable to the Company and subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to a domestic relations order.

(f)Vesting. The Board may impose such restrictions on or conditions to the vesting and/or exercisability of an Option or SAR as determined by the Board. Except as otherwise provided in the applicable Award Agreement or other written agreement between a Participant and

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the Company or an Affiliate, vesting of Options and SARs will cease upon termination of the Participant's Continuous Service.

(g)Termination of Continuous Service for Cause. Except as explicitly otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service is terminated for Cause, the Participant's Options and SARs will terminate and be forfeited immediately upon such termination of Continuous Service, and the Participant will be prohibited from exercising any portion (including any vested portion) of such Awards on and after the date of such termination of Continuous Service and the Participant will have no further right, title or interest in such forfeited Award, the shares of Common Stock subject to the forfeited Award, or any consideration in respect of the forfeited Award.

(h)Post-Termination Exercise Period Following Termination of Continuous Service for Reasons Other than Cause. Subject to Section 4(i), if a Participant's Continuous Service terminates for any reason other than for Cause, the Participant may exercise his or her Option or SAR to the extent vested, but only within the following period of time or, if applicable, such other period of time provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate; provided, however, that in no event may such Award be exercised after the expiration of its maximum term (as set forth in Section 4(a)):

(i) three months following the date of such termination if such termination is a termination without Cause (other than any termination due to the Participant's Disability or death);

(ii) 12 months following the date of such termination if such termination is due to the Participant's Disability;

(iii)18 months following the date of such termination if such termination is due to the Participant's death; or

(iv)18 months following the date of the Participant's death if such death occurs following the date of such termination but during the period such Award is otherwise exercisable (as provided in (i) or (ii) above).

Following the date of such termination, to the extent the Participant does not exercise such Award within the applicable Post-Termination Exercise Period (or, if earlier, prior to the expiration of the maximum term of such Award), such unexercised portion of the Award will terminate, and the Participant will have no further right, title or interest in the terminated Award, the shares of Common Stock subject to the terminated Award, or any consideration in respect of the terminated Award.

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(i)Restrictions on Exercise; Extension of Exercisability. A Participant may not exercise an Option or SAR at any time that the issuance of shares of Common Stock upon such exercise would violate Applicable Law. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service terminates for any reason other than for Cause and, at any time during the last thirty days of the applicable Post-Termination Exercise Period: (i) the exercise of the Participant's

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Option or SAR would be prohibited solely because the issuance of shares of Common Stock upon such exercise would violate Applicable Law, or (ii) the immediate sale of any shares of Common Stock issued upon such exercise would violate the Company's Trading Policy, then the applicable Post-Termination Exercise Period will be extended to the last day of the calendar month that commences following the date the Award would otherwise expire, with an additional extension of the exercise period to the last day of the next calendar month to apply if any of the foregoing restrictions apply at any time during such extended exercise period, generally without limitation as to the maximum permitted number of extensions; provided, however, that in no event may such Award be exercised after the expiration of its maximum term (as set forth in Section 4(a)).

(j)Non-Exempt Employees. No Option or SAR, whether or not vested, granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, will be first exercisable for any shares of Common Stock until at least six months following the date of grant of such Award. Notwithstanding the foregoing, in accordance with the provisions of the Worker Economic Opportunity Act, any vested portion of such Award may be exercised earlier than six months following the date of grant of such Award in the event of (i) such Participant's death or Disability, (ii) a Corporate Transaction in which such Award is not assumed, continued or substituted, (iii) a Change in Control, or (iv) such Participant's retirement (as such term may be defined in the Award Agreement or another applicable agreement or, in the absence of any such definition, in accordance with the Company's then current employment policies and guidelines). This Section 4(j) is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay.

(k)Whole Shares. Options and SARs may be exercised only with respect to whole shares of Common Stock or their equivalents.

5. AWARDS OTHER THAN OPTIONS AND STOCK APPRECIATION RIGHTS.

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(a)Restricted Stock Awards and RSU Awards. Each Restricted Stock Award and RSU Award will have such terms and conditions as determined by the Board; provided, however, that each Restricted Stock Award Agreement and RSU Award Agreement will conform (through incorporation of the provisions hereof by reference in the Award Agreement or otherwise) to the substance of each of the following provisions:

(i) Form of Award.

(1)Restricted Stock Awards: To the extent consistent with the Company's Bylaws, at the Board's election, shares of Common Stock subject to a Restricted Stock Award may be (i) held in book entry form subject to the Company's instructions until such shares become vested or any other restrictions lapse, or (ii) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. Unless otherwise determined by the Board, a Participant will have voting and other rights as a stockholder of the Company with respect to any shares subject to a Restricted Stock Award.

(2)RSU Awards: An RSU Award represents a Participant's right to be issued on a future date the number of shares of Common Stock that is equal to the number of

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restricted stock units subject to the RSU Award. As a holder of an RSU Award, a Participant is an unsecured creditor of the Company with respect to the Company's unfunded obligation, if any, to issue shares of Common Stock in settlement of such Award and nothing contained in the Plan or any RSU Agreement, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between a Participant and the Company or an Affiliate or any other person. A Participant will not have voting or any other rights as a stockholder of the Company with respect to any RSU Award (unless and until shares are actually issued in settlement of a vested RSU Award).

(ii) Consideration.

(1)Restricted Stock Awards: A Restricted Stock Award may be granted in consideration for (A) cash or check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of consideration (including future services) as a majority of the Company's Independent Directors or the Independent Compensation Committee may determine and permissible under Applicable Law.

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(2)RSU Awards: Unless otherwise determined by a majority of the Company's Independent Directors or the Independent Compensation Committee at the time of grant, an RSU Award will be granted in consideration for the Participant's services to the Company or an Affiliate, such that the Participant will not be required to make any payment to the Company (other than such services) with respect to the grant or vesting of the RSU Award, or the issuance of any shares of Common Stock pursuant to the RSU Award. If, at the time of grant, a majority of the Company's Independent Directors or the Independent Compensation Committee determines that any consideration must be paid by the Participant (in a form other than the Participant's services to the Company or an Affiliate) upon the issuance of any shares of Common Stock in settlement of the RSU Award, such consideration may be paid in any form of consideration as a majority of the Company's Independent Directors or the Independent Compensation Committee may determine and permissible under Applicable Law.

(iii)Vesting. The Board may impose such restrictions on or conditions to the vesting of a Restricted Stock Award or RSU Award as determined by the Board. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, vesting of Restricted Stock Awards and RSU Awards will cease upon termination of the Participant's Continuous Service.

(iv)Termination of Continuous Service. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service terminates for any reason, (i) the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant under his or her Restricted Stock Award that have not vested as of the date of such termination as set forth in the Restricted Stock Award Agreement and the Participant will have no further right, title or interest in the Restricted Stock Award, the shares of Common Stock subject to the Restricted Stock Award, or any consideration in respect of the Restricted Stock Award and (ii) any portion of his or her RSU Award that has not vested will be forfeited upon such termination and the Participant will have no further right, title or interest in

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the RSU Award, the shares of Common Stock issuable pursuant to the RSU Award, or any consideration in respect of the RSU Award.

(v) Dividends and Dividend Equivalents. Dividends or dividend equivalents may be paid or credited, as applicable, with respect to any shares of Common Stock subject to a Restricted

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Stock Award or RSU Award, as determined by the Board and specified in the Award Agreement.

(vi)Settlement of RSU Awards. An RSU Award may be settled by the issuance of shares of Common Stock or cash (or any combination thereof) or in any other form of payment, as determined by the Board and specified in the RSU Award Agreement. At the time of grant, the Board may determine to impose such restrictions or conditions that delay such delivery to a date following the vesting of the RSU Award.

(b)Performance Awards. With respect to any Performance Award, the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, the other terms and conditions of such Award, and the measure of whether and to what degree such Performance Goals have been attained will be determined by a majority of the Company's Independent Directors or the Independent Compensation Committee.

(c)Other Awards. Other forms of Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof, may be granted either alone or in addition to Awards provided for under Section 4 and the preceding provisions of this Section 5. Subject to the provisions of the Plan, a majority of the Company's Independent Directors or the Independent Compensation Committee will have sole and complete discretion to determine the persons to whom and the time or times at which such Other Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Awards and all other terms and conditions of such Other Awards.

6. Adjustments upon Changes in Common Stock; Other Corporate Events.

(a)Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board shall appropriately and proportionately adjust: (i) the class(es) and maximum number of shares of Common Stock subject to the Plan and; (ii) the class(es) and number of securities and exercise price, strike price or purchase price of Common Stock subject to outstanding Awards. The Board shall make such adjustments, and its determination shall be final, binding and conclusive. Notwithstanding the foregoing, no fractional shares or rights for fractional shares of Common Stock shall be created in order to implement any Capitalization Adjustment. The Board shall determine an appropriate equivalent benefit, if any, for any fractional shares or rights to fractional shares that might be created by the adjustments referred to in the preceding provisions of this Section.

(b)Dissolution or Liquidation. Except as otherwise provided in the Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Awards (other than Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the

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Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Award is providing Continuous Service, provided, however, that the Board may determine to cause some or all Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

(c)Corporate Transaction. The following provisions will apply to Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of an Award.

(i) Awards May Be Assumed. In the event of a Corporate Transaction, any surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) may assume or continue any or all Awards outstanding under the Plan or may substitute similar awards for Awards outstanding under the Plan (including but not limited to, awards to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction), and any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to Awards may be assigned by the Company to the successor of the Company (or the successor's parent company, if any), in connection with such Corporate Transaction. A surviving corporation or acquiring corporation (or its parent) may choose to assume or continue only a portion of an Award or substitute a similar award for only a portion of an Award, or may choose to assume, continue or substitute the Awards held by some, but not all Participants. The terms of any assumption, continuation or substitution will be set by the Board.

(ii) Awards Held by Current Participants. In the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Awards or substitute similar awards for such outstanding Awards, then with respect to Awards that have not been assumed, continued or substituted and that are held by Participants whose Continuous Service has not terminated prior to the effective time of the Corporate Transaction (referred to as the "***Current Participants***"), the vesting of such Awards (and, with respect to Options and Stock Appreciation Rights, the time when such Awards may be exercised) will be accelerated in full to a date prior to the effective time of such Corporate Transaction (contingent upon the effectiveness of the Corporate Transaction) as the Board determines (or, if the Board does not determine such a date, to the date that is five (5) days prior to

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the effective time of the Corporate Transaction), and such Awards will terminate if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction, and any reacquisition or repurchase rights held by the Company with respect to such Awards will lapse (contingent upon the effectiveness of the Corporate Transaction). With respect to the vesting of Performance Awards that will accelerate upon the occurrence of a Corporate Transaction pursuant to this subsection (ii) and that have multiple vesting levels depending on the level of performance, unless otherwise provided in the Award Agreement, the vesting of such Performance Awards will accelerate at 100% of the target level upon the occurrence of the Corporate Transaction in which the Awards are not assumed, continued or substituted in accordance with Section 6(c)(i). With respect to the vesting of Awards that will accelerate upon the occurrence of a Corporate Transaction pursuant to this subsection (ii) and are settled in the form of a cash payment, such cash payment will be made no later than 30 days following the

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occurrence of the Corporate Transaction or such later date as required to comply with Section 409A of the Code.

(iii)Awards Held by Persons other than Current Participants. In the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Awards or substitute similar awards for such outstanding Awards, then with respect to Awards that have not been assumed, continued or substituted and that are held by persons other than Current Participants, such Awards will terminate if not exercised (if applicable) prior to the occurrence of the Corporate Transaction; provided, however, that any reacquisition or repurchase rights held by the Company with respect to such Awards will not terminate and may continue to be exercised notwithstanding the Corporate Transaction.

