As confidentially submitted to the Securities and Exchange Commission on January 3, 2022. This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

### FORM S-1 **REGISTRATION STATEMENT**

UNDER THE SECURITIES ACT OF 1933

### Vera Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

2834 (Primary Standard Industrial Classification Code Number)

81-2744449 (I.R.S. Employer Identification Number)

Vera Therapeutics, Inc. 8000 Marina Boulevard, Suite 120 Brisbane, California 94005

(650) 770-0077 (Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Marshall Fordyce, M.D. President and Chief Executive Officer 8000 Marina Boulevard, Suite 120

Brisbane, California 94005 (650) 770-0077 (Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Jodie Bourdet **Brett White** Alexa Ekman Cooley LLP 3 Embarcadero Center, 20th Floor San Francisco, California 94111 (415) 693-2000

X

Sean Grant **Chief Financial Officer** 8000 Marina Boulevard, Suite 120 Brisbane, California 94005 (650) 770-0077

Heidi Mayon Jesse Nevarez Goodwin Procter LLP 601 Marshall Street Redwood City, California 94063 (650) 752-3100

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective. If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\Box$ 

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\Box$ 

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\Box$ 

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

Non-accelerated filer

Accelerated filer  $\times$ Smaller reporting company

Emerging growth company X

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 Section7(a)(2)(B) of the Securities Act.

#### CALCULATION OF REGISTRATION FEE

		Proposed maximum	Proposed maximum	
Title of each class of	Amount to be	aggregate offering	aggregate	Amount of
securities to be registered	registered(1)	price per share(2)	offering price(2)	registration fee(2)
Class A Common stock, par value \$0.001 per share				

shares of Class A common stock that the underwriters have the option to purchase. (1) Includes

Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(c) under the Securities Act, using the average of the high and low prices of (2)the Registrant's Class A common stock as reported on the Nasdaq Global Market on , 2022, which was approximately \$ per share

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated , 2022

Preliminary prospectus

shares



### Class A common stock

We are offering shares of our Class A common stock.

Our Class A common stock is listed on the Nasdaq Global Market under the symbol "VERA." On price of our Class A common stock on the Nasdaq Global Market was \$ per share.

We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced reporting requirements.

We have two classes of common stock: Class A common stock and Class B common stock. The rights of the holders of Class A common stock and Class B common stock are identical, except with respect to voting and conversion. Each share of Class A common stock is entitled to one vote and shares of Class B common stock are non-voting, except as may be required by law. Each share of Class B common stock may be converted at any time into one share of Class A common stock at the option of its holder, subject to the ownership limitations provided for in our amended and restated certificate of incorporation.

	Per share	Total
Public offering price	\$	\$
Underwriting discounts and commissions(1)	\$	\$
Proceeds to Vera Therapeutics, Inc., before expenses	\$	\$

(1) See the section titled "Underwriting" beginning on page 209 for a description of the compensation payable to the underwriters.

We have granted the underwriters an option to purchase up to additional shares of Class A common stock from us at the public offering price, less underwriting discounts and commissions, within 30 days from the date of this prospectus.

Investing in our Class A common stock involves a high degree of risk. See the section titled "<u>Risk factors</u>" beginning on page 16 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on or about , 2022.

J.P. Morgan

Cowen

**Evercore ISI** 

, 2022.

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Neither we nor the underwriters have authorized anyone to provide you any information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our securities and the distribution of this prospectus outside of the United States.

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### **Prospectus summary**

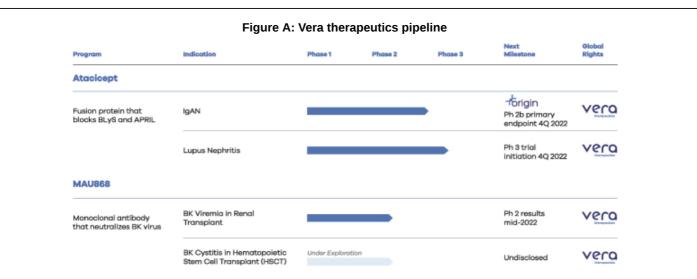
This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our securities. You should read this entire prospectus carefully, including the sections in this prospectus titled "Risk factors" and "Management's discussion and analysis of financial condition and results of operations," and our financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless otherwise indicated, all references in this prospectus to "Vera," the "company," "we," "our," "us" or similar terms refer to Vera Therapeutics, Inc.

#### Overview

We are a late-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases. We expect to initiate multiple registration-enabling trials over the next 18 months. Our lead product candidate, atacicept, a self-administered fusion protein that blocks both B lymphocyte stimulator (BLyS) and a proliferation-inducing ligand (APRIL), is currently being evaluated for the treatment of immunoglobulin A nephropathy (IgAN) in the Phase 2b ORIGIN trial, which we expect will complete enrollment in mid-2022 and report topline results in the fourth guarter of 2022. If these data are positive, we plan to seek an accelerated approval path in the United States from the U.S. Food and Drug Administration (FDA) and in the European Union (EU) from the European Medicines Agency (EMA) while initiating a pivotal Phase 3 clinical trial in 2023. We plan to initiate a Phase 3 clinical trial of atacicept in lupus nephritis (LN), a severe renal manifestation of systemic lupus erythematosus (SLE), in the fourth quarter of 2022 based on positive feedback from the FDA's review of promising clinical results in a Phase 2 clinical trial of atacicept in high disease activity patients with SLE. In December 2021, we obtained worldwide, exclusive development and commercial rights from Amplyx Pharmaceuticals, Inc. (Amplyx), a wholly owned subsidiary of Pfizer, for MAU868, a potentially first-in-class monoclonal antibody to treat BK virus (BKV) infections. We believe MAU868 is the only 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. In an interim analysis of Phase 2 data in BK viremia among kidney transplant recipients, MAU868 was shown to be well tolerated and demonstrated a clinically significant reduction of virologic activity. We expect to share full results from the interim analysis in mid-2022 and expect to initiate a Phase 2b or Phase 3 clinical trial in 2023. We believe that our current pipeline programs, shown in Figure A, leverage the deep expertise of the Vera Therapeutics team and have strong commercial synergies. We currently hold global rights to all of our pipeline programs.

In December 2021, we also entered into a Loan and Security Agreement (Loan Agreement) with Oxford Finance LLC, a Delaware limited liability company, as lender (Oxford) and collateral agent. The Loan Agreement provides for a term loan in an aggregate maximum principal amount of \$50.0 million (Loan). Of this amount, \$5.0 million was funded at closing on December 17, 2021 and the balance of which is available to be drawn between January 3, 2022 and December 31, 2022. 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.

<sup>1</sup> 



#### **Financial update**

As of December 31, 2021, we estimate that we had approximately \$ million of cash, cash equivalents and investments. This amount has not been audited, reviewed, or compiled by our independent registered public accounting firm. Our actual total cash, cash equivalents and investments as of December 31, 2021 may differ from this amount after we complete our comprehensive accounting procedures for the period ended December 31, 2021. Our audited financial statements for the year ended December 31, 2021 will not be available until after this offering is completed and, consequently, will not be available to you prior to investing in this offering.

#### Atacicept

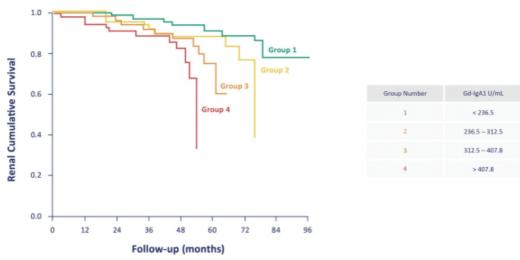
Atacicept is a fully humanized fusion protein that impacts the B-cell pathway, which has well characterized implications in immunologic diseases. Specifically, atacicept contains the soluble transmembrane activator and calcium-modulating cyclophilin ligand interactor (TACI) receptor that binds to the cytokines BLyS and APRIL. These cytokines are members of the tumor necrosis factor family that promote B-cell survival and autoantibody production associated with IgAN and other immunologic diseases. Dual blockade of BlyS and APRIL has been shown to be more potent than blocking BLyS alone or APRIL alone and has the benefit of targeting long-lived plasma cells, in addition to B cells, thus reducing autoantibody production, including Gd-IgA1, IgA, IgG and IgM. Therefore, atacicept's mechanism acts directly on the source of certain immunologic diseases, including IgAN and LN. Through an integrated analysis of randomized, double-blind, placebo-controlled clinical trials in over 1,500 patients to date, atacicept has a well-characterized clinical safety profile.

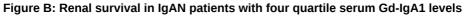
#### Atacicept in IgAN

We estimate there are approximately 126,000 biopsy-confirmed IgAN patients in the United States, 136,000 in the European Union, and 130,000 in Japan. Up to 50% of patients diagnosed with IgAN develop end-stage renal disease (ESRD) within 20 years from initial diagnosis, requiring dialysis or kidney transplant. ESRD causes considerable morbidity and impact on patients' lives and represents a significant health economic burden, which was estimated to be \$49.2 billion in the United States in 2018. Despite this high level of morbidity, the

current standard of care consists of off-label use of renin-angiotensin-aldosterone system (RAAS) inhibitors, including angiotensinconverting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs), and potentially steroids. We estimate the U.S. market opportunity for novel therapeutics in IgAN is approximately \$4.0 billion to \$8.0 billion annually, based on the disease prevalence and the segment of IgAN patients at high risk of progressing to ESRD. In Europe and Japan, we estimate the annual market opportunity for novel IgAN therapeutics to be \$1.0 billion and \$600 million, respectively.

Atacicept has been shown in a clinical trial to reduce Gd-IgA1, which is central to the pathogenesis of IgAN, and therefore has the potential to be the first disease modifying therapy for IgAN due to its ability to act on core pathophysiology processes. 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 levels of Gd-IgA1 may slow disease progression. 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 B below.

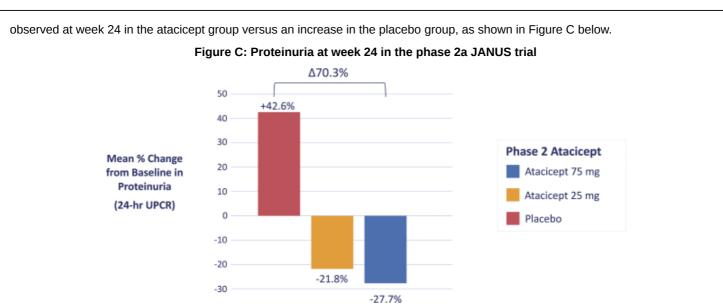




We believe that atacicept's mechanism has the potential to drive clinical success by measures designed to assess efficacy in IgAN and other immunologic diseases. BLyS inhibition has been clinically and commercially validated through the approval of Benlysta (belimumab) in both SLE and LN. Preclinical and clinical evidence supports that atacicept's mechanism of dual inhibition of BLyS and APRIL may provide improved clinical outcomes, measured by endpoints designed to assess efficacy, compared to inhibiting either signal alone.

On October 29, 2020, we entered into a worldwide, exclusive license to atacicept from Ares Trading S.A. (Ares), an affiliate of Merck KGaA, Darmstadt, Germany, which advanced atacicept in randomized, double-blind, placebo-controlled clinical trials for several autoimmune diseases in over 1,500 patients. We believe the large and well-characterized clinical data set for atacicept provides a competitive advantage for us versus other approved and emerging therapies in development, many of which are either earlier in development and have clinical profiles that are not as well characterized or are characterized by the well-known acute and chronic side effects of corticosteroids that limit their medical use.

In IgAN, Merck KGaA, Darmstadt, Germany, conducted a randomized, double-blind, placebo-controlled Phase 2a clinical trial that enrolled 16 patients, known as JANUS. A clinically meaningful reduction in proteinuria was



Atacicept 75 mg also showed a 60% reduction of Gd-IgA1 at 24 weeks (as shown in Figure D below), the largest magnitude in reduction of Gd-IgA1 in IgAN patients by any molecule in a randomized controlled trial for IgAN. Clear dose-dependent reductions of serum Gd-IgA1 were observed over the 72-week period studied, with atacicept 75 mg reducing Gd-IgA1 significantly (60%) and durably.

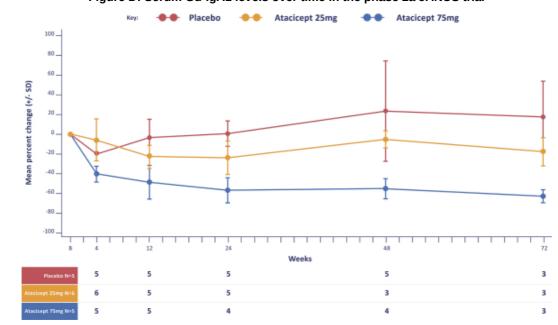


Figure D: Serum Gd-IgA1 levels over time in the phase 2a JANUS trial

We are conducting a global, randomized, double-blind, placebo-controlled Phase 2b clinical trial in IgAN, which we refer to as ORIGIN. The ORIGIN trial is evaluating three subcutaneous weekly doses of atacicept (25 mg, 75 mg and 150 mg) and their impact on the reduction of proteinuria as the primary endpoint. A significant reduction in proteinuria, as measured by urine protein to creatinine ratio (UPCR) in a 24-hour urine collection, is associated with improved renal outcomes in patients with IgAN. UPCR is a surrogate endpoint endorsed by the FDA for primary glomerular diseases associated with significant proteinuria, including IgAN. The ORIGIN trial is powered to demonstrate a statistically significant difference between atacicept and placebo in decrease of proteinuria. Given the FDA's recent approval of TARPEYO (developed by Calliditas Therapeutics AB under the name Nefecon), we believe this provides validation for the use of proteinuria as a surrogate for accelerated approval. Secondary endpoints include the difference in kidney function between treated and placebo patients as measured by estimated glomerular filtration rate (eGFR) and reduction in Gd-IgA1. We are currently enrolling the Phase 2b ORIGIN trial and expect to enroll a total of 105 patients at multiple global sites and to report topline results in the fourth quarter of 2022.

#### Atacicept in LN

Based on positive feedback from the FDA's review of promising clinical results in a Phase 2 clinical trial of atacicept in high disease activity patients with SLE, we are planning to initiate a Phase 3 clinical trial of atacicept in fourth guarter 2022 as a potential treatment for patients with LN, a severe renal manifestation of SLE. We estimate that there are approximately 110,000 LN patients in the United States, 69,000 in the European Union, and 22,000 in Japan. We estimate the market for novel LN therapeutics annually to be approximately \$2.0 to \$5.0 billion, \$600 million and \$200 million in the United States, Europe and Japan, respectively. Significant unmet need for improved efficacy persists for these patients despite the recent approval of the first two LN-specific therapies. Fewer than half of patients treated for LN have a complete response to therapy, and among patients without a complete response, over half will have non-functioning kidneys within five years. Benlysta (belimumab), a BlyS-only inhibitor, is one of the two therapies approved for patients with LN. Both BlyS and APRIL levels are increased in patients with SLE, suggesting that dual inhibition by atacicept may be more potent than blocking BLyS alone and has the benefit of targeting plasma cells in addition to B cells. Merck KGaA, Darmstadt, Germany previously initiated a randomized, double-blind, placebo-controlled Phase 2/3 clinical trial of atacicept in LN, the APRIL-LN trial, 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 subjects developing hypogammaglobulinemia with induction therapy (mycophenolate mofetil (MMF) and corticosteroids (CS)) which continued to worsen when initiating atacicept and subsequently two subjects 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 High Disease Activity patient segment (defined as Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) <sup>3</sup> 10 at screening), including reduction of renal flares, which we believe supports atacicept's applicability in LN. Because both preclinical and clinical evidence suggests atacicept's dual inhibition of BLyS and APRIL may provide improved clinical outcomes, measured by endpoints designed to assess efficacy, compared to inhibiting either signal alone, we believe there is a strong rationale to conduct a clinical trial of atacicept in LN.

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

response at 52 weeks. We plan to initiate patient screening for our Phase 3 clinical trial in LN in the fourth quarter of 2022.

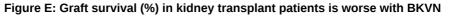
#### **MAU868**

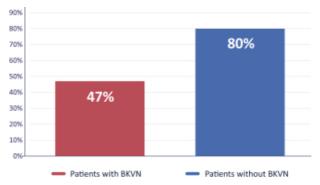
In December 2021, we obtained worldwide, exclusive development and commercial rights from Amplyx, a wholly owned subsidiary of Pfizer, for MAU868, a potentially first-in-class monoclonal antibody to treat BKV infections. We believe MAU868 is the only clinicalstage neutralizing monoclonal antibody that 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 an interim analysis of Phase 2 data in BK viremia among kidney transplant recipients, MAU868 was shown to be well tolerated and demonstrated a clinically significant reduction of virologic activity. We expect to share full results from the interim analysis in mid-2022 and expect to initiate a Phase 2b or Phase 3 clinical trial in 2023.

#### MAU868 in BK viremia among kidney transplant recipients

We are developing MAU868 as a potential treatment for BK viremia in kidney transplant recipients. While up to 90% of healthy adults have been infected with the 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 BKV Nephropathy (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 E, BKVN is a leading cause of allograft loss, a devastating outcome for kidney transplant recipients.





Currently, there are no approved treatment options for BK viremia or BKVN. In mid-2022, we expect to share full Cohort 1 and Cohort 2 results from the Phase 2 trial conducted by Amplyx, and initiate a Phase 2b or Phase 3 clinical trial in 2023. 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.

#### Our patent portfolio; potential market exclusivity

As of December 31, 2021, our licensed patent portfolio related to atacicept contains approximately 15 issued U.S. patents, as well as foreign counterparts of a subset of these patents in several foreign countries, including countries within the European Patent Cooperation and the Eurasian Patent Organization. Our licensed patent portfolio related to atacicept also includes a pending Patent Cooperation Treaty (PCT) application and a counterpart Taiwanese application. Because atacicept is a biologic, marketing approval would also provide 12 years of market exclusivity from the approval date of a Biologics License Application (BLA) in the United States. Additionally, we plan to seek orphan drug designation for atacicept in IgAN from the FDA and EMA, which would allow us to obtain regulatory exclusivity protection from the approval date for seven years in the United States and 10 years in the European Union. Our licensed patent portfolio covering MAU868 includes three issued U.S. patents, a pending US application, as well as certain foreign counterparts of a subset of these patents granted in Australia, China, and Taiwan, and pending applications in other jurisdictions such as Canada, Mexico, Europe and Japan. In addition, there is a pending PCT application, and a counterpart application in Taiwan.

#### 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.
- Establish clear line-of-sight to successful products.
- · Build a leading biotech company that delivers innovative medicines to patients.

These principles have guided us to the successful in-licensing of atacicept from Ares and obtaining the rights to MAU868 from Amplyx, in each case with worldwide rights for development and commercialization in all indications. We take a gated-capital raise approach and scale product candidate investment and exposure in close step with key development milestones to ensure high return on development costs.

The near-term objectives to achieve our goal include:

- · Complete global development of atacicept in IgAN.
- · Complete global development of atacicept in LN.
- Complete global development of MAU868 in BK viremia in kidney transplant recipients and explore treatment of BK cystitis in HSCT patients.
- · Build and scale organizational capabilities to support commercialization of atacicept and MAU868.
- Explore additional disease areas where atacicept holds significant therapeutic promise.
- Expand our pipeline by acquiring or in-licensing product candidates for immunologic diseases with unmet needs.

#### Our 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 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, Tad Thomas, Ph.D., who was formerly Associate Vice President, Technical Operations at Codexis, Inc. and held previous manufacturing leadership roles at Bayer HealthCare LLC and other biopharmaceutical companies; and Senior Vice President, Finance and Chief Accounting Officer, Joseph Young, who was formerly Senior Vice President, Finance and Treasurer at Plexxikon Inc.

#### **Risks related to our business**

Investing in our securities involves substantial risk. The risks, described under the section titled "Risk factors" immediately following this prospectus summary, may cause us to not realize the full benefits of our strengths or may cause us to be unable to successfully execute all or part of our strategy. Some of the more significant risks and challenges include, without limitation, the following:

- We have not completed any clinical trials for our lead product candidate, atacicept, and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on
  acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development
  programs of our product candidates or future commercialization efforts.
- We have incurred net losses since inception, and we expect to continue to incur net losses for the foreseeable future. In addition, we may be unable to continue as a going concern over the long-term.
- We are substantially dependent on the success of our product candidates, atacicept and MAU868, which are currently in the clinical development stage. If we are unable to complete development of, obtain regulatory approval for and commercialize our product candidates in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with IgAN, the availability of competitive products, and significant competition for recruiting patients in clinical trials.

- The incidence and prevalence for target patient populations of atacicept in specific indications are based on estimates and thirdparty sources. If the market opportunities for atacicept, or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.
- Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than us.
- · Changes in methods of manufacturing or formulation of our product candidates may result in additional costs or delays.
- Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.
- Even if any product candidate we develop receives regulatory approval, it could be subject to significant post-marketing regulatory requirements and will be subject to continued regulatory oversight.
- Biosimilars to our product candidates may provide competition sooner than anticipated.
- The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our clinical trials.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies. If we or our potential
  licensors, licensees, or collaborators are unable to obtain or maintain patent protection with respect to our product candidates,
  proprietary technologies and their uses, our business, financial condition, results of operations and prospects could be significantly
  harmed.
- The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees and key consultants.
- We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.
- If we breach our license agreement with Ares, an affiliate of Merck KGaA, Darmstadt, Germany, related to atacicept, or the license
  agreement with Novartis International Pharmaceutical AG (Novartis) related to MAU868, we could lose the ability to continue the
  development and commercialization of atacicept or MAU868, respectively.
- We may be required to make significant payments under our license agreements related to atacicept and MAU868.

- If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.
- Patent terms may be inadequate to protect our competitive position on atacicept, MAU868 or any future product candidates we may develop for an adequate amount of time.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations (CROs), to conduct certain aspects of our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize atacicept, MAU868 or future product candidates we may develop and our business, financial condition, results of operations and prospects could be significantly harmed.
- The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our thirdparty 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.
- We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our Class A common stock.
- Our principal stockholders and management own a significant percentage of our outstanding voting stock and will be able to exert significant control over matters subject to stockholder approval.
- Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law could
  make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our
  stockholders to replace or remove our current management.
- We may be subject to securities litigation, which is expensive and could divert management attention.

#### **Corporate information**

We were initially incorporated in Delaware in May 2016 under the name CDF Therapeutics, Inc. In October 2017, we changed our name to Trucode Gene Repair, Inc., and in April 2020, we changed our name to Vera Therapeutics, Inc. Our principal executive offices are located at 8000 Marina Boulevard, Suite 120, Brisbane, California 94005, and our telephone number is (650) 770-0077. Our website address is www.veratx.com. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

We use the VERA THERAPEUTICS word mark, Vera Therapeutics logo and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this

prospectus, including logos, artwork and other visual displays, may appear without the <sup>®</sup> or <sup>TM</sup> symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

#### Implications of being an emerging growth company and smaller reporting company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). We may take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm under Section 404 of the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) December 31, 2026; (iii) the date on which we are deemed to be a "large accelerated filer," under the rules of the SEC, which means the market value of equity securities that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th; and (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not "emerging growth companies."

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended (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 \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a non-accelerated filer, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

The offering		
Class A common stock offered	shares.	
Underwriters' option to purchase additional shares of Class A common stock	We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of our Class A common stock at the public offering price, less underwriting discounts and commissions.	
Total Class A and Class B common stock to be outstanding after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).	
Use of proceeds	We estimate that the net proceeds from this offering will be approximately \$ million (or approximately \$ million if the underwriters' option to purchase additional shares is exercised in full), after deducting underwriting discounts and commissions and estimated offering expenses payable by us.	
	We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund: a Phase 3 clinical trial of atacicept in LN; clinical development of MAU868 for the treatment of BKV in kidney transplant patients and potential additional indications; and the remainder for general corporate purposes, including working capital, operating expenses and capital expenditures. See the section titled "Use of proceeds" for additional information.	
Voting rights	We have two classes of common stock: Class A common stock and Class B common stock. The rights of the holders of Class A common stock and Class B common stock are identical, except with respect to voting and conversion.	
	Each share of Class A common stock is entitled to one vote and shares of Class B common stock are non-voting, except as may be required by law. Each share of Class B common stock may be converted into one share of Class A common stock at the option of its holder, subject to the ownership limitations provided for in our amended and restated certificate of incorporation. See the section titled "Description of capital stock" for additional information.	
Risk factors	See the section titled "Risk factors" beginning on page 17 and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our securities.	
Nasdaq Global Market trading symbol	"VERA"	
	A common stock and Class B common stock to be outstanding after this offering is based on non stock and 309,238 shares of Class B common stock	

outstanding as of September 30, 2021, including 4,137 shares of our unvested restricted Class A common stock subject to repurchase as of such date, and excludes, as of September 30, 2021:

- 2,894,671 shares of our Class A common stock issuable upon the exercise of outstanding stock options as of September 30, 2021, with a weighted-average exercise price of \$5.43 per share;
- 1,510,665 shares of our Class A common stock available for future issuance under the 2021 Equity Incentive Plan (2021 Plan) as
  of September 30, 2021, an additional 1,048,419 shares of our Class A common stock that were reserved for future issuance on
  January 1, 2022 in accordance with the terms of the 2021 Plan, as well as any future automatic annual increases in the number of
  shares of Class A common stock reserved for issuance under our 2021 Plan and any shares of Class A common stock underlying
  outstanding stock awards granted under our 2017 Equity Incentive Plan (2017 Plan) that expire or are repurchased, forfeited,
  cancelled or withheld, as more fully described in the section titled "Executive compensation—Equity benefit plans"; and
- 220,251 shares of our Class A common stock reserved for issuance under our 2021 Employee Stock Purchase Plan (ESPP), an additional 209,684 shares of our Class A common stock that were reserved for future issuance on January 1, 2022 in accordance with the terms of the ESPP, and any future automatic annual increases in the number of shares of Class A common stock reserved for future issuance under our ESPP.

Unless otherwise indicated, this prospectus assumes or gives effect to:

- a 11.5869-for-one reverse stock split of our common stock effected on May 7, 2021;
- the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 15,774,013 shares of our Class A common stock that was effected upon the closing of our initial public offering (IPO) in May 2021;
- · no exercise of the outstanding options described above;
- no exercise by the underwriters of their option to purchase additional shares of Class A common stock from us in this offering; and
- an assumed public offering price of \$ per share of Class A common stock, which is the last reported sale price of our Class A common stock on the Nasdaq Global Market on , 2022.

### Summary financial data

The following tables set forth a summary of our financial data as of, and for the periods ended on, the dates indicated. We have derived the summary statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2020, from our audited financial statements included elsewhere in this prospectus. The summary statement of operations and comprehensive loss data for the nine months ended September 30, 2021 and the balance sheet data as of September 30, 2021, are derived from our unaudited condensed financial statements and notes included elsewhere in this prospectus. We have prepared the unaudited condensed financial statements and notes included elsewhere in this prospectus. We have prepared the unaudited condensed financial statements and have included all adjustments, consisting of only normal recurring adjustments that, in our opinion, we consider necessary for a fair statement of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. You should read the following summary financial data together with the section titled "Management's discussion and analysis of financial condition and results of operations" and our financial statements and the related notes included elsewhere in this prospectus. The summary financial data included in this section are not intended to replace the financial statements and are qualified in their entirety by our financial statements and the related notes included elsewhere in their entirety by our financial statements and the related notes included elsewhere in their entirety by our financial statements and the related notes included elsewhere in their entirety by our financial statements and the related notes included elsewhere in their entirety by our financial statements and the related notes included elsewhere in their entirety by our financial statements and the related notes included elsewhere in their entirety by our financial s

		Year ended December 31,	 ine months ended ptember 30,
(in thousands, except share and per share data)	2019	2020	2021
Operating expenses:			
Research and development	\$ 7,290	\$ 45,206	\$ 9,731
General and administrative	4,410	4,039	8,086
Restructuring costs	261	2,996	
Total operating expenses	11,961	52,241	17,817
Loss from operations	(11,961)	(52,241)	(17,817)
Other income (expense):			
Interest income	159	8	9
Interest expense	(51)	(166)	—
Gain on the issuance of convertible notes	_	63	_
Change in fair value of convertible notes	—	(1,076)	—
Change in fair value of non-marketable equity securities			(645)
Gain on sale of PNAi technology			2,691
Total other income(expense), net	108	(1,171)	2,055
Loss before provision for income taxes	(11,853)	(53,412)	(15,762)
Provision for income taxes	(1)	(1)	_
Net loss and comprehensive loss(1)	\$ (11,854)	\$ (53,413)	\$ (15,762)
Net loss per common share, basic and diluted(1)	\$ (40.14)	\$ (166.93)	\$ (1.46)
Weighted-average shares used to compute net loss per common share, basic and diluted <sup>(1)</sup>	295,328	319,963	10,793,436

(1) See Note 2 to our audited financial statements and Note 2 to our unaudited condensed financial statements, each included elsewhere in this prospectus, for a description of how we compute basic and diluted net loss per share attributable to common stockholders.