(iv)Payment for Awards in Lieu of Exercise. Notwithstanding the foregoing, in the event an Award will terminate if not exercised prior to the effective time of a Corporate Transaction, the Board may provide, in its sole discretion, that the holder of such Award may not exercise such Award but will receive a payment, in such form as may be determined by the Board, equal in value, at the effective time, to the excess, if any, of (1) the value of the property the Participant would have received upon the exercise of the Award (including, at the discretion of the Board, any unvested portion of such Award), over (2) any exercise price payable by such holder in connection with such exercise.

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(d)Appointment of Stockholder Representative. As a condition to the receipt of an Award under this Plan, a Participant will be deemed to have agreed that the Award will be subject to the terms of any agreement governing a Corporate Transaction involving the Company, including, without limitation, a provision for the appointment of a stockholder representative that is authorized to act on the Participant's behalf with respect to any escrow, indemnities and any contingent consideration.

(e)No Restriction on Right to Undertake Transactions. The grant of any Award under the Plan and the issuance of shares pursuant to any Award does not affect or restrict in any way the right or power of the Company or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock or of options, rights or options to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

7. ADMINISTRATION.

(a)Administration by Board. The Board will administer the Plan; provided however, that Awards may only be granted by either (i) a majority of the Company's Independent Directors or (ii) the Independent Compensation Committee. Subject to those constraints and the other constraints of the Inducement Award Rules, the Board may delegate some of its powers of administration of the Plan to a Committee or Committees, as provided in subsection (c) below.

(b)Powers of Board. The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan and Inducement Award Rules:

(i) To determine from time to time (1) which of the persons eligible under the

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Plan will be granted Awards; (2) when and how each Award will be granted; (3) what type or combination of types of Award will be granted; (4) the provisions of each Award granted (which need not be identical), including the time or times when a person will be permitted to receive an issuance of Common Stock or other payment pursuant to an Award; (5) the number of shares of Common Stock or cash equivalent with respect to which an Award will be granted to each such person; (6) the Fair Market Value applicable to an Award; and (7) the terms of any Performance Award that is not

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valued in whole or in part by reference to, or otherwise based on, the Common Stock, including the amount of cash payment or other property that may be earned and the timing of payment; provided, however, that Awards may only be granted by either (i) a majority of the Company's Independent Directors or (ii) the Independent Compensation Committee.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement, in a manner and to the extent it deems necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate the time at which an Award may first be exercised or the time during which an Award or any part thereof will vest, notwithstanding the provisions in the Award Agreement stating the time at which it may first be exercised or the time during which it will vest.

(v) To prohibit the exercise of any Option, SAR or other exercisable Award during a period of up to 30 days prior to the consummation of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the shares of Common Stock or the share price of the Common Stock including any Corporate Transaction, for reasons of administrative convenience.

(vi) To suspend or terminate the Plan at any time. Suspension or termination of the Plan will not Materially Impair rights and obligations under any Award granted while the Plan is in effect except with the written consent of the affected Participant.

(vii) To amend the Plan in any respect the Board deems necessary or advisable; provided, however, that stockholder approval will be required for any amendment to the extent required by Applicable Law. Except as provided above, rights under any Award granted before amendment of the Plan will not be Materially Impaired by any amendment of the Plan unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(viii) To submit any amendment to the Plan for stockholder approval.

(ix) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; *provided however*, that, a

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Participant's rights under any Award will not be Materially Impaired by any such amendment unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(x) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in

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conflict with the provisions of the Plan or Awards.

(xi) To adopt such procedures and sub-plans as are necessary or appropriate to permit and facilitate participation in the Plan by, or take advantage of specific tax treatment for Awards granted to, Eligible Employees who are foreign nationals or employed outside the United States (provided that Board approval will not be necessary for immaterial modifications to the Plan or any Award Agreement to ensure or facilitate compliance with the laws of the relevant foreign jurisdiction).

(c) Delegation to Committee.

(i) General. Subject to the terms of Section 3(b), the Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to another Committee or a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. Each Committee may retain the authority to concurrently administer the Plan with the Committee or subcommittee to which it has delegated its authority hereunder and may, at any time, revest in such Committee some or all of the powers previously delegated. The Board may retain the authority to concurrently administer the Plan with any Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(ii) Rule 16b-3 Compliance. To the extent an Award is intended to qualify for the exemption from Section 16(b) of the Exchange Act that is available under Rule 16b-3 of the Exchange Act, the Award will be granted by a Committee that consists solely of two or more Non-Employee Directors, as determined under Rule 16b-3(b)(3) of the Exchange Act and thereafter any

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action establishing or modifying the terms of the Award will be approved by a Committee meeting such requirements to the extent necessary for such exemption to remain available.

(d)Effect of Board's Decision. All determinations, interpretations and constructions made by the Board or any Committee in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

(e)Cancellation and Re-Grant of Awards. Neither the Board nor any Committee will have the authority to: (i) reduce the exercise price or strike price of any outstanding Option or SAR, or (ii) cancel any outstanding Options or SARs that have an exercise price or strike price greater than the current Fair Market Value in exchange for cash or other Awards, unless the stockholders of the Company have approved such an action within twelve months prior to such an event.

EXHIBIT 10.7

8. TAX WITHHOLDING

(a)Withholding Authorization. As a condition to acceptance of any Award under the Plan, a Participant authorizes withholding from payroll and any other amounts payable to such Participant, and otherwise agrees to make adequate provision for (including), any sums required to satisfy any U.S. federal, state, local and/or foreign tax or social insurance contribution withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise, vesting or settlement of such Award, as applicable. Accordingly, a Participant may not be able to exercise an Award even though the Award is vested, and the Company shall have no obligation to issue shares of Common Stock subject to an Award, unless and until such obligations are satisfied.

(b)Satisfaction of Withholding Obligation. To the extent permitted by the terms of an Award Agreement, the Company may, in its sole discretion, satisfy any U.S. federal, state, local and/or foreign tax or social insurance withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award; (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant; (v) by allowing a Participant to effectuate a "cashless exercise" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board; or (vi) by such other method as may be set forth in the Award Agreement.

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(c)No Obligation to Notify or Minimize Taxes; No Liability to Claims. Except as required by Applicable Law the Company has no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Award. Furthermore, the Company has no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of an Award to the holder of such Award and will not be liable to any holder of an Award for any adverse tax consequences to such holder in connection with an Award. As a condition to accepting an Award under the Plan, each Participant (i) agrees to not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from such Award or other Company compensation and (ii) acknowledges that such Participant was advised to consult with his or her own personal tax, financial and other legal advisors regarding the tax consequences of the Award and has either done so or knowingly and voluntarily declined to do so. Additionally, each Participant acknowledges any Option or SAR granted under the Plan is exempt from Section 409A only if the exercise or strike price is at least equal to the "fair market value" of the Common Stock on the date of grant as determined by the Internal Revenue Service and there is no other impermissible deferral of compensation associated with the Award. Additionally, as a condition

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to accepting an Option or SAR granted under the Plan, each Participant agrees not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates in the event that the Internal Revenue Service asserts that such exercise price or strike price is less than the "fair market value" of the Common Stock on the date of grant as subsequently determined by the Internal Revenue Service.

(d)Withholding Indemnification. As a condition to accepting an Award under the Plan, in the event that the amount of the Company's and/or its Affiliate's withholding obligation in connection with such Award was greater than the amount actually withheld by the Company and/or its Affiliates, each Participant agrees to indemnify and hold the Company and/or its Affiliates harmless from any failure by the Company and/or its Affiliates to withhold the proper amount.

9. MISCELLANEOUS.

(a)Source of Shares. The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

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(b)Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock pursuant to Awards will constitute general funds of the Company.

(c)Corporate Action Constituting Grant of Awards. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action approving the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

(d)Stockholder Rights. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to such Award unless and until (i) such Participant has satisfied all requirements for exercise of the Award pursuant to its terms, if applicable, and (ii) the issuance of the Common Stock subject to such Award is reflected in the records of the Company.

(e)No Employment or Other Service Rights. Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or affect the right of the Company or an Affiliate to terminate at will and without regard to any future vesting opportunity that a Participant may have with respect to any Award (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director

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pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state or foreign jurisdiction in which the Company or the Affiliate is incorporated, as the case may be. Further, nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award will constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or service or confer any right or

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benefit under the Award or the Plan unless such right or benefit has specifically accrued under the terms of the Award Agreement and/or Plan.

(f)Change in Time Commitment. In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Award to the Participant, the Board may determine, to the extent permitted by Applicable Law, to (i) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (ii) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

(g)Execution of Additional Documents. As a condition to accepting an Award under the Plan, the Participant agrees to execute any additional documents or instruments necessary or desirable, as determined in the Plan Administrator's sole discretion, to carry out the purposes or intent of the Award, or facilitate compliance with securities and/or other regulatory requirements, in each case at the Plan Administrator's request.

(h)Electronic Delivery and Participation. Any reference herein or in an Award Agreement to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto) or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access). By accepting any Award the Participant consents to receive documents by electronic delivery and to participate in the Plan through any on-line electronic system established and maintained by the Plan Administrator or another third party selected by the Plan Administrator. The form of delivery of any Common Stock (e.g., a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

(i)Clawback/Recovery. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other Applicable Law and any clawback policy that the Company otherwise adopts, to the extent applicable and permissible under Applicable Law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously

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acquired shares of Common Stock or other cash or property upon the occurrence of Cause. No recovery of compensation under such a clawback

policy will be an event giving rise to a Participant's right to voluntarily terminate employment upon a "resignation for good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.

(j)Securities Law Compliance. A Participant will not be issued any shares in respect of an Award unless either (i) the shares are registered under the Securities Act; or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Each Award also must comply with other Applicable Law governing the Award, and a Participant will not receive such shares if the Company determines that such receipt would not be in material compliance with Applicable Law.

(k)Transfer or Assignment of Awards; Issued Shares. Except as expressly provided in the Plan or the form of Award Agreement, Awards granted under the Plan may not be transferred or assigned by the Participant. After the vested shares subject to an Award have been issued, or in the case of Restricted Stock and similar awards, after the issued shares have vested, the holder of such shares is free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such shares provided that any such actions are in compliance with the provisions herein, the terms of the Trading Policy and Applicable Law.

(l)Effect on Other Employee Benefit Plans. The value of any Award granted under the Plan, as determined upon grant, vesting or settlement, shall not be included as compensation, earnings, salaries, or other similar terms used when calculating any Participant's benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

(m)Deferrals. To the extent permitted by Applicable Law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may also establish programs and procedures for deferral elections to be made by Participants. Deferrals will be made in accordance with the requirements of Section 409A.

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(n)Section 409A. Unless otherwise expressly provided for in an Award Agreement, the Plan and Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A, and, to the extent not so exempt, in compliance with the requirements of Section 409A. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A, the Award Agreement evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section 409A is a "specified employee" for purposes of Section 409A, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A without regard to alternative definitions thereunder) will be issued or paid before the date that is six months and one day following the date of such Participant's "separation from service"

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or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A, and any amounts so deferred will be paid in a lump sum on the day after such six month period elapses, with the balance paid thereafter on the original schedule.

(o)CHOICE OF LAW. This Plan and any controversy arising out of or relating to this Plan shall be governed by, and construed in accordance with, the internal laws of the State of Delaware, without regard to conflict of law principles that would result in any application of any law other than the law of the State of Delaware.

10. COVENANTS OF THE COMPANY.

The Company will seek to obtain from each regulatory commission or agency, as may be deemed to be necessary, having jurisdiction over the Plan such authority as may be required to grant Awards and to issue and sell shares of Common Stock upon exercise or vesting of the Awards; provided, however, that this undertaking will not require the Company to register under the Securities Act the Plan, any Award or any Common Stock issued or issuable pursuant to any such Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary or

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advisable for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise or vesting of such Awards unless and until such authority is obtained. A Participant is not eligible for the grant of an Award or the subsequent issuance of Common Stock pursuant to the Award if such grant or issuance would be in violation of any Applicable Law.