	As o	As of September 30, 2021		
(unaudited, in thousands)	Actual	As adjusted(1)(2)		
Balance Sheet Data:				
Cash and cash equivalents	\$ 86,191	\$		
Working capital(3)	85,718			
Total assets	91,167			
Total liabilities	5,690			
Redeemable convertible preferred stock	—			
Accumulated deficit	(107,209)			
Total stockholders' equity (deficit)	\$ 85,477	\$		

(1) The as adjusted column reflects our issuance and sale of is the last reported sale price of our Class A common stock on the Nasdaq Global Market on estimated offering expenses payable by us.

(2) The as adjusted information is illustrative only and will depend on the actual public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed public offering price of \$ per share, which is the last reported sale price of our Class A common stock on the Nasdaq Global Market on , 2022, would increase or decrease, as applicable, each of cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by \$ million, assuming that the number of shares of Class A common stock offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease in the number of shares of class A common stock offered by us would increase or decrease, as applicable, each of cash and cash equivalents, working capital, total assets, and total stockholders' equity (deficit) by \$ million, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities. See our unaudited condensed financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

### **Risk factors**

Investing in our Class A common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and the section titled "Management's discussion and analysis of financial condition and results of operations" before deciding whether to invest in our Class A common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our Class A common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

#### 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-stage biotechnology company and we have no products approved for commercial sale, have not generated any revenue from product sales and have incurred losses since inception. To date, we have devoted substantially all of our resources and efforts to organizing and staffing our company, business planning, executing partnerships, raising capital, acquiring, developing and securing our technology and product candidates, and completing the Phase 2b clinical trial to further evaluate atacicept in patients with IgAN. 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.

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

Developing treatments for immunological and inflammatory diseases, including conducting nonclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses will increase in connection with our ongoing activities, particularly as we continue to conduct clinical trials of, and seek marketing approval for, our product candidates. We anticipate incurring significant costs associated with the development of our product candidates. Our expenses could increase beyond expectations if we are required by the FDA, or any comparable foreign regulatory authority to perform clinical trials or nonclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. In addition, if we obtain marketing approval for atacicept or MAU868, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. Because the design and outcome of

our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. We also will continue to incur costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of September 30, 2021, we had \$86.2 million in cash and cash equivalents. In December 2021, we entered into the Loan Agreement with Oxford, providing us with up to \$50.0 million of borrowing capacity. Of this amount, \$5.0 million was funded at closing of the Loan Agreement in December 2021. We believe, based on our current operating plan, that the net proceeds from this offering, together with our existing cash and cash equivalents and the funds available under the Loan Agreement with Oxford, will be sufficient to fund our operations at least into the fourth quarter of 2023. Our estimate as to how long we expect the net proceeds from this offering together with our existing cash and cash equivalents to be able to continue to fund our operating expenses and capital expenditures requirements 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, the ongoing COVID-19 pandemic and the macro-economic 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 other indications;
- initiate or continue nonclinical studies and clinical trials for atacicept, MAU868 and any additional product candidates that we may pursue in the future;
- continue our ongoing and planned research and development of MAU868 for the treatment of BKV disease in kidney transplant recipients and other indications;
- · seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets, and know-how;
- acquire, develop or in-license other product candidates and technologies and further expand our clinical product pipeline;
- attract, hire and retain additional clinical, scientific, quality control, and manufacturing management and administrative personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- · incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

We plan to use the net proceeds from this offering to advance and expand our clinical and nonclinical development programs and for working capital and other general corporate purposes. Advancing the

development of atacicept, MAU868 and any future product candidates we may develop will require a significant amount of capital. The net proceeds from this offering and our existing cash and cash equivalents will not be sufficient to fund all of the activities that are necessary to complete the development of our product candidates through approval and commercial launch.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Adequate additional financing may not be available to us on acceptable terms, or at all. Market volatility, including as a result of the COVID-19 pandemic, could also adversely impact 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 \$15.8 million and \$53.4 million for the nine months ended September 30, 2021 and year ended December 31, 2020, respectively. We had an accumulated deficit of \$107.2 million as of September 30, 2021. 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 lead product candidate, atacicept, is in clinical trials and MAU868 is in a Phase 2 clinical trial. As a result, we expect that it will be several years, if ever, before we have a commercialized product candidates in one of our lead indications, we expect that we will continue to incur substantial research and development and other expenses as we continue the clinical development programs for our product candidates in other indications.

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

In addition, our audited financial statements for the year ended December 31, 2020 included elsewhere in this prospectus have been prepared assuming we will continue as a going concern. However, we have incurred losses and negative cash flows from operations. As a development stage company, we expect to incur significant and increasing losses until regulatory approval is granted for our product candidates. Regulatory approval is not guaranteed and may never be obtained. As a result, these conditions raise substantial doubt about our ability to continue as a going concern over the long-term.

#### We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with our collaboration partners, to successfully complete the development of, and obtain the regulatory

approvals necessary to commercialize, atacicept, MAU868 and any future product candidates we may develop. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate revenue from product sales depends heavily on our and our current and potential future collaborators' success in:

- completing clinical development of product candidates and programs and identifying and developing new product candidates;
- seeking and obtaining marketing approvals for any product candidates that we develop;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a sales force, marketing, medical affairs and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- · achieving adequate access and reimbursement by government and third-party payors for product candidates that we develop;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for product candidates that we develop, if approved;
- obtaining market acceptance of product candidates that we develop as viable treatment options;
- · addressing any competing technological and market developments;
- maintaining our rights under our existing license agreement with Ares, Novartis and any similar agreements we may enter into in the future;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- · defending against third-party interference, infringement or other intellectual property-related claims, if any; and
- · attracting, hiring 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.

In December 2021, we entered into the Loan Agreement with Oxford, providing us with up to \$50.0 million of borrowing capacity. Of this amount, \$5.0 million was funded at closing of the Loan Agreement in December 2021. Our overall leverage and certain obligations and affirmative and negative covenants contained in the related documentation could adversely affect our financial health and business and future operations by

limiting our ability to, among other things, satisfy our obligations under the Loan Agreement, refinance our debt on terms acceptable to us or at all, plan for and adjust to changing business, industry and market conditions, use our available cash flow to fund future acquisitions and make dividend payments, and obtain additional financing for working capital, to fund growth or for general corporate purposes, even when necessary to maintain adequate liquidity.

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

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

We are substantially dependent on the success of our product candidates, atacicept and MAU868, which are currently in the clinical development stage. If we are unable to complete development of, obtain regulatory approval for and commercialize our product candidates in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

Our future success is heavily dependent on our ability to timely complete clinical trials, obtain marketing approval for and successfully commercialize our product candidates. We expect that a substantial portion of our efforts and expenses over the next several years will be devoted to the development of atacicept in our ongoing clinical trials in patients with IgAN, as well as our efforts to evaluate atacicept in LN and MAU868 in kidney transplant recipients. We are investing significant efforts and financial resources in the research and development of our product candidates, which will require additional clinical development, evaluation of clinical, nonclinical and manufacturing activities, marketing approval from government regulators, and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote our product candidates before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. Should our planned clinical development of atacicept 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 and commercialize our product candidates in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. We have never completed a clinical trial or submitted a BLA to the FDA or similar drug approval filings to comparable foreign authorities. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business, financial condition, results of operations and prospects will be significantly harmed.

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

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials. For example, atacicept has been the subject of clinical trials by prior sponsors, including a Phase 2 trial in SLE, that missed its primary endpoint in the overall study population. In the future, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or any potential future collaborator may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Any future delays or abandonment could harm our business, financial condition, results of operations and prospects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications.

Our future clinical trials may not be successful. If any product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business, financial condition, results of operations and prospects may be significantly harmed. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the dropout rate among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

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

In addition, we may rely in part on nonclinical, clinical and quality data generated by CROs and other third parties for regulatory submissions. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data

available to us, or, if applicable, make regulatory submissions in a timely manner, our development programs may be significantly delayed, and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase.

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

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

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

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- · obtaining approval from one or more institutional review boards (IRBs);
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- · changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- · study conduct issues, which could confound the clinical endpoints and/or data;
- manufacturing sufficient quantities of clinical trial material to supply the clinical trials;
- · subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- · delays in enrollment due to low prevalence or incidence rates of subjects with the applicable disease;
- delays in enrollment by subjects, or completion of the trial by subjects, due to the COVID-19 pandemic;
- · subjects choosing an alternative treatment or participating in competing clinical trials;

- · lack of adequate funding to continue the clinical trial;
- · subjects experiencing severe or unexpected drug-related adverse effects;
- regulatory authorities imposing a clinical hold;
- · occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- shutdowns, either temporarily or permanently, of any facility manufacturing our product candidates or any of their components, including by order from the FDA or comparable foreign regulatory authorities due to violations of current good manufacturing practice (cGMP), regulations or other applicable requirements;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices (GCP) or other regulatory requirements;
- · third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. For example, some hospitals delayed initiating clinical trials due to their focus on treating COVID-19 patients. Manufacturing timelines for drug product could be delayed, for example, due to a global shortage of syringes. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

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

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

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

Any delays in our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize atacicept, MAU868 or any other product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of atacicept, MAU868 or other product candidates could be significantly reduced. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

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

Identifying and qualifying patients to participate in our clinical trials is critical to our success. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. In particular, as a result of the inherent difficulties in diagnosing IgAN, the availability of competitive products such as TARPEYO, and the significant competition for recruiting the limited number of patients who have the diseases for which our product candidates are being developed, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all. Although we have engaged certain third-party investigators to assist with patient enrollment, there can be no assurance that we will be able to maintain our relationships with such third parties or that such third parties will be successful in helping us identify patients.

Factors that may generally affect patient enrollment include:

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

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

### We may develop atacicept, MAU868 and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.

We may develop atacicept, MAU868 and future product candidates in combination with one or more currently approved therapies. Even if atacicept, MAU868 or any product candidate we develop, were to receive marketing

approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate atacicept, MAU868 or any other future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell atacicept, MAU868 or any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with atacicept, MAU868 or any other product candidate we develop, we may be unable to obtain approval of or market atacicept, MAU868 or any other product candidate we develop.

# The incidence and prevalence for target patient populations of our product candidates in specific indications are based on estimates and third-party sources. If the market opportunities for atacicept, MAU868 or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our drug development strategy, including acquiring or in-licensing product candidates and determining indications on which to focus in nonclinical or clinical trials.

The incidence and prevalence for target patient populations of our product candidates in specific indications are based on estimates and third-party sources. These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, acceptance of our drugs by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to. If the market opportunities for atacicept, MAU868, or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve and sustain profitability might be materially and adversely affected.

#### Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

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

the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

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

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

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

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

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. The current standard-of-care for IgAN consists of treatment with RAAS inhibitors, including ACE inhibitors or ARBs, to control blood pressure, or steroids with or without other immunosuppressive agents to non-specifically reduce inflammation. Among emerging therapies, we consider our most direct competitors with respect to atacicept in IgAN to be the recently approved reformulated steroid from Calliditas Therapeutics AB, and programs in Phase 3 clinical development: Novartis Pharmaceuticals Corporation, Omeros Corporation, Travere Therapeutics, Inc., and Chinook Therapeutics Inc., and the following companies with programs in Phase 2 of clinical development: Chinook Therapeutics Inc., Alnylam Pharmaceuticals Inc., Apellis Pharmaceuticals, Inc., Reata Pharmaceuticals, Inc., RemeGen Co., Ltd., Visterra, Inc., Ionis Pharmaceuticals, Inc., Alexion Pharmaceuticals Inc. (Alexion), and DiaMedica Therapeutics, Inc. There is also a potential that SGLT2 inhibitors, including AstraZeneca plc's (AstraZeneca) Farxiga, which has completed Phase 3 clinical development, and C.H. Boehringer Sohn AG & Ko. KG's (Boehringer) jardiance, which is undergoing Phase 3 clinical development, will be approved broadly for chronic kidney disease and used in IgAN.

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. We expect that these paradigms will evolve with the recent FDA approvals of GlaxoSmithKline plc's Benlysta (belimumab) and Aurinia Pharmaceuticals Inc.'s Lupkynis (voclosporin), both of which we consider to be direct competitors. Our competitors include: Roche Holding AG and Novartis Pharmaceuticals Corporation, each of which have programs in Phase 3 clinical development; and BeiGene Ltd., Janssen Pharmaceuticals, Inc., AstraZeneca,

Alexion, Omeros Corporation, Kezar Life Science Inc., Bristol Myers Squibb, Boehringer, and Novartis Pharmaceuticals Corporation, each of which have programs in Phase 2 clinical development.

In the kidney transplant or HSCT setting, there are currently no anti-BKV therapies approved. The standard of care in both settings is to reduce immunosuppression as a first line, and potentially to offer intravenous immune globulin (IVIG) in kidney transplant recipients or antivirals with limited clinical evidence, including leflunomide and cidofovir, in either setting. There are few industry sponsored programs in development for these indications; we consider our most direct competitor to be Allovir's multi-virus specific T-cell therapy, Posoleucel, which is in a Phase 2 clinical trial for BK viremia in kidney transplant recipients, a Phase 3 clinical trial for treatment of virus-associated cystitis, and a Phase 2 clinical trial in multi-virus prevention following allogeneic HSCT.

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

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

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

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

#### Risks related to regulatory approval and other legal compliance matters

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

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

Applications for atacicept or MAU868 could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or comparable foreign regulatory authorities may determine that our product candidate is not safe and effective, only
  moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining
  marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full
  population for which we seek approval, resulting in a restrictive label and limiting commercial use;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials may not be sufficient to support the submission of a BLA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that the risk-benefit ratio for our proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products, such as TARPEYO;
- · the clinical indications for which the product candidate is approved;
- restrictions on use, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- our pricing and the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- · the availability of atacicept or MAU868 for use as a combination therapy;
- · relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- · the effectiveness of sales and marketing efforts;
- inclusion or exclusion of our product candidates from treatment guidelines established by various physician groups;
- unfavorable publicity relating to our product candidates or similar approved products or product candidates in development by third parties; and
- · the approval of other new therapies for the same indications.

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

### Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage, such inability could significantly harm our business, financial condition, results of operations and prospects.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent

completion of our development programs. If we succeed in marketing products, such claims could result in an FDA or other regulatory authority investigation of the safety and effectiveness of our product, our manufacturing processes and facilities or our marketing programs. FDA or other regulatory authority investigations could potentially lead to a recall of our product or more serious enforcement action, limitations on the approved indications for which it may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any product candidate, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could significantly harm our business, financial condition, results of operations and prospects.

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

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with the use of atacicept, MAU868 or any future product candidates we may develop. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. For example, Merck KGaA, Darmstadt, Germany previously conducted APRIL-LN, a study aimed to evaluate the efficacy and safety of atacicept in patients with active LN, receiving newly initiated CS and MMF. Two weeks before the initiation of atacicept, significant decreases in immunoglobulin G (igG) levels began unexpectedly with initiation of MMF and high-dose CS, and persisted upon initiation of atacicept, which led to trial termination. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

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

Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our nonclinical studies or previous clinical trials. Our product candidates may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, if atacicept, MAU868 or any future product candidates we may develop, are used in combination with other therapies, atacicept, MAU868 or any future product candidates we may develop may exacerbate adverse events associated with the therapy and it may not be possible to

determine whether it was caused by our product or the one with which it was combined. Patients treated with our product candidates may also be undergoing surgical, radiation, chemotherapy or other treatments, which can cause side effects or adverse events that are unrelated to our product candidates, but may still impact the success of our clinical trials. The inclusion of patients with advanced disease in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

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

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

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

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

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

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

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the marketed product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve atacicept or MAU868, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or applicable foreign regulatory authorities approve atacicept, MAU868 or any product candidate we develop in the future, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

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

The occurrence of any event or penalty described above may inhibit our ability to commercialize atacicept, MAU868, or any product candidate we may develop in the future, and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of atacicept, MAU868 or any product

candidate we may develop in the future. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not be able to achieve or sustain profitability.

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

### We are currently seeking orphan drug designation for atacicept for the treatment of IgAN, but even if designated we may not ultimately realize the potential benefits of orphan drug designation.

We are currently seeking orphan drug designation from the FDA and European Medicines Agency for atacicept for the treatment of IgAN. Under the Orphan Drug Act, the FDA may designate a drug product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States but where there is no reasonable expectation to recover the costs of developing and marketing a treatment drug in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. However, orphan drug designation neither shortens the development time nor regulatory review time of a product candidate nor gives the candidate any advantage in the regulatory review or approval process.

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

Similarly, in Europe, a medicinal product may receive orphan designation under Article 3 of Regulation (EC) 141/2000. This applies to products that are intended for a life-threatening or chronically debilitating condition and either (1) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (2) the product, without the benefits derived from orphan status, would be unlikely to generate sufficient returns in the EU to justify the necessary investment in its development. Moreover, in order to obtain orphan designation in the EU it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU or, if such a method exists, the product will be of significant benefit to those affected by the condition. In the EU, orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and applicants can benefit from specific regulatory assistance and scientific advice. Products receiving orphan designation in the EU can

receive 10 years of market exclusivity, during which time no "similar medicinal product" for the same indication may be placed on the market. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. However, the 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation—for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar medicinal product for the same indication at any time if:

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

If we do not receive or maintain orphan drug designation for atacicept for the treatment of IgAN, it could limit our ability to realize revenues.

## Even though MAU868 has Fast Track designation from FDA for the prevention of BK virus disease 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 virus disease 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 2b trial of atacicept in patients with IgAN are positive, we may seek accelerated approval with the FDA based on this trial, which we may not be granted. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as

irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. For example, UPCR is an accepted surrogate primary endpoint for clinical trials in IgAN, which could allow for a faster path to commercialization than rate of change/slope in glomerular filtration rate (GFR). We may seek accelerated approval based on the UPCR endpoint. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. Use of the accelerated approval pathway would entail submission of a BLA under Subpart E of the FDA regulations with the UPCR surrogate endpoint data while conducting the Phase 3 trial to collect change/slope in GFR data. 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. Additionally, unless and until converted to full approval at the time of satisfying the conditions of any accelerated approval letter, the sponsor must submit any promotional materials for the accelerated approval drug to FDA at least 30 days prior to use. Third-party payors may refuse to provide coverage or reimbursement for the drug until the confirmatory studies are complete. Additionally, if such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for atacicept or MAU868, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA, for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for atacicept, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for atacicept or MAU868 would result in a longer time period to commercialization of such product candidate, could increase the cost of development of atacicept or MAU868 and could harm our competitive position in the marketplace.

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, ACA), signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

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

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

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. If we obtain marketing approval of a product candidate, sales of such product will depend substantially, both in the United States and internationally, on the extent to which the costs of the product will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only at inadequate levels, we may not be able to successfully commercialize any product candidates we develop. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval. 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;
- appropriate for the sp
  cost-effective; and
- neither experimental nor investigational.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Governmental payors, as well as other third-party payors, including pharmacy benefit managers, have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and/or biosimilars. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our product. Nonetheless, atacicept, MAU868 or any future product candidates we may develop may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as atacicept, MAU868 or any future product candidates we may develop. In many countries, particularly the countries of the EU, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of atacicept, MAU868 or any future product candidates we may develop to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for atacicept, MAU868 or any future product candidates we may develop. Accordingly, in markets outside the United States, the reimbursement for any product that we commercialize may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

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

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

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of atacicept, MAU868 or any future product candidates we may develop. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not be able to achieve or sustain profitability.

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

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. 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 ACA 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 ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is also unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2031, unless additional congressional action is taken. COVID-19 pandemic relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations. In addition, Congress is considering additional health reform measures.

Moreover, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. In response, the FDA concurrently released a final rule and guidance in September 2020, which went into effect on November 30, 2020, providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an interim final rule implementing the Most Favored Nation (MFN) Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. As a result of litigation challenging the MFN Model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the MFN Model interim final rule. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to an order entered by the U.S. District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2023. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees have also been delayed until January 1, 2023. 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. No legislation or administrative actions have been finalized to implement these principles. 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 ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, achieve and sustain profitability or commercialize atacicept, MAU868 or any future product candidates we may develop. It is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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

approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for atacicept, MAU868 or future product candidates we may develop. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- · additional clinical trials to be conducted prior to obtaining approval;
- · changes to manufacturing methods;
- · recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

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

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower
  or qui tam actions, and civil monetary penalties laws prohibit individuals or entities from, among other things, knowingly presenting, or
  causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to
  avoid, decrease or conceal an obligation to pay money to the federal government;



- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their implementing regulations, also imposes obligations, including mandatory contractual terms, certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing
  arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private
  insurers.

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

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

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

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

## We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, and policies related to data privacy and security, and our actual or perceived failure to comply with such obligations could harm our business.

Our business is subject to stringent and evolving U.S. and foreign laws, rules, and regulations and contractual obligations relating to data privacy and security, including the collection, use, processing, disclosure, retention and security of personal information. The regulatory frameworks for data privacy and security are evolving and may result in increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions, including monetary penalties and prohibitions on processing personal information that could require us to change our business practices. Interpretation of these frameworks is likely to remain uncertain and potentially inconsistent for the foreseeable future. This evolution may create uncertainty in our business, affect our ability (or the ability of our collaborators, service providers, and contractors) to operate in certain jurisdictions or to collect, store, process, transfer, use or share personal information. This evolution could also necessitate the acceptance of more onerous obligations in our contracts and impose additional costs on us. Our efforts to bring our practices (and those of our collaborators, service providers, and contractors) into compliance with these obligations may not succeed for a variety of reasons, including due to internal or external factors such as resource allocation limitations or a lack of vendor cooperation. Noncompliance could result in the commencement of legal proceedings against us by governmental and regulatory entities, collaborators, data subjects or others.

Among the most stringent of these laws is the General Data Protection Regulation ((EU) 2016/679) (GDPR), which applies to the processing of personal information about clinical trials participants and other individuals in the EU and the UK. Companies that violate the GDPR can face private litigation, prohibitions on data processing and fines of up to the greater of 20 million Euros or 4% of their worldwide annual revenue. The GDPR requires us to give detailed disclosures about how we collect, use and share personal information; ensure any consents relied on to process personal information (including special categories of personal data, such as health data) meet the stricter GDPR requirements; contractually impose data protection requirements on vendors entrusted with personal information; maintain adequate data security measures; notify regulators and affected individuals of certain data breaches; meet extensive privacy governance and documentation requirements; and honor individuals' data protection rights, including their rights to access, correct and delete their personal information. European data protection authorities may interpret the GDPR and national laws implementing it differently and impose additional requirements or obligations on us, which further contribute to the complexity of processing personal information in or from Europe. Guidance on implementation and compliance with the

GDPR is often updated or otherwise revised. The GDPR may increase our responsibility and liability in relation to personal information that we process, and we may be required to implement additional mechanisms to comply with the GDPR. These mechanisms may be onerous and, if our efforts to comply with the GDPR or other applicable European data protection laws and regulations are not successful, our business in Europe could be adversely affected. In addition, further to the UK's exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law (referred to as the UK GDPR). The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the European's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

European data protection laws also generally prohibit the transfer of personal information from Europe to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. One of the primary safeguards used for transfers of personal information from the EU and Switzerland to the United States until recently was the Privacy Shield framework administered by the U.S. Department of Commerce, which was invalidated by a decision of the EU's highest court in July 2020. The same decision also cast doubt on the viability of one of the primary alternatives to the Privacy Shield, namely, the European Commission's Standard Contractual Clauses, as a vehicle for such transfers. Similarly, the Swiss Federal Data Protection and Information Commissioner has opined that the Privacy Shield is inadequate for transfers of data from Switzerland to the U.S. and raised similar questions regarding the Standard Contractual Clauses. At present, there are few, if any, viable alternatives to the Standard Contractual Clauses. At present, there are few, if any, viable alternatives to the Standard Contractual Clauses and, therefore, there is uncertainty regarding how to lawfully transfer personal information from Europe or the UK to the U.S. and other third countries. Failure to comply with the GDPR's cross-border data restrictions may increase our exposure to its heightened sanctions, restrict our clinical trial activities in Europe, and limit our ability to collaborate with CROs, service providers and other companies subject to European and UK data protection laws.

In addition, it is unclear whether the transfer of personal information from the EU to the UK will continue to remain lawful under the GDPR in light of Brexit. Pursuant to a post-Brexit trade deal between the UK and the EU, transfers of personal information from the European Economic Area to the UK are not considered restricted transfers under the GDPR for a period of up to six months from January 1, 2021. However, unless the EU Commission makes an adequacy finding with respect to the UK before the end of that period, the UK will be considered a "third country" under the GDPR and transfers of European personal information to the UK will require an approved compliance mechanism to render such transfers lawful under the GDPR. Although the UK's primary data protection legislation is designed to be consistent with the GDPR, uncertainty remains regarding how data transfers to and from the UK will be regulated after Brexit. This uncertainty and any restrictions on data transfers between the UK and the EU may further limit our ability to do business in the region. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

Privacy and data security laws in the United States are also increasingly complex and changing rapidly. Just over a month after the GDPR took effect, the California legislature passed the California Consumer Privacy Act of 2018 (CCPA), which took effect on January 1, 2020. The CCPA gives California residents certain rights similar to the individual rights given under the GDPR (including the right to access and delete their personal information, opt-out of certain personal information sharing, and receive detailed information about how their personal information is used), and provides for civil penalties for violations. Since the enactment of the CCPA, new privacy and data security laws have been proposed in more than half of the states and in United States

Congress, reflecting a trend toward more stringent privacy legislation in the United States that may increase our compliance costs and our exposure to liability. Further, a new California privacy law, the California Privacy Rights Act (CPRA) was passed by California voters on November 3, 2020. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). While certain clinical trials activities are exempt from the CCPA's requirements, other personal information that we handle may be subject to the CCPA, which may increase our compliance costs, exposure to regulatory enforcement action and other liabilities. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data 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.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

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

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

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

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

#### We are subject to various laws relating to foreign investment and the export of certain technologies, and our failure to comply with these laws or adequately monitor the compliance of our suppliers and others we do business with could subject us to substantial fines, penalties and even injunctions, the imposition of which on us could have a material adverse effect on the success of our business.

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

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

### The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our clinical trials.

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and since such time, actions taken around the world to help mitigate the spread of COVID-19 have included varying restrictions on travel, quarantines in certain areas, and forced closures for several types of public places and businesses The outbreak and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The effects of government orders and our work-from-home could slow our productivity or disrupt our business in the future, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices and limited the number of staff in any given research and development laboratory. As a result of the ongoing COVID-19 pandemic, we may experience additional disruptions that could severely impact our business, preclinical studies and clinical trials, including:

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

- limitations on employee resources that would otherwise be focused on the conduct of our nonclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- · interruption or delays to our sourced discovery and clinical activities.

Three vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020 and early 2021, one received full approval in August 2021 and more, including boosters, are likely to be authorized in the coming months. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials.

It is uncertain when restrictions will be fully lifted, and if so, when we will be able to resume pre-pandemic work routines. Imposition of government orders, including quarantine and shelter-in-place orders related to COVID-19 or other infectious diseases, is expected to continue to impact personnel at our and our third-party manufacturing facilities for the foreseeable future. The ongoing COVID-19 pandemic continues to evolve. The extent to which the COVID-19 pandemic continues to impact 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 ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing 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 the evolving COVID-19 pandemic continues to 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.

### 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.

We currently do not have, and have never had, a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market atacicept, MAU868 or any future product candidate we may develop. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize atacicept, MAU868 or any product candidate we may develop in the future will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of atacicept, MAU868 or any product candidate we may develop in the future that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize atacicept, MAU868 or any product candidate we may develop in the future which may receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for a product candidate, which we may license to others, we will rely on the assistance and guidance of those collaborators. For any product candidates for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

As an organization, we have never commercialized a product candidate. Factors that may affect our ability to commercialize our current or any future product candidate we may develop, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our current or any future product candidates we may develop and other unforeseen costs associated with creating an independent sales and marketing organization. Developing

a sales and marketing organization will be expensive and time-consuming and could delay the launch of atacicept, MAU868 or any future product candidate we may develop. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our current or any future product candidate we may develop, we may not generate revenues from such product candidate or be able to achieve or sustain profitability.

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

As of December 31, 2021, we had 17 full-time employees, including 11 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we continue to operate as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- · identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and other comparable foreign regulatory agencies' review process for atacicept, MAU868 and any other future product candidates we may develop, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

In addition, we expect to be conducting multiple clinical trials of atacicept for several different indications concurrently, as well as MAU868 for the treatment of BKV disease in kidney transplant recipients. Given the small size of our organization, we may encounter difficulties managing multiple clinical trials at the same time, which could negatively affect our ability to manage growth of our organization, particularly as we take on additional responsibility associated with being a public company. Our future financial performance and our ability to successfully develop and, if approved, commercialize, atacicept, MAU868 and any other future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of atacicept, MAU868 and any other future product candidates we may develop or otherwise advance our business. We cannot assure you that we will be able to manage our existing third party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize atacicept, MAU868 and any other future product candidates we may develop and, accordingly, may not achieve our research, development and commercialization goals.