11. Additional Rules for Awards Subject to Section 409A.

(a)Application. Unless the provisions of this Section of the Plan are expressly superseded by the provisions in the form of Award Agreement, the provisions of this Section shall apply and shall supersede anything to the contrary set forth in the Award Agreement for a Non- Exempt Award.

(b)Non-Exempt Awards Subject to Non-Exempt Severance Arrangements. To the extent a Non-Exempt Award is subject to Section 409A due to application of a Non-Exempt Severance Arrangement, the following provisions of this subsection (b) apply.

(i) If the Non-Exempt Award vests in the ordinary course during the Participant's Continuous Service in accordance with the vesting schedule set forth in the Award Agreement, and does not accelerate vesting under the terms of a Non-Exempt Severance Arrangement, in no event will the shares be issued in respect of such Non-Exempt Award any later than the later of: (i) December 31st of the calendar year that includes the applicable vesting date, or (ii) the 60th day that follows the applicable vesting date.

(ii) If vesting of the Non-Exempt Award accelerates under the terms of a Non- Exempt Severance Arrangement in connection with the Participant's Separation from Service, and such vesting acceleration provisions were in effect as of the date of grant of the Non-Exempt Award and, therefore, are part of the terms of such Non-Exempt Award as of the date of grant, then the shares will be earlier issued in settlement of such Non-Exempt Award upon the

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Participant's Separation from Service in accordance with the terms of the Non-Exempt Severance Arrangement, but in no event later than the 60th day that follows the date of the Participant's Separation from Service. However, if at the time the shares would otherwise be issued the Participant is subject to the distribution limitations contained in Section 409A applicable to "specified employees," as defined in Section 409A(a)(2)(B)(i) of the Code, such shares shall not be issued before the date that is six months following the date of such Participant's Separation from Service, or, if earlier, the date of the Participant's death that occurs within such six month period.

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(iii) If vesting of a Non-Exempt Award accelerates under the terms of a Non- Exempt Severance Arrangement in connection with a Participant's Separation from Service, and such vesting acceleration provisions were not in effect as of the date of grant of the Non-Exempt Award and, therefore, are not a part of the terms of such Non-Exempt Award on the date of grant, then such acceleration of vesting of the Non-Exempt Award shall not accelerate the issuance date of the shares, but the shares shall instead be issued on the same schedule as set forth in the Grant Notice as if they had vested in the ordinary course during the Participant's Continuous Service, notwithstanding the vesting acceleration of the Non-Exempt Award. Such issuance schedule is intended to satisfy the requirements of payment on a specified date or pursuant to a fixed schedule, as provided under Treasury Regulations Section 1.409A-3(a)(4).

(c) Treatment of Non-Exempt Awards Upon a Corporate Transaction for Employees and Consultants. The provisions of this subsection (c) shall apply and shall supersede anything to the contrary set forth in the Plan with respect to the permitted treatment of any Non- Exempt Award in connection with a Corporate Transaction if the Participant was either an Employee or Consultant upon the applicable date of grant of the Non-Exempt Award.

(i) Vested Non-Exempt Awards. The following provisions shall apply to any Vested Non-Exempt Award in connection with a Corporate Transaction:

(1) If the Corporate Transaction is also a Section 409A Change in Control then the Acquiring Entity may not assume, continue or substitute the Vested Non-Exempt Award. Upon the Section 409A Change in Control the settlement of the Vested Non-Exempt Award will automatically be accelerated and the shares will be immediately issued in respect of the Vested Non-Exempt Award. Alternatively, the Company may instead provide that the Participant will receive a cash settlement equal to the Fair Market Value of the shares that would otherwise be issued to the Participant upon the Section 409A Change in Control.

(2) If the Corporate Transaction is not also a Section 409A Change in Control, then the Acquiring Entity must either assume, continue or substitute each Vested Non- Exempt Award. The shares to be issued in respect of the Vested Non-Exempt Award shall be issued to the Participant by the Acquiring Entity on the same schedule that the shares would have been issued to the Participant if the Corporate Transaction had not occurred. In the Acquiring Entity's discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to the Participant on such issuance dates, with the determination of the Fair Market Value of the shares made on the date of the Corporate Transaction.

(ii) Unvested Non-Exempt Awards. The following provisions shall apply to any Unvested Non-Exempt Award unless otherwise determined by the Board pursuant to subsection (d)

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of this Section.

(1)In the event of a Corporate Transaction, the Acquiring Entity shall

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assume, continue or substitute any Unvested Non-Exempt Award. Unless otherwise determined by the Board, any Unvested Non-Exempt Award will remain subject to the same vesting and forfeiture restrictions that were applicable to the Award prior to the Corporate Transaction. The shares to be issued in respect of any Unvested Non-Exempt Award shall be issued to the Participant by the Acquiring Entity on the same schedule that the shares would have been issued to the Participant if the Corporate Transaction had not occurred. In the Acquiring Entity's discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to the Participant on such issuance dates, with the determination of Fair Market Value of the shares made on the date of the Corporate Transaction.

(2)If the Acquiring Entity will not assume, substitute or continue any Unvested Non-Exempt Award in connection with a Corporate Transaction, then such Award shall automatically terminate and be forfeited upon the Corporate Transaction with no consideration payable to any Participant in respect of such forfeited Unvested Non-Exempt Award. Notwithstanding the foregoing, to the extent permitted and in compliance with the requirements of Section 409A, the Board may in its discretion determine to elect to accelerate the vesting and settlement of the Unvested Non-Exempt Award upon the Corporate Transaction, or instead substitute a cash payment equal to the Fair Market Value of such shares that would otherwise be issued to the Participant, as further provided in Section 11(d)(ii) below. In the absence of such discretionary election by the Board, any Unvested Non-Exempt Award shall be forfeited without payment of any consideration to the affected Participants if the Acquiring Entity will not assume, substitute or continue the Unvested Non-Exempt Awards in connection with the Corporate Transaction.

(3)The foregoing treatment shall apply with respect to all Unvested Non-Exempt Awards upon any Corporate Transaction, and regardless of whether or not such Corporate Transaction is also a Section 409A Change in Control.

(d) If the RSU Award is a Non-Exempt Award, then the provisions in this Section 11(d)shall apply and supersede anything to the contrary that may be set forth in the Plan or the Award Agreement with respect to the permitted treatment of such Non-Exempt Award:

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(i) Any exercise by the Board of discretion to accelerate the vesting of a Non- Exempt Award shall not result in any acceleration of the scheduled issuance dates for the shares in respect of the Non-Exempt Award unless earlier issuance of the shares upon the applicable vesting dates would be in compliance with the requirements of Section 409A.

(ii) The Company explicitly reserves the right to earlier settle any Non-Exempt Award to the extent permitted and in compliance with the requirements of Section 409A, including pursuant to any of the exemptions available in Treasury Regulations Section 1.409A- 3(j)(4)(ix).

(iii) To the extent the terms of any Non-Exempt Award provide that it will be settled upon a Change in Control or Corporate Transaction, to the extent it is required for compliance with the requirements of Section 409A, the Change in Control or Corporate Transaction event triggering settlement must also constitute a Section 409A Change in Control. To the extent the terms of a Non-Exempt Award provides that it will be settled upon a termination of employment or termination of Continuous Service, to the extent it is required for compliance with the requirements of Section 409A, the termination event triggering settlement must also constitute a Separation From Service. However, if at the time the shares would otherwise be issued to a Participant in connection with a "separation from service" such Participant is subject to the

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distribution limitations contained in Section 409A applicable to "specified employees," as defined in Section 409A(a)(2)(B)(i) of the Code, such shares shall not be issued before the date that is six months following the date of the Participant's Separation From Service, or, if earlier, the date of the Participant's death that occurs within such six month period.

(iv) The provisions in this Section 11(d) for delivery of the shares in respect of the settlement of an RSU Award that is a Non-Exempt Award are intended to comply with the requirements of Section 409A so that the delivery of the shares to the Participant in respect of such Non-Exempt Award will not trigger the additional tax imposed under Section 409A, and any ambiguities herein will be so interpreted.

12. SEVERABILITY.

If all or any part of the Plan or any Award Agreement is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of the Plan or such Award Agreement not declared to be unlawful or invalid. Any Section of the Plan or any Award Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if

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possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

13. TERMINATION OF THE PLAN.

The Board may suspend or terminate the Plan at any time. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

14. DEFINITIONS.

As used in the Plan, the following definitions apply to the capitalized terms indicated below:

(a) "***Acquiring Entity***" means the surviving or acquiring corporation (or its parent company) in connection with a Corporate Transaction.

(b)"***Affiliate***" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 promulgated under the Securities Act. The Board may determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(c)"***Applicable Law***" means the Code and any applicable securities, federal, state, foreign, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, listing rule, regulation, judicial decision, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body (including under the authority of any applicable self-regulating organization such as the Nasdaq Stock Market, New York Stock Exchange, or the Financial Industry Regulatory Authority).

(d)"***Award***" means any right to receive Common Stock, cash or other property granted under the Plan (including a Nonstatutory Stock Option, a Restricted Stock Award, an RSU Award, a SAR, a Performance Award or any Other Award).

(e)"***Award Agreement***" means a written or electronic agreement between the Company and a Participant evidencing the terms and conditions of an Award. The Award Agreement generally consists of the Grant Notice and the agreement containing the written summary of the general terms and conditions applicable to the Award and which is provided, including through

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electronic means, to a Participant along with the Grant Notice.

(f)"***Board***" means the Board of Directors of the Company (or its designee). Any decision or determination made by the Board shall be a decision or determination that is made in the sole discretion of the Board (or its designee), and such decision or determination shall be final and binding on all Participants.

(g)"***Capitalization Adjustment***" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(h)"***Cause***" has the meaning ascribed to such term in any written agreement between a Participant and the Company defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) the Participant's dishonest statements or acts with respect to the Company or any Affiliate of the Company, or any current or prospective customers, suppliers, vendors or other third parties with which such entity does business; (ii) the Participant's commission of (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) the Participant's failure to perform the Participant's assigned duties and responsibilities to the reasonable satisfaction of the Company which failure continues, in the reasonable judgment of the Company, after written notice given to the Participant by the Company; (iv) the Participant's gross negligence, willful misconduct or insubordination with respect to the Company or any Affiliate of the Company; or(v) the Participant's material violation of any provision of any agreement(s) between the Participant and the Company relating to noncompetition, nonsolicitation, nondisclosure and/or assignment of inventions. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause will be made by the Board with respect to Participants who are executive officers of the Company and by the Company's chief executive officer with respect to Participants who are not executive officers of the Company. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

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(i)"***Change in Control***" or "***Change of Control***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur
(A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, or (C) solely because the level of Ownership held by any Exchange Act Person (the "*Subject Person*") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities

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by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representingmore than 50% of the combined outstanding voting power of the Acquiring Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the Acquiring Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii)there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the

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Company and its Subsidiaries to an Entity, more than 50% of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(iv) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the "***Incumbent Board***") cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing or any other provision of this Plan, (A) the term Change in Control shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, (B) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant shall supersede the foregoing definition with respect to Awards subject to such agreement; provided, however, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition shall apply, and (C) with respect to any nonqualified deferred compensation that becomes payable on account of the Change in Control, the transaction or event described in clause (i), (ii), (iii), or (iv) also constitutes a Section 409A Change in Control if required in order for the payment not to violate Section 409A of the Code.

(j) "***Code***" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(k) "***Committee***" means a committee of one or more Independent Directors to whom authority has been delegated by the Board or in accordance with Section 7(c) of the Plan.

(l) "***Common Stock***" means the Class A Common Stock of the Company.

EXHIBIT 10.7

(m) "***Company***" means Vera Therapeutics, Inc., a Delaware corporation.

(n) "***Consultant***" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services.