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

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

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act of 2017 (Tax Act) enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) signed into law on March 27, 2020, modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act 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 changes, and could increase our future U.S. tax expense. For example, proposals have recently been made in Congress to make various changes to the federal corporate income tax rules, although these have not yet been enacted. Among the changes made by the Tax Act were a reduction of the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs". We continue to examine the impact this tax reform legislation may have on our business. We urge investors to consult with their legal and tax advisers regarding the implications of the Tax Act and potential 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, 2020, we had federal and state net operating loss (NOL) carryforwards of \$10.2 million and \$3.5 million, respectively, that will begin expiring in the year 2037 and 2036, respectively, if not utilized. We also have \$33.8 million of federal NOL carryforwards as of December 31, 2020, that do not expire as a result of recent tax law changes. Our NOL carryforwards are subject to review and possible adjustment by the U.S. and state tax authorities. Our NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. Under the Tax Act, as modified by the CARES Act, NOLs arising in tax years beginning after December 31, 2017, and before

January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss, and NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, under the Tax Act as modified by the CARES Act, federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of current year taxable income for tax years beginning after December 31, 2020. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOL carryforwards and certain tax credits to offset taxable income and tax, respectively, in taxable years beginning after 2019 and before 2023. It is generally uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

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

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

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

- · differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- · economic weakness, including inflation, or political instability in particular foreign economies and markets;
- · compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- · foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- · business interruptions resulting from geo-political actions, including war and terrorism.

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

### Risks related to our intellectual property

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

Our commercial success depends in part on our and our current or future licensors', licensees' or collaborators' ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for atacicept, MAU868, and any future product candidates that we may develop and technologies related to their various uses. We generally seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad related to our proprietary technologies, and their manufacture and uses that are important to our business, as well as inventions and improvements that are important to the development and implementation of our business. Our owned and in-licensed patents and patent applications in both United States and certain foreign jurisdictions relate to atacicept, MAU868, and other products. There can be no assurance that the claims of our owned or in-licensed patents, or any patent application that issues as a patent, will exclude others from making, using or selling our product candidates or any future product candidates or products that are substantially similar to our product candidates or any future product candidates. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. We may seek to protect our proprietary position by acquiring or in-licensing additional relevant issued patents or pending applications from third parties. If we or our potential licensors, licensees or collaborators are unable to obtain or maintain patent protection with respect to atacicept, MAU868, and our other products, proprietary technologies and their uses, our business, financial condition, results of operations and prospects could be significantly harmed.

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

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

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. Thus, the degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to atacicept, MAU868, or any future product

candidates we may develop could significantly harm our business, financial condition, results of operations and prospects.

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

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting atacicept, MAU868, or any future product candidates we may develop by obtaining and defending patents. These risks and uncertainties include the following:

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

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

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

United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

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

## If we breach our license agreement with Ares, an affiliate of Merck KGaA, Darmstadt, Germany, related to atacicept, or the license agreement with Novartis related to MAU868, we could lose the ability to continue the development and commercialization of atacicept or MAU868, respectively.

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

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

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

In addition, we acquired worldwide, exclusive rights to atacicept pursuant to our license agreement (Ares Agreement) with Ares, and worldwide, exclusive rights to develop, manufacture and commercialize MAU868 pursuant to our asset purchase agreement with Amplyx (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 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 in an aggregate amount of up to \$69.0 million based on the achievement of certain clinical development, regulatory and sales milestones. Further, we are required to pay Novartis mid-to high-single digit percentage royalties based on net sales of MAU868 on a country-by-country and product-by-product basis. If milestone or other non-royalty obligations become due, we may not have sufficient funds available to meet our obligations, which will adversely affect our business operations and financial condition.

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

The patent positions of biotechnology companies generally are highly uncertain, involve complex legal and factual questions for which important legal principles remain unsolved and have been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect atacicept or MAU868 or which effectively prevent others from commercializing competitive technologies and product candidates. In addition, the laws of foreign countries may not protect our

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

Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Legal standards relating to valid and enforceable claim scope are unsettled in the United States and elsewhere and disputes challenging or re-defining scope are common in the biopharmaceutical industry. Even if patent applications we own or in-license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether atacicept, or MAU868, or any future product candidates we may develop will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could significantly harm our business, financial condition, results of operations and prospects.

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

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

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

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or other jurisdictions, or become involved in postgrant challenges such as opposition, derivation, revocation, reexamination, post-grant review (PGR) and *inter partes* review (IPR), or other similar proceedings, or in litigation, challenging our patent rights, including by challenging the validity or the claim of priority of our patents. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize atacicept, MAU868, or any future product candidates we may develop and compete directly with us, without payment to us. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of atacicept, MAU868, or any future product candidates we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, including art of which we were unaware, and art which was not raised during prosecution of any of our patents or patent applications. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates

that we may develop. Such a loss of patent protection would significantly impact our business, financial condition, results of operations and prospects. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates or could embolden competitors to launch products or take other steps that could disadvantage us in the marketplace or draw us into additional expensive and time consuming disputes. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

### Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- · we may not be able to detect infringement of our issued patents;
- others may be able to develop products that are similar to atacicept, MAU868, or any future product candidates we may develop, but that are not covered by the claims of the patents that we may in-license in the future or own;
- our competitors may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell atacicept, MAU868, or any future product candidates we may develop;
- we, or our current or future collaborators or license partners, might not have been the first to make the inventions covered by the issued
  patents or patent applications that we may in-license in the future or own;
- we, or our current or future collaborators or license partners, might be found not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we may in-license in the future or own will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents, for which we are not aware;
- issued patents that we hold rights to may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- issued patents may not have sufficient term or geographic scope to provide meaningful protection;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- · we may not develop additional proprietary technologies that are patentable;
- · the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets, and a third party may subsequently file a patent covering such intellectual property.

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

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

Our commercial success depends in part on avoiding infringement, misappropriation or other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. A finding by a court or administrative body that we infringe the claims of issued patents owned by third parties could preclude us from commercializing atacicept, MAU868, or any future product candidates we may develop.

Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import atacicept, MAU868, or any future product candidates we may develop and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology industry, including patent infringement lawsuits, and proceedings, such as oppositions, reexaminations, IPR proceedings and PGR proceedings, before the USPTO and/or corresponding foreign patent offices. In addition, many companies in intellectual property-dependent industries, including the biotechnology industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous third-party U.S. and foreign issued patents and pending patent applications may exist in the fields in which we are developing atacicept, MAU868, or any future product candidates we may develop. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of atacicept, MAU868, or any future product candidates we may develop.

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

As the biotechnology industry expands and more patents are issued, the risk increases that atacicept, MAU868, or any future product candidates we may develop, may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of atacicept, MAU868, or any future product candidates we may develop, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that atacicept, MAU868, or any future product candidates we may develop may infringe. In addition, identification of third-party patents is that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents,

incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Still further, we cannot rely on our experience that third parties have not so far alleged that we infringe their patent rights, as provisions of U.S. patent laws provide a safe harbor from patent infringement for therapeutic products under clinical development.

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

- · result in costly litigation that may cause negative publicity;
- · divert the time and attention of our technical personnel and management;
- · cause development delays;
- prevent us from commercializing atacicept, MAU868, or any future product candidates we may develop;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- · subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Any patent-related legal action against us claiming damages or seeking to enjoin commercial activities relating to our products, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market atacicept, MAU868, or any future product candidates we may develop. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or a future strategic partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign atacicept, MAU868, or any future product candidates we may develop processes to avoid infringement, if necessary.

An adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing atacicept, MAU868, or any future product candidates we may develop, which could significantly harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing atacicept, MAU868, and future product candidates and technologies.

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

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

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

While we may have in-licensed patents that cover atacicept and MAU868, it is possible that third parties may have blocking patents that prevent us from marketing, manufacturing or commercializing our patented products and practicing our in-licensed patented technology.

We may be unsuccessful in acquiring or in-licensing compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for practicing inventions claimed by our patents, including the manufacture, sale and use of atacicept, MAU868, and any future product candidates we may develop. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could significantly harm our business, financial condition, results of operations and prospects.

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

Competitors or other third parties may infringe, misappropriate or otherwise violate our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement or other intellectual property claims, which can be expensive and timeconsuming. In addition, in a patent infringement proceeding, a court may decide that a patent we may in-license in the future or own is not valid, is unenforceable, and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our owned or in-licensed patents do not cover the technology in question. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at atacicept, MAU868, or any future product candidates we may develop, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

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

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

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

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

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

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

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

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have an adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring atacicept, MAU868, or any future product candidates to market. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

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

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

Further, the United States has enacted and implemented wide-ranging patent reform legislation and the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies (including atacicept and MAU868) would adversely affect our business prospects and financial condition.

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

### We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

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

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could significantly harm our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

## Patent terms may be inadequate to protect our competitive position on atacicept, MAU868, or any future product candidates we may develop for an adequate amount of time.

Patents have a limited lifespan. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. Various extensions may be available, but there can be no assurance that any such extensions will be obtained, and the life of a patent, and the protection it affords, is limited. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. There is a risk that we may take action that detracts from any accrued patent term adjustment. Even if patents covering atacicept, MAU868, or any future product candidates we may develop are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

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

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended per approved drug product, and only those claims covering the approved drug product, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be impacted and our

competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

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

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we will not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These infringing products may compete with atacicept, MAU868, or any future product candidates we may develop, without any available recourse.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Because the legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceutical 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 four 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.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be significantly harmed.

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

## Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment, and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

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

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

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

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

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

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect

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

Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. Any of the foregoing could significantly harm our business, financial condition, results of operations and prospects.

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

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, lessees of shared multi-company property and other third parties. Many of our employees and consultants were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents or patent applications. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing atacicept, MAU868, or any future product candidates or technologies we may develop. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, and cause us to lose valuable intellectual property rights or personnel, which could significantly harm our business, financial condition, results of operations and prospects. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could

be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have an adverse effect on our ability to raise additional funds or otherwise significantly harm our business, financial condition, results of operations and prospects.

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

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

If we fail to comply with our obligations under any such license agreements, including obligations to make various milestone payments and royalty payments and other obligations, the licensor may have the right to terminate the license. If these agreements are terminated, we could lose intellectual property rights that are important to our business, be liable for any damages to such licensors or be prevented from developing and commercializing our product candidates, and competitors could have the freedom to seek regulatory approval of, and to market, products identical to ours. Termination of these agreements or reduction or elimination of our rights under these agreements may also result in our being required to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis.

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

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

We may need to obtain additional licenses from existing licensors and others to advance our research or allow commercialization of product candidates we develop. It is possible that we may be unable to obtain additional

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

### If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

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

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

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could significantly harm our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could significantly harm our business, financial condition and prospects.

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

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

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

### Risks related to our dependence on third parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize atacicept, MAU868 or future product candidates we may develop and our business, financial condition, results of operations and prospects could be significantly harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our nonclinical studies and clinical trials and to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our nonclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory

authorities for atacicept and MAU868 in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Failure to comply and maintain adequate documentation with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to atacicept or MAU868 and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of atacicept or MAU868, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize atacicept or MAU868. As a result, our results of operations and the commercial prospects for atacicept and MAU868 would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely, and our business, financial condition, results of operations and prospects could be significantly harmed.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. In addition, our CROs could fail to perform, we could terminate their agreements or they could go out of business. If our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding CROs involves substantial cost and requires management time and focus, and could delay development and commercialization of atacicept, MAU868 or any future product candidate we may develop. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business and financial condition.

The COVID-19 pandemic and government measures taken in response have also had a significant impact on our CROs, and we expect that they will face further disruption which may affect our ability to initiate and complete our nonclinical studies and clinical trials.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. There can be no assurance that we will

not encounter challenges or delays with CROs in the future or that these delays or challenges will not significantly harm our business, financial condition, results of operations and prospects.

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

In connection with our acquisition of MAU868, we have assumed the responsibility for ongoing clinical studies with MAU868, including related expenses and manufacturing and regulatory activities, which were previously managed and funded by Amplyx. This includes responsibility for the ongoing 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 for our ongoing clinical trials, and expect to continue to do so for additional clinical trials of our product candidates and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of atacicept, MAU868 or other product candidates necessary for the development or commercialization of atacicept, MAU868 or such other product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for clinical trials under the guidance of members of our organization. We do not have long-term 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. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our product candidates in the future will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects.

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

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party
  contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform
  according to the terms of the agreements between us and them;
- disruptions resulting from the impact of public health pandemics or epidemics (including, for example, the ongoing COVID-19 pandemic);

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

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

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

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

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

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

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

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

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

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result

in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

## We may enter into collaborations with third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of atacicept or MAU868.

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

We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not
  perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to
  continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic
  focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors
  such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;

- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

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

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

If we seek collaborations in the future, we will face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidates. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into additional collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

#### Risks related to this offering and the 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 since its trading began on May 14, 2021, to December 31, 2021, has ranged from a low of \$11.30 to a high of \$37.11. 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 prospectus, these factors include:

- the timing and results of nonclinical studies and clinical trials of our current or any future product candidates we may develop or those of our competitors;
- · regulatory actions with respect to our product candidate or our competitors' products;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- developments associated with our license with Ares, an affiliate of Merck KGaA, Darmstadt, Germany, including any termination or other change in our relationship with Ares or Merck KGaA, Darmstadt, Germany;
- developments associated with our license with Novartis, including any termination or other change in our relationship with Novartis or Amplyx;
- · actual or anticipated changes in our growth rate relative to our competitors;
- · regulatory or legal developments in the United States and other countries;
- · developments or disputes concerning patent applications, issued patents or other proprietary rights;
- · the recruitment or departure of key personnel;
- · the results of our efforts to in-license or acquire additional product candidates or products;
- · actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- · 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;
- · expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions.

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, as well as due to the COVID-19 pandemic. The COVID-19 outbreak continues to evolve. The extent to which the outbreak may impact our business, nonclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

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.

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

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 are implementing measures designed to improve our internal control over financial reporting to remediate this material weakness, including the following:

- · We are formalizing our internal control documentation and strengthening supervisory reviews by our management; and
- We have added additional accounting personnel and are segregating duties amongst accounting personnel.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

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 (Section 404) requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our annual report for our fiscal year ending December 31, 2021, 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.