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However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a “Consultant” for purposes of the Plan. Notwithstandingthe foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company’s securities to such person. Consultants are not eligible to receive Awards under the Plan with respect to their service in such capacity.

(o)“***Continuous Service***” means that the Participant’s service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Director or Consultant or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant’s service with the Company or an Affiliate, will not terminate a Participant’s Continuous Service; provided, however, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, such Participant’s Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director will not constitute an interruption of Continuous Service. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party’s sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Company or an Affiliate, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in an Award only to such extent as may be provided in the Company’s leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law. In addition, to the extent required for exemption from or compliance with Section 409A, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of “separation from service” as defined under Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definition thereunder).

(p)“***Corporate Transaction***” means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least 50% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the

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Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

EXHIBIT 10.7

Notwithstanding the foregoing or any other provision of this Plan, (A) the term Corporate Transaction shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, (B) the definition of Corporate Transaction (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant shall supersede the foregoing definition with respect to Awards subject to such agreement; provided, however, that if no definition of Corporate Transaction or any analogous term is set forth in such an individual written agreement, the foregoing definition shall apply, and
(C) with respect to any nonqualified deferred compensation that becomes payable on account of the Corporate Transaction, the transaction or event described in clause (i), (ii), (iii), or (iv) also constitutes a Section 409A Change in Control if required in order for the payment not to violate Section 409A of the Code.

(q) "***Director***" means a member of the Board. Directors are not eligible to receive Awards under the Plan with respect to their service in such capacity.

(r) "***determine***" or "***determined***" means as determined by the Board or the Committee (or its designee) in its sole discretion.

(s) "***Disability***" means, with respect to a Participant, such Participant is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months, as provided in Section 22(e)(3) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(t) "***Effective Date***" means February 1, 2024.

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(u)"***Employee***" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(v)"***Employer***" means the Company or the Affiliate of the Company that employs the Participant.

(w) "***Entity***" means a corporation, partnership, limited liability company or other entity.

(x)"***Exchange Act***" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(y)"***Exchange Act Person***" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that,

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as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities.

(z)"***Fair Market Value***" means, as of any date, unless otherwise determined by the Board, the value of the Common Stock (as determined on a per share or aggregate basis, as applicable) determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value will be the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) If there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date

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for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, or if otherwise determined by the Board, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

(aa) "***Governmental Body***" means any: (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or regulatory body, or quasi- governmental body of any nature (including any governmental division, department, administrative agency or bureau, commission, authority, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or Entity and any court or other tribunal, and for the avoidance of doubt, any tax authority) or other body exercising similar powers or authority; or (d) self-regulatory organization (including the Nasdaq Stock Market, New York Stock Exchange, and the Financial Industry Regulatory Authority).

(bb) "***Grant Notice***" means the notice provided to a Participant that he or she has been granted an Award under the Plan and which includes the name of the Participant, the type of Award, the date of grant of the Award, number of shares of Common Stock subject to the Award or potential cash payment right, (if any), the vesting schedule for the Award (if any) and other key terms applicable to the Award.

(cc) "***Materially Impair***" means any amendment to the terms of the Award that materially adversely affects the Participant's rights under the Award. A Participant's rights under an Award will not be deemed to have been Materially Impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights. For example, the following types of amendments to the terms of an Award do not Materially Impair the Participant's rights under the Award: (i) imposition of reasonable restrictions on the minimum number of shares subject to an Option or SAR that may be exercised; (ii) to clarify the manner of exemption from, or to bring the Award into compliance

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with or qualify it for an exemption from, Section 409A; or (iii) to comply with other Applicable Laws.

(dd) "***Non-Employee Director***" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly,

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from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("***Regulation S-K***")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or
(ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

(ee) "***Non-Exempt Award***" means any Award that is subject to, and not exempt from, Section 409A, including as the result of (i) a deferral of the issuance of the shares subject to the Award which is elected by the Participant or imposed by the Company, or (ii) the terms of any Non-Exempt Severance Arrangement.

(ff) "***Non-Exempt Severance Arrangement***" means a severance arrangement or other agreement between the Participant and the Company that provides for acceleration of vesting of an Award and issuance of the shares in respect of such Award upon the Participant's termination of employment or separation from service (as such term is defined in Section 409A(a)(2)(A)(i) of the Code (and without regard to any alternative definition thereunder)) ("***Separation from Service***") and such severance benefit does not satisfy the requirements for an exemption from application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(4), 1.409A-1(b)(9) or otherwise.

(gg) "***Nonstatutory Stock Option***" means any option granted pursuant to Section 4 of the Plan that does not qualify as an "incentive stock option" within the meaning of Section 422 of the Code.

(hh) "***Officer***" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(ii) "***Option***" means a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(jj) "***Option Agreement***" means a written or electronic agreement between the Company and the Optionholder evidencing the terms and conditions of the Option grant. The Option Agreement includes the Grant Notice for the Option and the agreement containing the written summary of the general terms and conditions applicable to the Option and which is provided, including through electronic means, to a Participant along with the Grant Notice. Each Option Agreement will be subject to the terms and conditions of the Plan.

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(kk) "***Optionholder***" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

EXHIBIT 10.7

(ll) "***Other Award***" means an award valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than 100% of the Fair Market Value at the time of grant) that is not a Nonstatutory Stock Option, SAR, Restricted Stock Award, RSU Award or Performance Award.

(mm) "***Other Award Agreement***" means a written or electronic agreement between the Company and a holder of an Other Award evidencing the terms and conditions of an Other Award grant. Each Other Award Agreement will be subject to the terms and conditions of the Plan.

(nn) "***Own,***" "***Owned,***" "***Owner,***" or "***Ownership***" means that a person or Entity will be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(oo) "***Participant***" means an Eligible Employee to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Award.

(pp) "***Performance Award***" means an Award that may vest or may be exercised or a cash award that may vest or become earned and paid contingent upon the attainment during a Performance Period of certain Performance Goals and which is granted under the terms and conditions of Section 5(b) pursuant to such terms as are approved by a majority of the Company's Independent Directors or the Independent Compensation Committee. In addition, to the extent permitted by Applicable Law and set forth in the applicable Award Agreement, a majority of the Company's Independent Directors or the Independent Compensation Committee may determine that cash or other property may be used in payment of Performance Awards. Performance Awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the Common Stock.

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(qq) "***Performance Criteria***" means one or more criteria that a majority of the Company's Independent Directors or the Independent Compensation Committee will select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that will be used to establish such Performance Goals may be based on any one of, or combination of, the following as determined by a majority of the Company's Independent Directors or the Independent Compensation Committee: earnings (including earnings per share and net earnings); earnings before interest, taxes and depreciation; earnings before interest, taxes, depreciation and amortization; total stockholder return; relative stockholder return; return on equity or average stockholder's equity; return on assets, investment, or capital employed; stock price; margin (including gross margin); income (before or after taxes); operating income; operating income after taxes; pre-tax profit; operating cash flow; sales or revenue targets; increases in revenue or product revenue; expenses and cost reduction goals; improvement in or attainment of working capital levels; economic value added (or an equivalent metric); market share; cash flow; cash flow per share; share price performance; debt reduction; customer satisfaction; stockholders' equity; capital expenditures; debt levels; operating profit or net operating profit; workforce diversity; growth of net income or operating income; billings; financing; regulatory milestones; stockholder liquidity; corporate governance and compliance; intellectual property; personnel

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matters; progress of internal research; progress of partnered programs; partner satisfaction; budget management; partner or collaborator achievements; internal controls, including those related to the Sarbanes-Oxley Act of 2002; investor relations, analysts and communication; implementation or completion of projects or processes; employee retention; number of users, including unique users; strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property); establishing relationships with respect to the marketing, distribution and sale of the Company's products; supply chain achievements; co-development, co-marketing, profit sharing, joint venture or other similar arrangements; individual performance goals; corporate development and planning goals; and other measures of performance selected by the Company's Independent Directors or the Independent Compensation Committee whether or not listed herein.

(rr) "***Performance Goals***" means, for a Performance Period, one or more goals established by a majority of the Company's Independent Directors or the Independent Compensation Committee for the Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or

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business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by a majority of the Company's Independent Directors or the Independent Compensation Committee (i) in the Award Agreement at the time the Award is granted or (ii) in such other document setting forth the Performance Goals at the time the Performance Goals are established, a majority of the Company's Independent Directors or the Independent Compensation Committee will appropriately make adjustments in the method of calculating the attainment of Performance Goals for a Performance Period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by the Company achieved performance objectives at targeted levels during the balance of a Performance Period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of common stock of the Company by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under the Company's bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles. In addition, a majority of the Company's Independent Directors or the Independent Compensation Committee may establish or provide for other adjustment items in the Award Agreement at the time the Award is granted or in such other document setting forth the Performance Goals at the time the Performance Goals are established. In addition, a majority of the Company's Independent Directors or the Independent Compensation Committee retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for such Performance Period. Partial achievement of the specified criteria may result in the

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payment or vesting corresponding to the degree of achievement as specified in the Award Agreement or the written terms of a Performance Award.

(ss) "***Performance Period***" means the period of time selected by a majority of the Company's Independent Directors or the Independent Compensation Committee over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant's right to vesting or exercise of an Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of a majority of the Company's Independent Directors or the Independent Compensation Committee.

(tt) "***Plan***" means this Vera Therapeutics, Inc. 2021 Inducement Plan, as amended from time to time.

(uu) "***Plan Administrator***" means the person, persons, and/or third-party administrator designated by the Company to administer the day to day operations of the Plan and the Company's other equity incentive programs.

(vv) "***Post-Termination Exercise Period***" means the period following termination of a Participant's Continuous Service within which an Option or SAR is exercisable, as specified in Section 4(h).

(ww) "***Restricted Stock Award***" or "***RSA***" means an Award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 5(a).

(xx) "***Restricted Stock Award Agreement***" means a written or electronic agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. The Restricted Stock Award Agreement includes the Grant Notice for the Restricted Stock Award and the agreement containing the written summary of the general terms and conditions applicable to the Restricted Stock Award and which is provided, including by electronic means, to a Participant along with the Grant Notice. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

(yy) "***RSU Award***" or "***RSU***" means an Award of restricted stock units representing the right to receive an issuance of shares of Common Stock which is granted pursuant to the terms and conditions of Section 5(a).

(zz) "***RSU Award Agreement***" means a written or electronic agreement between the Company and a holder of an RSU Award evidencing the terms and conditions of an RSU Award grant. The RSU Award Agreement includes the Grant Notice for the RSU Award and the agreement containing the written summary of the general terms and conditions applicable to the RSU Award and

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which is provided, including by electronic means, to a Participant along with the Grant Notice. Each RSU Award Agreement will be subject to the terms and conditions of the Plan.

(aaa) "***Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(bbb) "***Rule 405***" means Rule 405 promulgated under the Securities Act.

(ccc) "***Section 409A***" means Section 409A of the Code and the regulations and other guidance thereunder.

(ddd) "***Section 409A Change in Control***" means a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company's assets, as provided in Section 409A(a)(2)(A)(v) of the Code and Treasury Regulations Section 1.409A- 3(i)(5) (without regard to any alternative definition thereunder).

(eee) "***Securities Act***" means the Securities Act of 1933, as amended.

(fff) "***Share Reserve***" means the number of shares available for issuance under the Plan as set forth in Section 2(a).

(ggg) "***Stock Appreciation Right***" or "***SAR***" means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 4.

(hhh) "***SAR Agreement***" means a written or electronic agreement between the Company and a holder of a SAR evidencing the terms and conditions of a SAR grant. The SAR Agreement includes the Grant Notice for the SAR and the agreement containing the written summary of the general terms and conditions applicable to the SAR and which is provided, including by electronic means, to a Participant along with the Grant Notice. Each SAR Agreement will be subject to the terms and conditions of the Plan.