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

## Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- timing and variations in the level of expense related to the ongoing development of our product candidates or future development programs;
- · timing and status of enrollment for our clinical trials;
- impacts from the COVID-19 pandemic on us or third parties with which we engage;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;

- · additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if our current or any future product candidates we may develop receive regulatory approval, the timing and terms of such approval and market acceptance and demand for such product candidates;
- the timing and cost to establish a sales, marketing and distribution infrastructure to commercialize any products for which we may
  obtain marketing approval and intend to commercialize on our own or jointly with current or future collaborators;
- regulatory developments affecting atacicept, MAU868 or any future product candidate we may develop or those of our competitors; and
- · changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our Class A common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

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

#### If you purchase shares of our Class A common stock in this offering, you will experience substantial and immediate dilution.

The public offering price is substantially higher than the net tangible book value per share of our outstanding Class A common stock immediately following the closing of this offering. Based on the assumed public offering price of \$ per share, which is the last reported sale price of our Class A common stock on the Nasdaq Global Market on , 2022, if you purchase shares of our Class A common stock in this offering, you will experience substantial and immediate dilution in the as adjusted net tangible book value per share of \$ per share as of September 30, 2021. That is because the price that you pay will be substantially greater than the as adjusted net tangible book value per share of the Class A common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the public offering price when they purchased their shares of our capital stock. You will experience additional dilution when those holding stock options exercise their right to purchase Class A common stock under our equity

incentive plans or when we otherwise issue additional shares of Class A common stock. See the section titled "Dilution."

#### 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 after this offering or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

As of December 31, 2021, there were 20,968,376 shares of Class A common stock outstanding and held of record by 34 stockholders and 309,238 shares of Class B common stock outstanding and held of record by one stockholder. The number of record holders of our Class A common stock does not include DTC participants or beneficial owners holding shares through nominee names. The resale of shares of Class A common stock following this offering held by our officers and directors is currently prohibited or otherwise restricted as a result of lock-up agreements entered into by our officers and directors with the underwriters in connection with this offering. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning 91 days after the date of this prospectus. 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 and Class B 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 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 and the lock-up agreements entered into with the representatives in connection with our IPO.

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

## Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to atacicept, MAU868 or future product candidates we may develop on unfavorable terms to us.

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to atacicept, MAU868 or future product candidates we may develop, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

# We are an "emerging growth company," and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our Class A common stock less attractive to investors.

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

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

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

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least \$700 million of equity securities held by non-affiliates; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) December 31, 2026.

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

Pursuant to Section 404 we will be required to furnish a report by our management on our internal control over financial reporting, including, if required by our filing status, an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company or a non-accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as

documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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

#### Our management team has broad discretion to use the net proceeds from this offering and its investment of these proceeds may not yield a favorable return. They may invest the net proceeds from this offering in ways with which investors disagree.

We intend to use a portion of the net proceeds from this offering to advance and expand our clinical and nonclinical development programs and for working capital and for other general corporate purposes, which may include the hiring of additional personnel, capital expenditures and the costs of operating as a public company. See the section titled "Use of proceeds." However, within the scope of our plan, and in light of the various risks to our business, including those discussed in this "Risk factors" section and elsewhere in this prospectus, our management will have broad discretion over the use of net proceeds from this offering, and could spend the net proceeds in ways our stockholders may not agree with or that do not yield a favorable return, if at all. If we do not invest or apply the net proceeds from this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

## 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 between us and Oxford, dated December 17, 2021, restrict our ability to declare and pay dividends without the prior written consent of Oxford. Any return to stockholders will therefore be limited to any appreciation in the value of our Class A common stock, which is not certain.

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

Our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These

provisions also could limit the price that investors might be willing to pay in the future for shares of our Class A common stock, thereby depressing the market price of our Class A common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

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

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (DGCL), which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our Class A common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

# Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

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



jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law:

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

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

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying such offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions 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**

Our information technology systems, or those of any of our CROs, manufacturers, other contractors, consultants, third party vendors, collaborators, or potential future collaborators, may fail or suffer cybersecurity incidents, breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal information, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations, or otherwise harm our business.

In the course of our business, we collect, store and transmit proprietary, confidential and sensitive information, including personal information. The information and data processed and stored in our technology systems, and those of our research collaborators, CROs, contractors, consultants, and other third parties on which we depend to operate our business, may be vulnerable to security breaches, loss, damage, corruption, unauthorized access, use or disclosure, or misappropriation. Such incidents may also result from errors or malfeasance by our personnel or the personnel of the third parties we work with, malware, viruses, software vulnerabilities, hacking, denial of service attacks, social engineering (including phishing), ransomware, credential stuffing or other cyberattacks, including attacks by state-sponsored organizations or sophisticated groups of hackers.

While we have developed systems and processes designed to protect the integrity, confidentiality and security of the confidential and personal information under our control, we cannot assure you that any security measures that we or our third party service providers 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 breaches, identify them before our information is exploited, or react in a timely manner.

Additionally, as a result of the ongoing COVID-19 pandemic, certain functional areas of our workforce remain in a remote work environment and outside of our corporate network security protection boundaries, which imposes additional risks to our business, including increased risk of industrial espionage, phishing and other cybersecurity attacks, and unauthorized dissemination of proprietary or confidential information, any of which could have a material adverse effect on our business.

Despite our efforts to strengthen security and authentication measures, we have experienced an overall increase in cybersecurity incidents, none of which have caused material disruption to our business, or to our knowledge, involved a material security breach. However, we or the third parties we rely on could experience a material system failure, security breach or other cybersecurity incident in the future, which could interrupt our operations disrupt our development programs and have a material adverse effect on our business, financial condition and results of operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates, to analyze clinical trial samples and to conduct clinical trials, and cybersecurity incidents experienced by these third parties could have a material adverse effect on our business. Security breaches and other cybersecurity incidents affecting us or the third parties we rely on could also result in substantial remediation costs and expose us to litigation, regulatory enforcement action, fines, penalties, and other liabilities.

We cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could adversely affect our reputation, business, financial condition and results of operations.

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

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

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

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

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

## 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 reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in

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

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

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

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

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

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

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

## Special note regarding forward-looking statements

This prospectus contains "forward-looking statements" within the meaning of Section 27A of the Securities Act, Section 21E of the Exchange Act and the safe harbor provisions for the U.S. Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned nonclinical studies and clinical trials, results of nonclinical studies, clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- 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, including our atacicept Phase 2b clinical trial and MAU868 Phase 2 clinical trial;
- 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 the ongoing COVID-19 pandemic on our business and operations, including enrollment in our clinical trial;
- the implementation of our strategic plans for our business and current product candidates or any other product candidates we may develop;
- the size of the market opportunity for our product candidates in each of the diseases we target;
- our reliance on third parties to conduct nonclinical research activities, and for the manufacture of our product candidates;
- · the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our estimates of the number of patients in the United States who suffer from the diseases we target and the number of subjects that will enroll in our clinical trials;

- the progress and focus of our current and future clinical trials, and the reporting of data from those trials;
- · our ability to advance product candidates into and successfully complete clinical trials;
- the ability of our clinical trials to demonstrate the safety and efficacy of our product candidates, and other positive results;
- the success of competing therapies that are or may become available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our potential and ability to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
- the rate and degree of market acceptance of our product candidates, as well as the pricing and reimbursement of our product candidates, if approved;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates;
- · our plans and ability to obtain and protect intellectual property rights;
- the scope of protection we are able to establish and maintain for intellectual property rights, including atacicept, MAU868 and any other product candidates we may develop;
- our ability to retain the continued service of our key personnel and to identify, hire, and then retain additional qualified personnel;
- our expectations regarding the impact of the COVID-19 pandemic on our business and operations, including clinical trials, manufacturing suppliers, collaborators, use of CROs and employees;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act and as a smaller reporting company under the Exchange Act; and
- our anticipated use of our existing cash and cash equivalents and the net proceeds from this offering.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk factors" and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

## Market, industry and other data

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section titled "Risk factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

### Use of proceeds

We estimate that we will receive net proceeds from this offering of approximately \$million (or approximately \$million if the underwriters' option to purchase additional shares of our Class A common stock is exercised in full) based on the assumed public offering price of \$per share, which is the last reported sale price of our Class A common stock on the Nasdaq Global Market on , 2022 and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed public offering price of \$ per share, which is the last reported sale price of our Class A common stock on the Nasdaq Global Market on , 2022, would increase or decrease, as applicable, the net proceeds to us from this offering by approximately \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 100,000 shares in the number of shares of Class A common stock offered by us would increase or decrease, as applicable, the net proceeds to us from this offering by approximately \$ million, assuming the public offering price of \$ per share, which is the last reported sale price of our Class A common stock on the Nasdaq Global Market on , 2022, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses

payable by us.

We currently intend to use the net proceeds we receive from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$ million to fund a Phase 3 clinical trial of atacicept in LN;
- approximately \$ million to fund clinical development of MAU868 for the treatment of BKV in kidney transplant patients and potential additional indications;
- the remainder for general corporate purposes, including working capital, operating expenses and capital expenditures.

We believe, based on our current operating plan, that the net proceeds from this offering, together with our existing cash and cash equivalents and the funds available under the Loan Agreement with Oxford, will be sufficient to fund our operations at least into the fourth quarter of 2023. However, our expected use of proceeds from this offering described above represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the closing of this offering or the actual amounts that we will spend on the uses set forth above. The net proceeds from this offering, together with our cash and cash equivalents, will not be sufficient for us to fund atacicept in IgAN or LN or MAU868 in kidney transplant recipients with BK viremia through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of atacicept in IgAN, LN, and MAU868 in kidney transplant patients with BK viremia, and any future product candidates we may develop.

The amounts and timing of our actual expenditures will depend on numerous factors, including the time and cost necessary to conduct our planned clinical trials, the results of our planned clinical trials and other factors described in the section titled "Risk factors" in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes.

We will have broad discretion over how to use the net proceeds to us from this offering. We intend to invest the net proceeds to us from the offering that are not used as described above in short-term, investment-grade, interest-bearing instruments.

## **Dividend policy**

We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws, and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. 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. Our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

## Capitalization

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2021 on:

- an actual basis; and
- on an adjusted basis to give effect to our issuance and sale of assumed public offering price of \$ per share, which is the last reported sale price of our Class A common stock in this offering at the Nasdaq Global Market on expenses payable by us.

The as adjusted information below is illustrative only, and our capitalization following the completion of this offering is subject to adjustment based on the actual public offering price of our Class A common stock and other terms of this offering determined at pricing.

You should read this table together with the sections titled "Management's discussion and analysis of financial condition and results of operations" and "Description of capital stock" and our financial statements and related notes included elsewhere in this prospectus.

		As of Septe	mber 30, 2021
			As
(In thousands, except share amounts)		Actual	adjusted
Cash and cash equivalents	\$	86,191	\$
Stockholders' deficit (equity)			
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as			
of September 30, 2021			
Class A common stock, \$0.001 par value; 500,000,000 shares authorized and 20,968,376 issued and			
outstanding as of September 30, 2021		21	
Class B Common stock, \$0.001 par value; 14,600,000 shares authorized and 309,238 shares issued			
and outstanding as of September 30, 2021			
Additional paid-in capital		192,665	
Accumulated deficit	(	(107,209)	(107,209)
Total stockholders' equity (deficit)		85,477	
Total capitalization	\$	85,477	\$

A \$1.00 increase (decrease) in the assumed public offering price of \$ per share, which is the last reported sale price of our Class A common stock on the Nasdag Global Market on , 2022, would increase (decrease) each of our as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 100,000 shares in the number of shares Class A common stock offered by us would increase (decrease) each of our as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately \$ million. per share, which is the last reported sale price of our Class A common stock on assuming the assumed public offering price of \$ the Nasdag Global Market on , 2022, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The foregoing discussion and table above assume no issuance of Class B common stock in connection with this offering and exclude, as of September 30, 2021:

- 2,894,671 shares of our Class A common stock issuable upon the exercise of outstanding stock options as of September 30, 2021, with a weighted-average exercise price of \$5.43 per share;
- 1,510,665 shares of our Class A common stock available for future issuance under the 2021 Plan as of September 30, 2021, an additional 1,048,419 shares of our Class A common stock that were reserved for future issuance on January 1, 2022 in accordance with the terms of the 2021 Plan, as well as any future automatic annual increases in the number of shares of Class A common stock reserved for issuance under our 2021 Plan and any shares of Class A common stock underlying outstanding stock awards granted under our 2017 Plan that expire or are repurchased, forfeited, cancelled or withheld, as more fully described in the section titled "Executive compensation—Equity benefit plans"; and
- 220,251 shares of our Class A common stock reserved for issuance under our ESPP, an additional 209,684 shares of our Class A common stock that were reserved for future issuance on January 1, 2022 in accordance with the terms of the ESPP, and any future automatic annual increases in the number of shares of Class A common stock reserved for future issuance under our ESPP.

## Dilution

If you invest in our Class A common stock in this offering, your interest will be diluted to the extent of the difference between the public offering price per share of Class A common stock and the as adjusted net tangible book value per share immediately after this offering.

As of September 30, 2021, we had a historical net tangible book value of \$85.5 million, or \$4.08 per share of Class A common stock, based on the 20,968,376 shares of Class A common stock outstanding as of such date, including 4,137 shares subject to repurchase as of such date. Our historical net tangible book value per share represents total tangible assets less total liabilities, divided by the number of shares of Class A common stock outstanding as of September 30, 2021, including 4,137 shares of Class A common stock subject to repurchase as of repurchase as of such date.

After giving effect to our issuance and sale of shares of Class A common stock in this offering at the assumed public offering price of \$ per share, which is the last reported sale price of our Class A common stock on the Nasdaq Global Market on , 2022, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2021 would have been \$ million, or \$ per share. This amount represents an immediate increase in our as adjusted net tangible book value of \$ per share to our existing stockholders and an immediate dilution in our as adjusted net tangible book value of \$ per share to investors purchasing Class A common stock in this offering. We determine dilution by subtracting the as adjusted net tangible book value per share after this offering from the amount of cash paid by an investor for a share of Class A common stock in this offering. The following table illustrates this dilution on a per share basis:

Assumed public offering price per share		\$
Historical net tangible book value per share as of September 30, 2021	\$4.08	
Increase in net tangible book value per share attributable to investors purchasing shares in this offering	\$	
As adjusted net tangible book value per share after this offering		\$
Dilution in as adjusted net tangible book value per share to investors purchasing shares in this offering		\$

The dilution information discussed above is illustrative only and may change based on the actual public offering price and other terms of per share, which is the last reported sale this offering. Each \$1.00 increase or decrease in the assumed public offering price of \$ price of our Class A common stock on the Nasdag Global Market on , 2022, would increase or decrease, as applicable, our as adjusted net tangible book value per share after this offering by \$ per share and increase or decrease, as applicable, the dilution per share, in each case assuming the number of shares of Class A common to investors purchasing shares in this offering by \$ stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase of 100,000 in the number of shares of Class A per share and common stock offered by us would increase the as adjusted net tangible book value after this offering by \$ decrease the dilution per share to new investors participating in this offering by \$ per share, and a decrease of 100,000 shares of Class A common stock offered by us would decrease the as adjusted net tangible book value by \$ per share, and increase the dilution per share to new investors in this offering by \$ per share, in each case assuming the assumed public offering price of per share, which is the last reported sale price of our Class A common stock on the Nasdaq Global Market on \$ 2022, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of Class A common stock in full, the net tangible book value per share, as adjusted to give effect to this offering, would be \$ per share, and the dilution in pro forma net tangible book value per share to investors in this offering would be \$ per share, in each case assuming a public offering price of \$ per share, which is the last reported sale price of our Class A common stock on the Nasdag Global Market on , 2022.

The foregoing discussion and tables above exclude, as of September 30, 2021:

- 2,894,671 shares of our Class A common stock issuable upon the exercise of outstanding stock options as of September 30, 2021, with a weighted-average exercise price of \$5.43 per share;
- 1,510,665 shares of our Class A common stock available for future issuance under the 2021 Plan as of September 30, 2021, an additional 1,048,419 shares of our Class A common stock that were reserved for future issuance on January 1, 2022 in accordance with the terms of the 2021 Plan, as well as any future automatic annual increases in the number of shares of Class A common stock reserved for issuance under our 2021 Plan and any shares of Class A common stock underlying outstanding stock awards granted under our 2017 Plan that expire or are repurchased, forfeited, cancelled or withheld, as more fully described in the section titled "Executive compensation—Equity benefit plans"; and
- 220,251 shares of our Class A common stock reserved for issuance under our ESPP, an additional 209,684 shares of our Class A common stock that were reserved for future issuance on January 1, 2022 in accordance with the terms of the ESPP, and any future automatic annual increases in the number of shares of Class A common stock reserved for future issuance under our ESPP.

To the extent that any outstanding options are exercised or new options or other convertible securities are issued under our stock-based compensation plans, or we issue additional shares of Class A common stock and Class B common stock in the future, there will be further dilution to investors participating in this offering.

# Management's discussion and analysis of financial condition and results of operations

The following discussion should be read in conjunction with our financial statements and related notes thereto included elsewhere in this prospectus. In addition to historical information, this discussion contains forward-looking statements that involve risks, uncertainties and assumptions that could cause actual results to differ materially from management's expectations. Factors that could cause such differences are discussed in the sections titled "Special note regarding forward-looking statements" and "Risk factors." We are not undertaking any obligation to update any forward-looking statements or other statements we may make in the following discussion or elsewhere in this document even though these statements may be affected by events or circumstances occurring after the forward-looking statements or other statements were made. Therefore, no reader of this document should rely on these statements being current as of any time other than the time at which this document is declared effective by the SEC.

#### Overview

We are a late-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases. We expect to initiate multiple registration-enabling trials over the next 18 months. Our lead product candidate atacicept is currently being evaluated for the treatment of IgAN in the Phase 2b ORIGIN trial which we expect will complete enrollment in mid-2022 and report topline results in the fourth quarter of 2022. If these data are positive, we plan to seek an accelerated approval path in the United States by the FDA and in the European Union by the EMA while initiating a pivotal Phase 3 clinical trial in 2023. In addition, based on positive feedback from the FDA's review of promising clinical results in a Phase 2 clinical trial of atacicept in high disease activity patients with SLE, we plan to initiate a Phase 3 study of atacicept in LN, a severe renal manifestation of SLE, in the fourth quarter of 2022. In December 2021, we obtained from Amplyx, a wholly owned subsidiary of Pfizer, development and commercial rights to MAU868, which, we believe, is the only clinical-stage neutralizing monoclonal antibody that is directed against BK virus, a polyoma virus that can have devastating consequences in certain settings such as kidney transplant and hematopoietic stem cell transplant. In an interim analysis of Phase 2 data in BK viremia among kidney transplant recipients, MAU868 was shown to be well tolerated and demonstrated a clinically significant reduction of virologic activity. We expect to share full results from the interim analysis in mid-2022 and expect to initiate a Phase 3 clinical trial in 2023. We believe that our current pipeline programs leverage the deep expertise of the Vera Therapeutics team and have strong commercial synergies. We currently hold global rights to all of our pipeline programs.

Since our inception, we have devoted substantially all of our resources to our research and development efforts, pre-clinical studies and clinical trials, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

We do not have any product candidates approved for commercial sale, and we have not generated any revenue from product sales. Our ability to generate revenue sufficient to achieve profitability, if ever, will depend on the successful development and eventual commercialization of one or more of our product candidates, which we expect will take a number of years, if ever. We also do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for nonclinical and clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing approval. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

To date, we have funded our operations primarily through proceeds from the sale of shares of our Class A common stock, redeemable convertible preferred stock, debt financing and convertible promissory notes. As of September 30, 2021, we had \$86.2 million in unrestricted cash and cash equivalents. Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents and proceeds from the \$50.0 million Loan Agreement with Oxford, will be sufficient to fund our planned operating expenses and capital expenditure requirements at least into the fourth quarter of 2023.

We have incurred significant operating losses since the commencement of our operations. Our net losses were \$15.8 million and \$10.5 million for the nine months ended September 30, 2021 and 2020, 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 September 30, 2021, we had an accumulated deficit of \$107.2 million. Our primary use of cash is to fund operating expenses, which consist primarily 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 prepaid expense, accounts payable and other current liabilities balances.

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

- continue our ongoing and planned research and development of our product candidates, atacicept for the treatment of IgAN and LN, and MAU868 for the treatment of BK viremia;
- · conduct clinical trials and nonclinical studies for atacicept and MAU868;
- · seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know-how;
- attract, hire and retain additional clinical, scientific, quality control, manufacturing management and administrative personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- · incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

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

We will require substantial additional funding to develop our product candidates and support our continuing operations. Until such time that we can generate significant revenue from product sales or other sources, if

ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which could include income from collaborations, strategic partnerships, or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and otherwise. 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.

#### COVID-19 pandemic

Since it was reported to have surfaced in December 2019, a novel strain of coronavirus (COVID-19) has spread across the world and has been declared a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have intensified and governments around the world, including in the United States, Europe and Asia, have implemented travel restrictions, social distancing requirements, stay-at-home orders and have delayed the commencement of non-COVID-19-related clinical trials, among other restrictions. As a result, the current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as contributing to significant volatility and negative pressure on the U.S. economy and in financial markets.

As a result of the outbreak, many companies have experienced disruptions in their operations and in markets served. To date, we have initiated some and may take additional, temporary precautionary measures intended to help ensure our employees' well-being and minimize business disruption. For the safety of our employees and their families, we have reduced the amount of time we expect our employees to spend onsite in our facilities. Certain of our third-party service providers have also experienced shutdowns or other business disruptions. We are continuing to assess the impact of the COVID-19 pandemic on our current and future business and operations, including our expenses and clinical trials and other development timelines, as well as on our industry and the healthcare system.

As a result of the COVID-19 pandemic, we have and may in the future experience severe disruptions, including:

- interruption of or delays in receiving products and supplies from the third parties on which we rely, due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- · limitations on our business operations by the local, state, or federal government;
- business disruptions caused by workplace, laboratory and office closures and an increased reliance on employees working from home, travel limitations, cybersecurity 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 activities, including because of sickness of
  employees or their families or the desire of employees to avoid contact with large groups of people.

#### **Results of operations**

#### Comparisons of the nine months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the periods presented.

		onths ended ptember 30,		Change
(dollars in thousands)	2021	2020	Amount	%
Operating expenses:				
Research and development	\$ 9,731	\$ 5,362	\$ 4,369	81%
General and administrative	8,066	2,903	5,163	178%
Restructuring costs	—	1,416	(1,416)	*
Total operating expenses	17,817	9,681	8,136	84%
Loss from operations	(17,817)	(9,681)	(8,136)	84%
Other income (expense):				
Interest income	9	6	3	*
Interest expense	_	(151)	151	*
Gain on issuance of convertible notes		63	(63)	*
Change in fair value of convertible notes		(775)	775	*
Change in fair value of convertible notes		(359)	359	*
Change in fair value of non-marketable equity securities	(645)	_	(645)	*
Gain on sale of PNAi technology	2,691		2,691	*
Total other income (expense)	2,055	(857)	2,912	*
Net loss and comprehensive loss	\$(15,762)	\$(10,538)	\$(5,224)	50%

Not meaningful

#### Research and development expenses

Research and development expenses represent a substantial portion of our operating expenses. Our research and development expenses consist primarily of direct and indirect expenses incurred in connection with the discovery and development of our product candidates. Since October 2020, we have been engaged in the development of atacicept.

Research and development expenses are recorded as expense in the period they are incurred, 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. 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.

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

		ths ended tember 30,		Change
(dollars in thousands)	2021	2020	Amount	%
Direct research and development expenses				
Consulting and contract research	\$ 6,687	\$ 1,372	\$ 5,315	387%
Internal laboratory expenses	_	1,289	(1,289)	*
Indirect research and development expenses				
Compensation and related benefits	3,029	1,327	1,702	128%
Facilities, depreciation and other	15	1,374	(1,359)	(99)%
Research and development expenses	\$ 9,731	\$ 5,362	\$ 4,369	81%

\* Not meaningful

Research and development expenses increased by \$4.4 million, or 81%, to \$9.7 million in the nine months ended September 30, 2021, from \$5.4 million in the nine months ended September 30, 2020. The increase was primarily due to an increase of \$5.3 million in consulting and contract research expense resulting from the Phase 2b clinical trial of atacicept initiating and enrolling during the current period, an increase of \$1.7 million of employee compensation and related expenses resulting from the increased headcount to support clinical development of atacicept during the current period. These were partially offset by decreases of \$1.3 million of internal research and development expenses resulting from our ceasing of internal research in September 2020 and \$1.4 million for facilities, depreciation and other expenses, as a result of the vacating and sublease of our leased facilities in South San Francisco in November 2020.

#### General and administrative

General and administrative expenses consist primarily of compensation and personnel-related expenses, including stock-based compensation, for our personnel in executive management, legal, finance, human resources, and other administrative functions. General and administrative expenses also include professional fees paid for accounting, auditing, legal, tax and consulting services, and other general overhead costs to support our operations. General and administrative expenses are recorded as expense in the period they are 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.

	Nine months ended September 30,			Change
(dollars in thousands)	2021	2020	Amount	%
General and administrative	\$ 8,086	\$ 2,903	\$ 5,183	179%

General and administrative expenses increased by \$5.2 million, or 179%, to \$8.1 million in the nine months ended September 30, 2021, from \$2.9 million in the nine months ended September 30, 2020, due primarily to increases of \$2.0 million of payroll and related expenses including stock-based compensation, an increase of \$1.1 million in insurance premium expense, an increase of \$0.8 million in legal expenses, an increase of \$0.5 million in cash and stock-based compensation to non-employee directors, all as a result of being a public company during the current period.

#### **Restructuring costs**

Restructuring costs primarily consist of contract termination costs related to leases and employee termination costs.

	Nine months ended September 30,			
(dollars in thousands)	2021 2020	Amount	%	
Restructuring Costs	— 1,416	(1,416)	*	

Not meaningful

We restructured in September 2020, resulting in the termination of certain employees and vacating of leased facilities.

#### Total other income (expense)

	Three months ended				
	Se	pteml	oer 30,	Cha	ange
(dollars in thousands)	2021		2020	Amount	%
Total other income (expense)	2,055	\$	(857)	2,942	*

Not meaningful

Total other income increased by \$2.9 million to \$2.1 million in the nine months ended September 30, 2021, from \$(0.9) million (expense) in the nine months ended September 30, 2020, due to other income of \$2.7 million recognized in the current period from the sale of assets to NeuBase Therapeutics, Inc. (NeuBase), partially offset by \$0.7 million of other expense recognized in the current period due to unrealized losses from non-marketable equity securities. We recorded \$0.8 million of other expense due to the change in fair value of convertible notes during the period in 2020.

#### Comparisons of the years ended December 31, 2019 and 2020

The following table summarizes our results of operations for the periods presented.

	De	Year ended ecember 31,		Change
(dollars in thousands)	2019	2020	Amount	%
Operating expenses:				
Research and development	\$ 7,290	\$ 45,206	\$ 37,916	520%
General and administrative	4,410	4,039	(371)	(8)%
Restructuring costs	261	2,996	2,735	1,048
Total operating expenses	11,961	52,241	40,280	337%
Loss from operations	(11,961)	(52,241)	(40,280)	337%
Other income (expense):				
Interest income	159	8	(151)	(95)%
Interest expense	(51)	(166)	(115)	225%
Gain on issuance of convertible notes		63	63	*
Change in fair value of convertible notes	_	(1,076)	(1,076)	*
Total other income (expense)	108	(1,171)	(1,279)	(1,184)%
Loss before provision for income taxes	(11,853)	(53,412)	(41,559)	351%
Provision for income taxes	(1)	(1)	0	0%
Net loss and comprehensive loss	\$(11,854)	\$(53,413)	\$(41,559)	351%

\* Not meaningful

#### Research and development expenses

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

		∕ear ended cember 31,		Change
(dollars in thousands)	2019	2020	Amount	%
Direct preclinical and clinical expenses				
Consulting and outside services	\$1,289	\$ 1,706	\$ 417	32%
Equipment	1,426	622	(804)	(56)%
License	—	38,121	38,121	*
Indirect preclinical and clinical expenses				
Compensation and related benefits	2,052	1,902	(150)	(7)%
Facilities, depreciation and other	2,523	2,855	332	13%
Research and development	\$7,290	\$45,206	\$37,916	520%

\* Not meaningful

Research and development expenses increased by \$37.9 million, or 520%, to \$45.2 million in 2020 from \$7.3 million in 2019. The increase was primarily due to payments made to Ares pursuant to our exclusive license of atacicept, consisting of an initial payment of \$13.1 million payable in shares of our Series C redeemable convertible preferred stock and subsequent cash milestone payments of \$25.0 million, and an increase of \$0.4 million in consulting and outside services expense resulting primarily from services commenced by clinical research organizations to initiate the Phase 2b clinical trial of atacicept, which were partially offset by

decreases of \$0.8 million of equipment expense, as we recorded such expense through September 2020 at which time we ceased using our laboratory equipment for preclinical activities, and \$0.2 million of compensation and benefits expense, resulting from our ceasing use of laboratory equipment and reducing our preclinical workforce in September 2020. Facilities, depreciation and other expenses of \$2.9 million in 2020 include an impairment charge of \$1.0 million resulting from our disposal of furniture and laboratory equipment associated with the preclinical activities that we ceased in September 2020.