(iii) "***Subsidiary***" means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes

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of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and
(ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

(jjj) "***Trading Policy***" means the Company's policy permitting certain individuals to sell Company shares only during certain "window" periods and/or otherwise restricts the ability of certain individuals to transfer or encumber Company shares, as in effect from time to time.

(kkk) "***Unvested Non-Exempt Award***" means the portion of any Non-Exempt Award that had not vested in accordance with its terms upon or prior to the date of any Corporate Transaction.

(lll) "***Vested Non-Exempt Award***" means the portion of any Non-Exempt Award that had vested in accordance with its terms upon or prior to the date of a Corporate Transaction.

EXHIBIT 10.8

VERA THERAPEUTICS, INC.

STOCK OPTION GRANT NOTICE
(2024 INDUCEMENT PLAN)

Vera Therapeutics, Inc. (the "***Company***"), pursuant to its 2024 Inducement Plan (as may be amended and/or restated as of the Date of Grant set forth below, the "***Plan***"), has granted to Optionholder an Option to purchase the number of shares of the Common Stock set forth below (the "***Option***")as an inducement material to you entering into employment with the Company in compliance with Nasdaq Listing Rule 5635(c)(4). The Option is subject to all of the terms and conditions as set forth in this Stock Option Grant Notice (the "***Grant Notice***") and in the Plan, the Option Agreement, and the Notice of Exercise, all of which are attached to this Grant Notice and incorporated into this Grant Notice in their entirety. Capitalized terms not explicitly defined in this Grant Notice but defined in the Plan or the Option Agreement shall have the meanings set forth in the Plan or the Option Agreement, as applicable. If the Company uses an electronic capitalization table system (such as Carta or Shareworks) and the fields below are blank or the information is otherwise provided in a different format electronically, the blank fields and other information (such as exercise schedule and type of grant) shall be deemed to come from the electronic capitalization system and is considered part of this Grant Notice.

Optionholder: **[●]**

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Date of Grant:	[●]
Vesting Commencement Date:	[●]
Number of Shares of Common Stock Subject to Option:	[●]
Exercise Price (Per Share):	[●]
Total Exercise Price:	[●]
Expiration Date:	[●]
Exercise Schedule:	Same as Vesting Schedule
Type of Grant:	Nonstatutory Stock Option

Vesting Schedule: [**Sample of standard vesting:** 12/48ths of the total shares will vest on the first anniversary of the Vesting Commencement Date, and 1/48th of the total shares will vest each month thereafter on the same day of the month as the Vesting Commencement Date (or if there is no corresponding day, on the last day of the month), subject to Optionholder's Continuous Service through each such date.]

Optionholder Acknowledgements: By Optionholder's signature below or by electronic acceptance or authentication in a form authorized by the Company, Optionholder understands and agrees that the Option is governed by this Stock Option Grant Notice, and the provisions of the Plan and the Option Agreement and the Notice of Exercise, all of which are made a part of this document.

By accepting this Option, Optionholder consents to receive this Grant Notice, the Option Agreement, the Plan, and any other Plan-related documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company. Optionholder represents that he or she has read and is familiar with the provisions of the Plan and the Option Agreement. Optionholder acknowledges and agrees that this Grant Notice and the Option Agreement may not be modified, amended or revised except in writing signed by Optionholder and a duly authorized officer of the Company.

Optionholder further acknowledges that in the event of any conflict between the provisions in this Grant Notice, the Option Agreement, the Notice of Exercise and the terms of the Plan, the terms of the Plan shall

EXHIBIT 10.8

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control. Optionholder further acknowledges that the Option Agreement sets forth the entire understanding between Optionholder and the Company regarding the acquisition of Common Stock and supersedes all prior oral and written agreements, promises and/or representations on that subject with the exception of: (i) any other equity award concurrently granted to Optionholder; and (ii) any written employment agreement, offer letter, severance agreement, written severance plan or policy, or other written agreement between the Company and Optionholder in each case that specifies the terms that should govern this Option.

Optionholder further acknowledges that this Grant Notice has been prepared on behalf of the Company by Cooley LLP, counsel to the Company and that Cooley LLP does not represent, and is not acting on behalf of, Optionholder in any capacity. Optionholder has been provided with an opportunity to consult with Optionholder's own counsel with respect to this Grant Notice.

This Grant Notice may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

Vera Therapeutics, Inc.	**Optionholder:**
By: _____ (Signature)	By: _____ (Signature)
Title: _____	Email: _____
Date: _____	Date: _____

Attachments: Option Agreement, 2024 Inducement Plan and Notice of Exercise

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EXHIBIT 10.8

ATTACHMENT I

OPTION AGREEMENT

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VERA THERAPEUTICS, INC.

INDUCEMENT AWARD UNDER THE 2024 INDUCEMENT PLAN

OPTION AGREEMENT
(NONSTATUTORY STOCK OPTION)

Pursuant to your Stock Option Grant Notice ("***Grant Notice***") and this Option Agreement, Vera Therapeutics, Inc. (the "***Company***") has granted you an Option award under its 2024 Inducement Plan (the "***Plan***") to purchase the number of shares of the Company's Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Noticeas an inducement material to you entering into employment with the Company in compliance with Nasdaq Listing Rule 5635(c)(4). The Option is granted to you effective as of the date of grant set forth in the Grant Notice (the "***Date of Grant***"). If there is any conflict between the terms in this Option Agreement and the Plan, the terms of the Plan will control. Capitalized terms not explicitly defined in this Option Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan.

The details of your Option, in addition to those set forth in the Grant Notice and the Plan, are as follows:

1. Vesting. Your Option will vest as provided in your Grant Notice, subject to the provisions contained herein and the terms of the Plan. Vesting will cease upon the termination of your Continuous Service.

2. Number of Shares and Exercise Price. The number of shares of Common Stock subject to your Option and your exercise price per share in your Grant Notice will be adjusted for Capitalization Adjustments.

3. Exercise Restriction for Non-Exempt Employees. If you are an Employee eligible for overtime compensation under the Fair Labor Standards Act of 1938, as amended (that is, a "***Non-Exempt Employee***"), and except as otherwise provided in the Plan, you may not exercise your Option until you have completed at least six months of Continuous Service measured from the Date of Grant, even if you have already been an employee for more than six months. Consistent with the provisions of the Worker Economic Opportunity Act, you may exercise your Option as to any vested portion prior to such six month anniversary in the case of (i) your death or disability, (ii) a Corporate Transaction in which your Option is not assumed, continued or substituted, (iii) a Change in Control or (iv) your termination of Continuous Service on your "retirement" (as defined in the Company's benefit plans).

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4. Exercise prior to Vesting ("Early Exercise"). If permitted in your Grant Notice (*i.e.*, the "Exercise Schedule" indicates "Early Exercise Permitted") and subject to the provisions of your Option, you may elect at any time that is both (i) during the period of your Continuous Service and (ii) during the term of your Option, to exercise all or part of your Option, including the unvested portion of your Option; *provided, however,* that:

(a) a partial exercise of your Option will be deemed to cover first vested shares of Common Stock and then the earliest vesting installment of unvested shares of Common Stock;

(b) any shares of Common Stock so purchased from installments that have not vested as of the date of exercise will be subject to the purchase Option in favor of the Company as described in the Company's form of Early Exercise Stock Purchase Agreement; and

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(c) you will enter into the Company's form of Early Exercise Stock Purchase Agreement with a vesting schedule that will result in the same vesting as if no early exercise had occurred.

5. Method of Payment. You must pay the full amount of the exercise price for the shares you wish to exercise. The permitted methods of payment are as follows:

(a) by cash, check, bank draft, electronic funds transfer or money order payable to the Company;

(b) subject to Company and/or Board consent at the time of exercise and provided that at the time of exercise the Common Stock is publicly traded, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. This manner of payment is also known as a "broker-assisted exercise", "same day sale", or "sell to cover";

(c) subject to Company and/or Board consent at the time of exercise and provided that at the time of exercise the Common Stock is publicly traded, by delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your Option, will include

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delivery to the Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company. You may not exercise your Option by delivery to the Company of Common Stock if doing so would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock;

(d) subject to Company and/or Board consent at the time of exercise, and provided that the Option is a Nonstatutory Stock Option, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise of the Option by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price plus, to the extent permitted by the Company and/or Board at the time of exercise, the aggregate withholding obligations in respect of the Option exercise; provided, further that you must pay any remaining balance of the aggregate exercise price not satisfied by the "net exercise" in cash or other permitted form of payment. Shares of Common Stock will no longer be subject to the Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are used to pay the exercise price pursuant to the "net exercise," (B) shares are delivered to you as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations;

(e) subject to the consent of the Company and/or Board at the time of exercise, according to a deferred payment or similar arrangement with you; *provided, however*, that interest will compound at least annually and will be charged at the minimum rate of interest necessary to avoid (A) the imputation of interest income to the Company and compensation income to the Optionholder under any applicable provisions of the Code, and (B) the classification of the Option as a liability for financial accounting purposes; or

(f) in any other form of legal consideration that may be acceptable to the Board.

6. Whole Shares. You may exercise your Option only for whole shares of Common Stock.

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7. Securities Law Compliance. In no event may you exercise your Option unless the shares of Common Stock issuable upon exercise are then registered under the Securities Act or, if not registered, the Company has determined that your exercise and the issuance of the shares would be exempt from the registration requirements of the Securities Act. The exercise of your Option also must comply with all other applicable laws and regulations governing your Option, and you may not exercise your Option if the Company determines that such exercise would not be in material compliance with such laws and regulations (including any restrictions on exercise required for compliance with Treas. Reg. 1.401(k)-1(d)(3), if applicable).

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8. Term. You may not exercise your Option before the Date of Grant or after the expiration of the Option's term. Except as set forth in your Grant Notice, the term of your Option expires, subject to the provisions of Section 4(h) of the Plan, upon the earliest of the following:

(a) immediately upon the termination of your Continuous Service for Cause;

(b) three months after the termination of your Continuous Service for any reason other than Cause,your Disability or your death (except as otherwise provided in Section 8(d) below); *provided, however,* that if during any part of such three month period your Option is not exercisable solely because of the condition set forth in the section above relating to "Securities Law Compliance," your Option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three months after the termination of your Continuous Service; *provided further,* that if (i) you are a Non-Exempt Employee, (ii) your Continuous Service terminates within six months after the Date of Grant, and (iii) you have vested in a portion of your Option at the time of your termination of Continuous Service, your Option will not expire until the earlier of (x) the later of (A) the date that is seven months after the Date of Grant, and (B) the date that is three months after the termination of your Continuous Service, and (y) the Expiration Date;

(c) 12 months after the termination of your Continuous Service due to your Disability (except as otherwise provided in Section 8(d) below);

(d) 18 months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates for any reason other than Cause;

(e) the Expiration Date indicated in your Grant Notice; or

(f) the day before the 10th anniversary of the Date of Grant.

9. Exercise.

(a) You may exercise the vested portion of your Option (and the unvested portion of your Option if your Grant Notice so permits) during its term by delivering a Notice of Exercise (in a form designated by the Company) together with the exercise price to the Secretary of the Company, or to such other person as the Company may designate, during regular business hours. If required by the Company, your exercise may be made contingent on your execution of any additional documents specified by the Company (including, without limitation, any voting agreement or other agreement between the Company and some or all of its stockholders).

(b) By exercising your Option you agree that, as a condition to any exercise of your Option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of (i) the exercise of your

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Option, (ii) the lapse of any substantial risk of forfeiture to which the shares of Common Stock are subject at the time of exercise, or (iii) the disposition of shares of Common Stock acquired upon such exercise.

(c) By exercising your Option you agree that you will not sell, dispose of, transfer, make any short sale of, grant any option for the purchase of, or enter into any hedging or similar transaction with the same economic effect as a sale with respect to any shares of Common Stock or other securities of the Company held by you, for a period of 180 days following the effective date of a registration statement of the Company filed under the Securities Act or such longer period as the underwriters or the Company will request to facilitate compliance with applicable FINRA rules (the "***Lock-Up Period***"); *provided, however*, that nothing contained in this section will prevent the exercise of a repurchase option, if any, in favor of the Company during the Lock-Up Period. You further agree to execute and deliver such other agreements as may be reasonably requested by the Company or the underwriters that are consistent with the foregoing or that are necessary to give further effect thereto. In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to your shares of Common Stock until the end of such period. You also agree that any transferee of any shares of Common Stock (or other securities) of the Company held by you will be bound by this Section 9(c). The underwriters of the Company's stock are intended third party beneficiaries of this Section 9(c) and will have the right, power and authority to enforce the provisions hereof as though they were a party hereto.

10.Transferability. Except as otherwise provided in this Section 10, your Option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you.

(a) **Certain Trusts**. Upon receiving written permission from the Board or its duly authorized designee, you may transfer your Option to a trust if you are considered to be the sole beneficial owner (determined under Section 671 of the Code and applicable state law) while the Option is held in the trust. You and the trustee must enter into transfer and other agreements required by the Company.

(b) **Domestic Relations Orders**. Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your Option pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulation 1.421-1(b)(2) that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this Option with the Company prior to finalizing the domestic relations order or marital settlement agreement to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

(c) **Beneficiary Designation**. Upon receiving written permission from the Board or its duly authorized designee, you may, by delivering written notice to the Company, in a form approved by the Company

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and any broker designated by the Company to handle option exercises, designate a third party who, on your death, will thereafter be entitled to exercise this Option and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, your executor or administrator of your estate will be entitled to exercise this Option and receive, on behalf of your estate, the Common Stock or other consideration resulting from such exercise.

11. Option not a Service Contract. Your Option is not an employment or service contract, and nothing in your Option will be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your Option will obligate the Company or an Affiliate, their respective

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stockholders, boards of directors, officers or employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

12. Withholding Obligations.

(a) At the time you exercise your Option, in whole or in part, and at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a "same day sale" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your Option.

(b) Upon your request and subject to approval by the Company, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your Option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid classification of your Option as a liability for financial accounting purposes). If the date of determination of any tax withholding obligation is deferred to a date later than the date of exercise of your Option, share withholding pursuant to the preceding sentence will not be permitted unless you make a proper and timely election under Section 83(b) of the Code, covering the aggregate number of shares of Common Stock acquired upon such exercise with respect to which such determination is otherwise deferred, to accelerate the determination of such tax withholding

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obligation to the date of exercise of your Option. Notwithstanding the filing of such election, shares of Common Stock will be withheld solely from fully vested shares of Common Stock determined as of the date of exercise of your Option that are otherwise issuable to you upon such exercise. Any adverse consequences to you arising in connection with such share withholding procedure will be your sole responsibility.

(c) You may not exercise your Option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your Option when desired even though your Option is vested, and the Company will have no obligation to issue a certificate for such shares of Common Stock or release such shares of Common Stock from any escrow provided for herein, if applicable, unless such obligations are satisfied.

13.Tax Consequences. You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your Option or your other compensation. In particular, you acknowledge that this Option is exempt from Section 409A of the Code only if the exercise price per share specified in the Grant Notice is at least equal to the “fair market value” per share of the Common Stock on the Date of Grant and there is no other impermissible deferral of compensation associated with the Option. Because the Common Stock is not traded on an established securities market, the Fair Market Value is determined by the Board, perhaps in consultation with an independent valuation firm retained by the Company. You acknowledge that there is no guarantee that the Internal Revenue Service will agree with the valuation as determined by the Board, and you will not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates in the event that the Internal Revenue Service asserts that the valuation determined by the Board is less than the “fair market value” as subsequently determined by the Internal Revenue Service.

14.Notices. Any notices provided for in your Option or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Option, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

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15.Governing Plan Document. Your Option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. If there is any conflict between the provisions of your Option and those of the Plan, the provisions of the Plan will control.

6.

ATTACHMENT II

2024 INDUCEMENT PLAN

ATTACHMENT III

NOTICE OF EXERCISE

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VERA THERAPEUTICS, INC.

NOTICE OF EXERCISE

This constitutes notice to **Vera Therapeutics, Inc.** (the "***Company***") under my stock option that I elect to purchase the below number of shares of Common Stock of the Company (the "***Shares***") for the price set forth below. Capitalized terms not explicitly defined in this Notice of Exercise but defined in the Stock Option Grant Notice, Option Agreement or 2024 Inducement Plan, as may be amended from time to time, (the "***Plan***") shall have the meanings set forth in the Stock Option Grant Notice, Stock Option Agreement and Plan. Use of certain payment methods is subject to Company and/or Board consent and certain additional requirements set forth in the Option Agreement and the Plan. If the Company uses an electronic capitalization table system (such as Carta or Shareworks) and the fields below are blank, the blank fields shall be deemed to come from the electronic capitalization system and is considered part of this Notice of Exercise.

Option Information

Type of Option: Nonstatutory

Stock Option dated: _____

Number of Shares as to which Option is exercised: _____

Certificates to be issued in name of: _____

Exercise Information

Date of Exercise: _____

Total exercise price: _____

Cash: _____

Regulation T Program (cashless exercise): _____

Value of _____ Shares delivered with this notice: _____

Value of _____ Shares pursuant to net exercise: _____

By this exercise, I agree (i) to provide such additional documents as you may require pursuant to the terms of the Plan, Stock Option Grant Notice and the Option Agreement, and (ii) to provide for the payment by me to you (in the manner designated by you) of your withholding obligation, if any, relating to the exercise of this Option. I further agree that this Notice of Exercise may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

I further agree that, if required by the Company (or a representative of the underwriters) in connection with the first underwritten registration of the offering of any securities of the Company under the Securities Act, I will not sell, dispose of, transfer, make any short sale of, grant any option for the purchase of, or enter into any hedging or similar transaction with the same economic effect as a sale with respect to any shares of Common Stock or other securities of the Company for a period of 180 days following the effective date of a registration statement of the Company filed under the Securities Act (or

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such longer period as the underwriters or the Company will request to facilitate compliance with applicable FINRA rules) (the "***Lock-Up Period***"). I further agree to execute and deliver such other agreements as may be reasonably requested by the Company or the underwriters that are consistent with the foregoing or that are necessary to give further effect thereto. In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to securities subject to the foregoing restrictions until the end of such period.

Very truly yours,

(Signature)

Name (Please Print)

Address of Record: _____

Email: _____

EXHIBIT 10.9

VERA THERAPEUTICS, INC.

2024 INDUCEMENT PLAN

RESTRICTED STOCK UNIT GRANT NOTICE

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Vera Therapeutics, Inc. (the "***Company***") has awarded to you (the "***Participant***") the number of restricted stock units specified, and on the terms set forth, below in consideration of your future services (the "***RSU Award***"). Your RSU Award is subject to all of the terms and conditions as set forth herein, in the Company's 2024Inducement Plan (the "***Plan***") and the Award Agreement (the "***Agreement***"), which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein but defined in the Plan or the Agreement shall have the meanings set forth in the Plan or the Agreement.

Participant:

Date of Grant:

Vesting Commencement Date:

Number of Restricted Stock Units:

Vesting Schedule: [_____].Notwithstanding the foregoing, vesting shall terminate upon the Participant's termination of Continuous Service.

Issuance Schedule: One share of Common Stock will be issued for each restricted stock unit that vests at the time set forth in Section 5 of the Agreement.

Participant Acknowledgements: By your signature below or by electronic acceptance or authentication in a form authorized by the Company, you understand and agree that:

- The RSU Award is governed by this RSU Award Grant Notice (the "***Grant Notice***"), and the provisions of the Plan and the Agreement, all of which are made a part of this document. Unless otherwise provided in the Plan, this Grant Notice and the Agreement (together, the "***RSU Award Agreement***") may not be modified, amended or revised except in a writing signed by you and a duly authorized officer of the Company.
- You have read and are familiar with the provisions of the Plan, the RSU Award Agreement and the Prospectus. In t event of any conflict between the provisions in the RSU Award Agreement, or the Prospectus and the terms of the Pla the terms of the Plan shall control.
- The RSU Award Agreement sets forth the entire understanding between you and the Company regarding t acquisition of Common Stock and supersedes all prior oral and written agreements, promises and/or representations that subject with the exception of: (i) any other equity award concurrently granted to you; and (ii) any writt employment agreement, offer letter, severance agreement, written severance plan or policy, or other written agreeme between the Company and you in each case that specifies the terms that should govern this RSU Award.

VERA THERAPEUTICS, INC. **PARTICIPANT:**

By:

Signature Signature

Title: Date:

Date:

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EXHIBIT 10.9

ATTACHMENTS: Award Agreement (RSU Award), 2024Inducement Plan

VERA THERAPEUTICS, INC.

2024 INDUCEMENT PLAN

AWARD AGREEMENT (RSU AWARD)

As reflected by your Restricted Stock Unit Grant Notice ("***Grant Notice***"), Vera Therapeutics, Inc. (the "***Company***") has granted you an RSU Award under the Company's 2024 Inducement Plan (the "***Plan***") for the number of restricted stock units as indicated in your Grant Notice (the "***RSU Award***"). This RSU Award is granted in compliance with Nasdaq Listing Rule 5635(c)(4) as a material inducement to you entering into employment with the Company. The terms of your RSU Award as specified in this Award Agreement for your RSU Award (the "***Agreement***") and the Grant Notice constitute your "***RSU Award Agreement***". Defined terms not explicitly defined in this Agreement but defined in the Grant Notice or the Plan shall have the same definitions as in the Grant Notice or Plan, as applicable.

The general terms applicable to your RSU Award are as follows:

1. GOVERNING PLAN DOCUMENT. Your RSU Award is subject to all the provisions of the Plan, including but not limited to the provisions in:

(a) Section 6 of the Plan regarding the impact of a Capitalization Adjustment, dissolution, liquidation, or Corporate Transaction on your RSU Award;

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(b) Section 9(e) of the Plan regarding the Company's retained rights to terminate your Continuous Service notwithstanding the grant of the RSU Award; and

(c) Section 8(c) of the Plan regarding the tax consequences of your RSU Award.

Your RSU Award is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the RSU Award Agreement and the provisions of the Plan, the provisions of the Plan shall control.

2. Grant of the RSU Award. This RSU Award represents your right to be issued on a future date the number of shares of the Company's Common Stock that is equal to the number of restricted stock units indicated in the Grant Notice as modified to reflect any Capitalization Adjustment and subject to your satisfaction of the vesting conditions set forth therein (the "***Restricted Stock Units***"). Any additional Restricted Stock Units that become subject to the RSU Award pursuant to Capitalization Adjustments as set forth in the Plan and the provisions of Section 3 below, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Restricted Stock Units covered by your RSU Award.

3. Dividends. You shall receive no benefit or adjustment to your RSU Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment as provided in the Plan; provided, however, that this sentence shall not apply with respect to any shares of Common Stock that are delivered to you in connection with your RSU Award after such shares have been delivered to you.

4. Withholding Obligations. As further provided in Section 8 of the Plan, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for, any sums required to satisfy the federal, state, local and foreign tax withholding

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obligations, if any, which arise in connection with your RSU Award (the "***Withholding Obligation***") in accordance with the withholding procedures established by the Company. Unless the Withholding Obligation is satisfied, the Company shall have no obligation to deliver to you any Common Stock in respect of the RSU Award. In the event the Withholding Obligation of the Company arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Withholding Obligation was greater

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than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

5. Date of Issuance.

(a) The issuance of shares in respect of the Restricted Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the Withholding Obligation, if any, in the event one or more Restricted Stock Units vests, the Company shall issue to you one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 above, and subject to any different provisions in the Grant Notice). Each issuance date determined by this paragraph is referred to as an "***Original Issuance Date***."

(b) If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if:

(i) the Original Issuance Date does not occur (1) during an "open window period" applicable to you, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities, or (2) on a date when you are otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market (including but not limited to under a previously established written trading plan that meets the requirements of Rule 10b5-1 under the Exchange Act and was entered into in compliance with the Company's policies (a "***10b5-1 Arrangement***")), *and*

(ii)either (1) a Withholding Obligation does not apply, or (2) the Company decides, prior to the Original Issuance Date, (A) not to satisfy the Withholding Obligation by withholding shares of Common Stock from the shares otherwise due, on the Original Issuance Date, to you under this Award, and (B) not to permit you to enter into a "same day sale" commitment with a broker-dealer (including but not limited to a commitment under a 10b5-1 Arrangement) and (C) not to permit you to pay your Withholding Obligation in cash,

then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day when you are not prohibited from selling shares of the Company's Common Stock in the open public market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if and only if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the shares of Common Stock under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

(c) To the extent the RSU Award is a Non-Exempt Award, the provisions of Section 11 of the Plan shall apply.

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6. Transferability. Except as otherwise provided in the Plan, your RSU Award is not transferable, except by will or by the applicable laws of descent and distribution.

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7. Corporate Transaction. Your RSU Award is subject to the terms of any agreement governing a Corporate Transaction involving the Company, including, without limitation, a provision for the appointment of a stockholder representative that is authorized to act on your behalf with respect to any escrow, indemnities and any contingent consideration.

8. No Liability for Taxes. As a condition to accepting the RSU Award, you hereby (a) agree to not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from the RSU Award or other Company compensation and (b) acknowledge that you were advised to consult with your own personal tax, financial and other legal advisors regarding the tax consequences of the RSU Award and have either done so or knowingly and voluntarily declined to do so.

9. Severability. If any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid will, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

10.Other Documents. You hereby acknowledge receipt of or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Prospectus. In addition, you acknowledge receipt of the Company's Trading Policy.

11.Questions. If you have questions regarding these or any other terms and conditions applicable to your RSU Award, including a summary of the applicable federal income tax consequences please see the Prospectus.

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EXHIBIT 10.11

VERA THERAPEUTICS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY
AMENDED AND RESTATED MARCH 28, 2023 EFFECTIVE JANUARY 1, 2024

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 $10,000
   b. Member of the Compensation Committee: $5,000 $6,000
   c. Member of the Nominating and Corporate Governance Committee: $4,000 $5,000

3. Annual Committee Chair Service Retainer (inclusive of Committee Member Service Retainer):
   a. Chairperson of the Audit Committee: $15,000 $20,000
   b. Chairperson of the Compensation Committee: $10,000 $12,000

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c. Chairperson of the Nominating and Corporate Governance Committee: $8,000 $10,000

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

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term of 10 years from the date of grant (subject to earlier termination in connection with a

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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.

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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 December 6, 2023

EXHIBIT 10.14

January 3, 2024
Celia Lin, M.D.
Via Email
Dear Celia:
This letter sets forth the substance of the separation agreement (the "**Agreement**") that Vera Therapeutics, Inc. (the "**Company**") is offering to you to aid in your employment transition. By executing and delivering this Agreement, you and the Company agree as follows:

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1. Separation. Your last day of employment with the Company will be January 3, 2024 (the "**Separation Date**").

2. Accrued Salary and Paid Time Off. On the Separation Date, the Company will pay you all accrued salary and all accrued and, if applicable, any unused vacation earned through the Separation Date, subject to standard payroll deductions and withholdings. You are entitled to this payment regardless of whether or not you sign this Agreement.

3. Severance Benefits. Pursuant to the terms of your offer letter agreement with the Company dated May 7, 2021 (the "**Offer Letter**"), if you timely sign this Agreement, allow it to become effective, and comply with your obligations under it (collectively, the "**Severance Preconditions**"), then the Company will provide you with the following severance benefits (collectively, the "**Severance Benefits**"):

(a) Severance Pay. The Company will pay you, as severance, an amount equivalent to nine months of your base salary in effect as of the Separation Date, subject to standard payroll deductions and withholdings. This amount will be paid to you in a lump sum severance payment (the "**Severance Pay**"). The Severance Pay will be paid to you within two of the Company's regularly scheduled payroll dates after the Effective Date (as defined below).

(b) Bonus. You acknowledge that as of the Separation Date, you will not have earned and will not be entitled to any 2023 bonus payment. As an additional severance benefit, the Company will pay you the cash equivalent of your 2023 target bonus that you could have earned had you met the conditions for earning it, as calculated at the sole discretion of the Company, subject to standard payroll deductions and withholdings. This amount will be paid out to you by no later than March 15, 2024, in accordance with the Company's regular bonus payout schedule.

(c) Health Insurance. To the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, you will be eligible to continue your group health insurance benefits at your own expense following the Separation Date. Later, you may be able to convert to an individual policy through the provider of the Company's health insurance, if you wish. You will be provided with a separate notice describing your rights and obligations under COBRA and a form for electing COBRA coverage. As an additional severance benefit, provided that you timely elect continued coverage under COBRA, then the Company shall reimburse you or pay directly (at the Company's discretion) for the COBRA premiums to continue your health insurance coverage (including coverage for eligible dependents, if applicable) through the period (the "**COBRA Premium Period**") starting on the Separation Date and ending on the earliest to occur of: (i) nine months after the Separation Date; (ii) the date you become eligible for group health insurance coverage through a new employer; or (iii) the date you cease to be

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eligible for COBRA coverage for any reason. You must timely pay your premiums, and then provide documentation to the Company, to obtain reimbursement for your COBRA premiums under this Section 3(c). In the event you become covered under another employer's group health plan or otherwise cease to be eligible for COBRA during the COBRA Premium Period, you must immediately notify the Company in writing. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA premiums without a substantial risk of violating applicable law, then the Company instead shall pay you a fully taxable cash payment equal to the remaining COBRA premiums due under this Section, subject to applicable tax withholdings, which you may, but are not obligated to, use toward the cost of COBRA premiums.

4. EQUITY AWARDS. Under the terms of your equity award agreement(s) and the applicable plan documents, vesting of your equity awards will cease as of the Separation Date. Your right to exercise any vested shares, and all other rights and obligations with respect to your equity award(s), will be as set forth in the applicable award agreement, grant notice and applicable plan documents.

5. CONSULTING PERIOD. Beginning on January 3, 2024, the Company will engage you as a consultant on the terms set forth herein.

(a) Term. If: (i) you timely sign, date, and return this Agreement to the Company and allow all of the releases contained herein to become effective; and (ii) you comply with all of your obligations to the Company hereunder (collectively, the "**Preconditions**"), then the Company will continue your engagement as a consultant through July 3, 2024, unless terminated earlier pursuant to the terms set forth below or extended by mutual written agreement. If you do not timely execute and return this Agreement, or you revoke your signature after you sign it, or you otherwise do not satisfy the Preconditions, then your consulting engagement will end immediately upon the failure of any of the Preconditions (as determined by the Company in its discretion). The Company is under no legal obligation to retain your services as a consultant after the Separation Date and therefore this Consulting Period constitutes consideration for your obligations as specified herein. The full term of your consulting engagement as described in this Section 3 will be referred to as the "**Consulting Period**".

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(b) Consulting Services. During the Consulting Period, you will provide consulting services as may be requested by the Company (the "**Consulting Services**"). You will exercise the highest degree of professionalism and utilize your expertise and creative talents in performing these services. You will make yourself available to perform such Consulting Services throughout the Consulting Period, on an as-needed basis, up to a maximum of 10 hours per week. The Consulting Services will constitute a permanent reduction in your services to the Company to not more than 20% of the average level of bona fide services you provided to the Company during the 36-month period immediately preceding the Separation Date (or such lesser period of time you have been with the Company), such that any such Consulting Services shall be deemed a "separation from service" under Section 409A (as defined below). You will not be required to report to the Company's offices during the Consulting Period, except as specifically requested by the Company. When providing such services, you shall abide by the Company's policies and procedures.

(c) Consulting Fees. During the Consulting Period, you will receive consulting fees at a rate of $400 per hour ("**Consulting Fees**"). The Consulting Fees will be paid within 30 days of receipt by Company of each invoice for Consulting Services, which you shall submit monthly. You shall seek advance written approval prior to incurring any expenses for which you will seek reimbursement in connection with your duties during the Consulting Period.

EXHIBIT 10.14

(d) Independent Contractor Relationship. During the Consulting Period, your relationship with the Company will be that of an independent contractor, and nothing in this Agreement is intended to, or should be construed to, create a partnership, agency, joint venture or employment relationship after the Separation Date. Except as expressly provided in this Agreement, you will not be entitled to, and will not receive, any benefits which the Company may make available to its employees, including but not limited to, group health or life insurance, profit-sharing or retirement benefits.

(e) Taxes and Withholding. As an independent contractor, the Company will not withhold from the Consulting Fees any amount for taxes, social security or other payroll deductions. The Company will issue you a Form 1099 with respect to your Consulting Fees. You acknowledge that you will be entirely responsible for payment of any such taxes, and you hereby indemnify, defend and save harmless the

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Company, and its officers and directors in their individual capacity, from any liability for any taxes, penalties or interest that may be assessed by any taxing authority with respect to all compensation you receive under this Agreement, with the exception of the employer's share of social security, if any.

(f) Limitations on Authority. During the Consulting Period, you will have no responsibilities or authority as a consultant to the Company other than as provided above. You will have no authority to bind the Company to any contractual obligations, whether written, oral or implied, except with the prior written authorization of an officer of the Company. You will not represent or purport to represent the Company in any manner whatsoever to any third party unless authorized in advance by the Company, in writing, to do so.

(g) Confidential Information and Inventions. During the Consulting Period and thereafter, you will not use or disclose, in any manner that is not authorized by the Company or essential to your performance of specifically requested Consulting Services, any confidential or proprietary information or materials of the Company that you obtain or develop in the course of performing the Consulting Services. Any and all work product you create in the course of performing the Consulting Services will be the sole and exclusive property of the Company. You hereby assign to the Company all right, title, and interest in all inventions, techniques, processes, materials, and other intellectual property developed in the course of performing the Consulting Services. You further acknowledge and reaffirm your continuing obligations, both during the Consulting Period and thereafter (as applicable), under the Employee Confidential Information and Inventions Assignment Agreement entered into between you and the Company, a copy of which is attached hereto as **Exhibit A** and incorporated herein by reference.

(h) Other Work Activities. Throughout the Consulting Period, you shall have the right to engage in employment, consulting, or other work relationships in addition to your work for the Company. In order to protect the trade secrets and confidential and proprietary information of the Company, during the Consulting Period, you will notify the Company in writing, and obtain the Company's written consent, before you obtain employment with, or perform competitive work for, any business entity that is competitive with the Company, or engage in any other work activity, or preparation for work activity, competitive with the Company.

(i) Termination of Consulting Period. The Consulting Period will end on the earliest to occur of: (i) July 3, 2024, unless the Consulting Period is extended as agreed upon in a writing signed by both you and an authorized representative of the Company; (ii) 10 days after you provide written notice that you are terminating the Consulting Period for any reason; (iii) 10 days after the Company provides you with written notice that it is terminating the Consulting Period for any reason; or (iv)

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immediately upon the Company's written notice to you that you have breached your obligations hereunder or have breached any of your obligations under your Employee Confidential Information and Inventions Assignment Agreement.

6. OTHER COMPENSATION OR BENEFITS. You acknowledge that, except as expressly provided in this Agreement, you have not earned and will not receive from the Company any additional compensation (including base salary, bonus, incentive compensation, or equity), severance, or benefits before or after the Separation Date, with the exception of any vested right you may have under the express terms of a written ERISA-qualified benefit plan (e.g., 401(k) account) or any vested stock options. You further acknowledge that the offer of benefits herein satisfies and exceeds any severance or other benefits you may be eligible for or entitled to receive under the Offer Letter and any other agreement, plan or policy, and that upon your execution of this Agreement, any and all of the Company's obligations to provide you any severance or other separation benefits under the Offer Letter and any other agreement, plan or policy is hereby waived and extinguished.

7. EXPENSE REIMBURSEMENTS. Within ten days after the Separation Date, you will submit your final documented expense reimbursement statement reflecting all business expenses you incurred through the Separation Date, if any, for which you seek reimbursement. The Company will reimburse you for these expenses pursuant to its regular business practice.

8. RELEASE OF CLAIMS.

(a) General Release of Claims. In exchange for the consideration provided to you under this Agreement to which you would not otherwise be entitled, you hereby generally and completely release the Company, and its affiliated, related, parent and subsidiary entities, and its and their current and former directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, insurers, affiliates, and assigns from any and all claims, liabilities, demands, causes of action, and obligations, both known and unknown, arising from or in any way related to events, acts, conduct, or omissions occurring at any time prior to and including the date you sign this Agreement.

(b) Scope of Release. This general release includes, but is not limited to: (i) all claims arising from or in any way related to your employment with the Company or the termination of that employment; (ii) all

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claims related to your compensation or benefits from the Company, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, equity awards, or any other ownership, equity, or profits interests in the Company; (iii) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (iv) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (v) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the California Labor Code (as amended), the California Family Rights Act, the Age Discrimination in Employment Act ("**ADEA**") and the California Fair Employment and Housing Act (as amended). **You acknowledge that you have been advised, pursuant to California Government Code Section 12964.5(b)(4), that you have the right to consult an attorney regarding this Agreement and that you were given a reasonable time period of not less than five business days in which to do so.** In the event you sign this Agreement prior to the end of the reasonable time period provided by the Company, your decision to accept such shortening of time is knowing and voluntary and is not induced by the Company through fraud, misrepresentation, or a threat to withdraw or alter the offer

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prior to the expiration of the reasonable time period, or by providing different terms to employees who sign such an agreement prior to the expiration of the time period.

(c) ADEA Release. You acknowledge that you are knowingly and voluntarily waiving and releasing any rights you have under the ADEA, and that the consideration given for the waiver and releases you have given in this Agreement is in addition to anything of value to which you were already entitled. You further acknowledge that you have been advised, as required by the ADEA, that: (i) your waiver and release does not apply to any rights or claims arising after the date you sign this Agreement; (ii) you should consult with an attorney prior to signing this Agreement (although you may choose voluntarily not to do so); (iii) you have 21 days to consider this Agreement (although you may choose voluntarily to sign it sooner); (iv) you have seven days following the date you sign this Agreement to revoke this Agreement (in a written revocation sent to the Company); and (v) this Agreement will not be effective until the date upon which the revocation

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period has expired, which will be the eighth day after you sign this Agreement provided that you do not revoke it (the "**Effective Date**").

(d) Section 1542 Waiver. In giving the release herein, which includes claims which may be unknown to you at present, you acknowledge that you have read and understand Section 1542 of the California Civil Code, which reads as follows: **"A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."** You hereby expressly waive and relinquish all rights and benefits under that section and any law of any other jurisdiction of similar effect with respect to your release of claims herein, including but not limited to your release of unknown claims.

(e) Exceptions. Notwithstanding the foregoing, you are not releasing the Company hereby from: (i) any obligation to indemnify you pursuant to the Articles and Bylaws of the Company, any valid fully executed indemnification agreement with the Company, applicable law, or applicable directors and officers liability insurance; (ii) any claims that cannot be waived by law; or (iii) any claims for breach of this Agreement.

(f) Protected Rights. You understand that nothing in this Agreement limits your ability to file a charge or complaint with the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the California Civil Rights Department, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission ("**Government Agencies**"). You further understand this Agreement does not limit your ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that, to maximum extent permitted by law, you are otherwise waiving any and all rights you may have to individual relief based on any claims that you have released and any rights you have waived by signing this Agreement. Nothing in this Agreement (i) prevents you from discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that you have reason to believe is unlawful; or (ii) waives any rights you may have under Section 7 of the National Labor Relations Act (subject to the release of claims set forth herein).

9. RETURN OF COMPANY PROPERTY. Within five days after the Separation Date, or as otherwise agreed by the parties, you will return to the Company all Company documents (and all

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copies thereof) and other Company property in your possession or control, including, but not limited to, Company files, notes, account and device login and password information, product and services information, drawings, records, plans, forecasts, reports, studies, analyses, proposals, agreements, drafts, financial and operational information, research and development information, sales and marketing information, customer lists, prospect information, pipeline reports, sales reports, personnel information, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computing and electronic devices, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind which contain or embody any proprietary or confidential information of the Company (and all reproductions or embodiments thereof in whole or in part). You will make a diligent search to locate any such documents, property and information by the close of business on the Separation Date or as soon as possible thereafter. If you have used any personally owned computer or other electronic device, server, or e-mail system to receive, store, review, prepare or transmit any Company confidential or proprietary data, materials or information, within five days after the Separation Date, you shall provide the Company with a computer-useable copy of such information and then permanently delete and expunge such Company confidential or proprietary information from those systems; and you will provide the Company access to your system as requested to verify that the necessary copying and/or deletion is completed. **Your timely compliance with this paragraph is a condition to your receipt of the Severance Benefits provided under this Agreement.**

10. CONFIDENTIAL INFORMATION OBLIGATIONS. You acknowledge and reaffirm your continuing obligations under your Employee Confidential Information and Inventions Assignment Agreement, a copy of which is attached hereto as Exhibit A and incorporated herein by reference.

11. NON-DISPARAGEMENT. Except to the extent permitted by the “Protected Rights” Section above, you agree not to disparage the Company, its officers, directors, employees, shareholders, parents, subsidiaries, affiliates, and agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation; provided that you may respond accurately and fully to any request for information if required by legal process or in connection with a government investigation. In addition, nothing in this provision or this Agreement prohibits or restrains you from making disclosures protected under the whistleblower provisions of federal or state law or from exercising your rights to engage in protected speech under Section 7 of the National Labor Relations Act, if applicable.

12. NO VOLUNTARY ADVERSE ACTION. You will not voluntarily (except in response to legal compulsion or as permitted under the section of this Agreement entitled “Protected Rights”) assist any person in bringing or pursuing any proposed or pending litigation, arbitration, administrative claim or other formal

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proceeding against the Company, its parent or subsidiary entities, affiliates, officers, directors, employees or agents.

13. Cooperation. You will cooperate fully with the Company in connection with its actual or contemplated defense, prosecution, or investigation of any claims or demands by or against third parties, or other matters arising from events, acts, or failures to act that occurred during the period of your employment by the Company. Such cooperation includes, without limitation, making yourself available to the Company upon reasonable notice, without subpoena, to provide complete, truthful and accurate information in witness interviews, depositions, and trial testimony. The Company will reimburse you for reasonable out-of-pocket expenses you incur in connection with any such cooperation (excluding foregone wages) and will make reasonable efforts to accommodate your scheduling needs.

Exhibit 10.14

14. No Admissions. The promises and payments in consideration of this Agreement shall not be construed to be an admission of any liability or obligation by the Company to you or to any other person, and that the Company makes no such admission.

15. Section 409A. All payments and benefits provided under this Agreement are intended to satisfy the requirements for an exemption from application of Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and other guidance thereunder and any state law of similar effect (collectively, "**Section 409A**") to the maximum extent that an exemption is available and any ambiguities herein shall be interpreted accordingly; provided, however, that to the extent such an exemption is not available, such payments and benefits are intended to comply with the requirements of Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly. For purposes of Section 409A, any installment payments provided under this Agreement will each be treated as a separate payment. Except as otherwise expressly provided herein, to the extent any expense reimbursement or the provision of any in-kind benefit under the this Agreement is determined to be subject to (and not exempt from) Section 409A, the amount of any such expenses eligible for reimbursement, or the provision of any in-kind benefit, in one calendar year shall not affect the expenses eligible for reimbursement or in kind benefits to be provided in any other calendar year, in no event shall any expenses be reimbursed after the last day of the calendar year following the calendar year in which you incurred such expenses, and in no event will any right to reimbursement or the provision of any in-kind

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benefit be subject to liquidation or exchange for another benefit. To the extent required under Section 409A, any payments to be made under this Agreement in connection with a termination of employment will only be made if such termination constitutes a “separation from service” under Section 409A.

16. REPRESENTATIONS. You hereby represent that you have: been paid all compensation owed and for all hours worked; received all leave and leave benefits and protections for which you are eligible pursuant to the Family and Medical Leave Act, the California Family Rights Act, or otherwise; and not suffered any on-the-job injury for which you have not already filed a workers’ compensation claim.

17. MISCELLANEOUS. This Agreement constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with regard to its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified by the court so as to be rendered enforceable to the fullest extent permitted by law, consistent with the intent of the parties. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of California without regard to conflict of laws principles. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement shall be in writing and shall not be deemed to be a waiver of any successive breach. This Agreement may be delivered and executed via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and shall

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EXHIBIT 10.14

be deemed to have been duly and validly delivered and executed and be valid and effective for all purposes.

If this Agreement is acceptable to you, please sign below and return the original to me. You have 21 calendar days to decide whether to accept this Agreement, and the Company’s offer contained herein will

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automatically expire if you do not sign and return it within that timeframe.

We wish you the best in your future endeavors.

Sincerely,

By:

2 Marshall W. Fordyce, M.D.

Chief Executive Officer

I HAVE READ, UNDERSTAND AND AGREE FULLY TO THE FOREGOING AGREEMENT:

283652977 v1 Celia Lin, M.D.

Date

EXHIBIT 10.14

EXHIBIT A

EMPLOYEE CONFIDENTIAL INFORMATION AND INVENTIONS AGREEMENT

EXHIBIT 23.1

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 March 26, 2024, with respect to the financial

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statements of Vera Therapeutics, Inc.

/s/ KPMG LLP

San Francisco, California
March 28, 2023 26, 2024

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 f 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 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 wh this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to l designed under our supervision, to provide reasonable assurance regarding the reliability to financial reporting an 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 ou

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conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covere this report based on such evaluation; and

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control ov 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 t registrant's internal control over financial reporting.

Date: March 28, 2023 March 26, 2024

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 f 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 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

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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 wh this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to designed under our supervision, to provide reasonable assurance regarding the reliability to financial reporting an 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 ou conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covere 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 registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that ha materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporti and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control ov 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 t registrant's internal control over financial reporting.

Date: March 28, 2023 March 26, 2024

By: /s/ Sean Grant

Sean Grant

Chief Financial Officer

(Principal Financial Officer)

EXHIBIT 32.1

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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 December 31, 2023, 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, a amended; and

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

Date: March 28, 2023 March 26, 2024

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 December 31, 2023 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, a amended; and

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

By

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Date: March 28, 2023 March 26, 2024

: **/s/ Sean Grant**

Sean Grant

Chief Financial Officer

(Principal Financial Officer)

EXHIBIT 97.1

VERA THERAPEUTICS, INC.

INCENTIVE COMPENSATION RECOUPMENT POLICY

As adopted on November 6, 2023

1. INTRODUCTION

The Compensation Committee (the "***Compensation Committee***") of the Board of Directors (the "***Board***") of Vera Therapeutics, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

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"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within

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or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regard to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.
"***SEC***" means the U.S. Securities and Exchange Commission.

4. RECOUPMENT

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to

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recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in

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connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the

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Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. ADMINISTRATION

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. SEVERABILITY

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall

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not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. NO IMPAIRMENT OF OTHER REMEDIES

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

EXHIBIT 97.1

8. AMENDMENT; TERMINATION

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. SUCCESSORS

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. REQUIRED FILINGS

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

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