#### General and administrative

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

	Year ended December 31,			Change
(dollars in thousands)	2019	2020	Amount	%
General and administrative	\$4,410	\$4,039	\$ (371)	(8)%

General and administrative expenses decreased by \$0.4 million, or 8%, to \$4.0 million in 2020 from \$4.4 million in 2019, due primarily to lower rent expense of \$0.7 million and lower compensation and benefits of \$0.1 million resulting from our ceasing preclinical activities during the year. These decreases were partially offset by an increase in professional services of \$0.3 million and an impairment charge of \$0.1 million associated with the disposal of office equipment.

#### **Restructuring costs**

	Year ended			
(dollars in thousands)		ember 31, 2020	Amount	Change %
Restructuring costs	\$261	\$2,996	\$ 2,735	1,048%

Restructuring costs increased by \$2.7 million, or 1,048%, to \$3.0 million in 2020 from \$0.3 million in 2019, due primarily due to our restructuring in September 2020, which resulted in our termination of certain of our employees, vacating leased facilities, and ceasing use of leased equipment that had been focused on our preclinical research and development activities. Restructuring costs in 2019 resulted from vacating our lab and office facilities in Massachusetts.

#### Total other income (expense)

	Year ended December 31,			Change		
(dollars in thousands)	2019	2020	Amount	%		
Total other income (expense)	\$108	\$(1,171)	\$(1,279)	(1,184)%		

The decrease of \$1.3 million in total other income (expense) to \$1.2 million other expense in 2020 from \$0.1 million other income in 2019 resulted from a loss due to an increase of \$1.1 million in the fair value of our convertible notes for which we elected to account for at fair value, a \$0.1 million increase in interest expense attributable to the issuance of such notes, which converted into shares of our Series C redeemable convertible preferred stock during 2020, and a \$0.2 million decrease in interest income due a lower level of available cash invested in 2020.

# Liquidity and capital resources

To date, we have funded our operations primarily through the issuance and sale of redeemable convertible preferred stock and convertible notes, net proceeds from our IPO and net proceeds from our Loan and Security Agreement (Loan Agreement) with Oxford Finance LLC (Oxford). From our inception through September 30, 2021, we have raised aggregate net cash proceeds of \$190.0 million from the issuance and sale of redeemable convertible preferred stock, convertible notes and our IPO. Since the date of our incorporation, we have not generated any revenue from product sales and have incurred substantial operating losses and negative cash flows from operations.

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

We anticipate that we will continue to incur net losses for the foreseeable future as we continue research and development activities of atacicept and MAU868, hire additional staff, including clinical, operational, financial and management personnel, and incur additional expenses associated with operating as a public company. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our clinical development activities and our product candidate portfolio. We expect that our research and development and general and administrative costs will increase substantially as a result of our acquisition of MAU868, including in connection with conducting additional clinical trials and clinical trials for our research programs and product candidates, contracting with third parties to support nonclinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources.

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

As of September 30, 2021, we had unrestricted cash and cash equivalents balance of \$86.2 million, as compared to \$53.7 million and \$3.2 million as of December 31, 2020 and 2019, respectively. We expect that our existing cash and cash equivalents, together with the proceeds from our Loan Agreement with Oxford and net proceeds from this offering, will be sufficient to fund our operations at least into the fourth quarter of 2023.

### Cash flows

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

		Year ended December 31,		Nine months ended September 30,	
(in thousands)	2019	2020	2020	2021	
Net cash used in operating activities	\$(10,289)	\$(34,809)	\$(7,427)	\$(17,270)	
Net cash provided by (used in) investing activities	(125)	(42)	(99)	796	
Net cash provided by (used in) financing activities	(137)	85,290	5,489	48,961	
Net increase (decrease) in cash and cash equivalents	\$(10,551)	\$ 50,439	\$(2,037)	\$ 32,487	

# **Operating activities**

In the nine months ended September 30, 2021, we used \$17.3 million of cash in operating activities, attributable to a net loss of \$15.8 million, a \$2.7 million non-cash gain on sale of assets to NeuBase, and a \$3.0 million increase in prepaid expenses and other current assets resulting mostly from prepaid insurance premiums, partially offset by a \$2.2 million increase in accrued and other current liabilities resulting mostly from accrued expenses for research and development activities, and \$2.0 million of non-cash stock-based compensation expense.

In the nine months ended September 30, 2020, we used \$7.4 million of cash in operating activities, attributable to a net loss of \$10.5 million, partially offset by the non-cash expenses of \$1.2 million resulting from an impairment loss on property, equipment and intangible assets resulting from our restructuring, \$0.9 million from depreciation, amortization and accretion, and a \$0.8 million decrease in the fair value of convertible notes.

In 2020, we used \$34.8 million of cash used in operating activities, attributable to a net loss of \$53.4 million, partially offset by non-cash expenses of \$13.1 million resulting from a license payment made in shares of redeemable convertible preferred stock, an increase of \$2.4 million in the liability for restructuring, net of cash paid, a net change of \$0.1 million in our net operating assets and liabilities, and \$2.9 million of other non-cash expenses, of which \$1.2 million was an impairment charge associated with the disposal of property, equipment and intangible assets, \$1.1 million was attributable to the change in fair value on convertible notes payable, \$0.3 million of stock-based compensation and \$0.3 million of depreciation and amortization. The net change of \$0.1 million in our net operating assets and liabilities resulted primarily from a \$0.5 million decrease in other liabilities, a \$0.6 million increase in accounts payable and a \$0.1 million decrease in other assets, which were partially offset by a \$0.1 million increase in prepaid expense and other assets.

In 2019, we used \$10.3 million of cash in operating activities, attributable to a net loss of \$11.9 million, partially offset by a net change in our net operating assets and liabilities of \$0.5 million, the accrual for restructuring costs, net of cash paid, of \$0.2 million, and non-cash expenses of \$0.9 million, of which \$0.5 million was for depreciation and amortization, \$0.3 million was for stock-based compensation and \$0.1 million was for the loss on disposal of property and equipment. The change in our net operating assets and liabilities resulted primarily from a decrease in prepaid expenses and other current assets of \$0.3 million, a decrease in grants receivable of \$0.2 million, an increase in accrued and other current liabilities of \$0.1 million, and an increase in other liabilities of \$0.3 million, which were partially offset by a decrease in accounts payable of \$0.3 million.

# Investing activities

In the nine months ended September 30, 2021, our investing activities provided \$0.8 million of cash resulting from the sale of assets to NeuBase.

In the nine months ended September 30, 2020, our investing activities used \$0.1 million of cash in the purchase of property and equipment.

In 2020, we used \$42,000 of cash for investing activities as a result of the purchase of \$0.1 million of equipment, partially offset by our receipt of proceeds in the amount of \$57,000 from the sale of equipment.

In 2019, we used \$0.1 million of cash for investing activities, resulting from the purchase of property and equipment used for research and development activities and for general and administrative operations.

# **Financing activities**

In the nine months ended September 30, 2021, our financing activities provided \$49.0 million of cash resulting from \$51.2 million proceeds 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.

In the nine months ended September 30, 2020, our financing activities provided \$5.5 million of cash resulting from \$5.6 million in proceeds from the issuance of convertible notes payable that were subsequently converted into Series C redeemable convertible preferred stock later in 2020.

In 2020, our financing activities provided \$85.3 million of cash resulting from \$79.6 million in proceeds from our issuance of Series C redeemable convertible preferred stock, net of issuance costs, proceeds of \$5.6 million from our issuance of convertible notes payable that were converted into Series C redeemable convertible preferred stock, and proceeds of \$0.2 million from the exercise of stock options to purchase Class A common stock, partially offset by the payment of \$0.1 million of capital lease obligations.

In 2019, cash used in financing activities was \$0.1 million. This was attributable to the payment of capital lease obligations totaling \$0.2 million, partially offset by the proceeds from the exercise of stock options totaling \$0.1 million.

#### Contractual obligations

The following table summarizes our contractual obligations as of December 31, 2020.

		Pa			Payments due by period		
		Less than			More than		
(In thousands)	Total	1 year	1-3 years	3-5 years	5 years		
Operating leases	\$11,780	\$ 2,838	\$ 4,646	\$ 4,296	\$ —		

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. Payments associated with these agreements are not included in this table of contractual obligations.

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

During 2019, we vacated our leased facilities in Woburn, Massachusetts and recorded a discounted lease-related restructuring liability, which was calculated as the present value of the estimated future facility costs for which we would obtain no future economic benefit over the remaining term of the lease, which ended in July 2021.

During 2020, we vacated the leased facilities in South San Francisco. Our total future minimum commitment due pursuant to this lease is \$11.1 million. 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 \$11.1 million minimum lease commitment on the facilities.

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

In addition to the office leases, we have future minimum lease payments of \$0.6 million for leases on research and laboratory equipment.

### 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 in an aggregate

maximum principal amount of \$50.0 million, of which \$5.0 million was funded on December 17, 2021 and the balance of which is available to be drawn between January 3, 2022 and December 31, 2022. 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.

The final maturity date of the Loan is December 17, 2026, which may, upon achieving either (i) positive Phase 2b clinical trial data of atacicept in IgAN or (ii) positive pivotal trial data of atacicept in LN, at our option, be extended by 12 months (the Maturity Date Extension). We are required to make monthly interest-only payments for 48 months (extended to 60 months if the Maturity Date Extension is exercised) followed by full amortization through maturity.

Initially, through December 30, 2021, the Loan bears interest at a per annum rate of 8.254%. Thereafter, the Loan will bear interest at a floating per annum rate (based on the actual number of days elapsed divided by a year of 360 days) equal to the greater of (i) 8.25% and (ii) the sum of (a) the greater of (x) the 30-day U.S. LIBOR rate reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue and (y) 0.09%, plus (b) 8.16%. The Loan Agreement also provides for the selection of an alternative benchmark rate in the event of the discontinuance of LIBOR or any subsequent benchmark rate.

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 5.0% (7.0% if the Maturity Date Extension is exercised) of the aggregate principal amount of the Loan (the Final Fee). Any prepayments of the Loan, whether mandatory or voluntary, must include an amount equal to the sum of (a) the portion of the outstanding principal of the Loan being prepaid plus accrued and unpaid interest thereon through the prepayment date, (b) the Final Fee, (c) the Lender's expenses and all other obligations that are due and payable to the Lender, and (d) a prepayment fee of (i) 3.0% of the portion of the Loan being prepaid if the repayment is on or before the first anniversary of the funding date of such term loan or (ii) 2.0% of the portion of the Loan being prepaid if the repayment is after the first anniversary of the funding date but on or before the second anniversary of the funding date of such term loan (the Prepayment Fee). There is no Prepayment Fee for any prepayments occurring after the second anniversary of the funding date of such term loan.

Our obligations under the Loan Agreement are secured by a security interest in all of our assets, other than our intellectual property, which is subject to a negative pledge. The Loan Agreement does not contain any financial related covenants. Included in the Loan Agreement are customary representations and covenants that, subject to exceptions, restrict our ability to, among other things: declare dividends or redeem or repurchase equity interests; incur additional liens; make loans and investments; incur additional indebtedness; engage in mergers, acquisitions and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that are not related to our existing business.

Upon the occurrence of an event of default, a default interest rate of an additional 5.0% may be applied to the outstanding loan balances, and the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. Events of default under the Loan Agreement include customary events of default, including, but not limited to: (i) failure to (a) make any payment of principal or interest on its due date, or (b) pay any other obligations within three business days after such obligations are due and payable; (ii) failure to perform any obligation under specified covenants; (iii) the occurrence of a material adverse change; (iv) we or any of our subsidiaries being or becoming insolvent, beginning an insolvency proceeding, or becoming subject to an insolvency proceeding that is not dismissed or stayed within 45 days; (v) a default under any agreement with a third party resulting in a right by such third

party to accelerate the maturity of any indebtedness in an amount in excess of \$500,000 or that could reasonably be expected to have a material adverse change; (vi) the rendering of judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least \$500,000 that remain unsatisfied, unvacated, or unstayed for a period of 10 days after the entry thereof; (vii) revocation, rescission, suspension or adverse modification of any governmental approval, or non-renewal of a governmental approval in the ordinary course for a full term, that could reasonably be expected to result in a material adverse change; and (viii) failure of a lien created under the Loan Agreement or any other loan document to constitute a valid and perfected lien on any of the collateral purported to be secured thereby, subject to no prior or equal lien, other than permitted liens.

### Internal control over financial reporting

In the preparation of our financial statements for 2020, we determined a material weakness in our internal control over financial reporting existed during 2019, which material weakness remained unremediated as of December 31, 2020. See the section titled "Risk factors—We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our Class A common stock."

#### Off-balance sheet arrangements

Since the date of our incorporation, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

### Critical accounting policies, significant judgments and use of estimates

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities, at the date of the financial statements, as well as revenue and 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 contract costs and accruals

We enter into various research and development and other agreements with commercial firms, researchers and others for provisions of goods and services from time to time. These agreements are generally cancellable, and the related costs are recorded as research and development expenses as incurred. We record accruals for

estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, we analyze progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from our estimates.

#### Stock-based compensation

We maintain a stock-based compensation plan as a long-term incentive for employees, non-employee directors, consultants and advisors. The plan allows for the issuance of a variety of equity incentive awards, including incentive stock options, non-qualified stock options and restricted stock awards. We account for stock-based compensation by measuring and recognizing compensation expense for all share-based awards made to employees and non-employees based on estimated grant-date fair values. We use the straight-line method to allocate compensation cost to reporting periods over the requisite service period, which is generally the vesting period. We recognize actual forfeitures by reducing the stock-based compensation expense in the same period as the forfeitures occur. We estimate the fair value of share-based awards to employees and non-employees using the Black-Scholes model.

Estimating the fair value of equity-settled awards as of the grant date using the Black-Scholes option pricing model is affected by assumptions regarding a number of complex variables. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. These inputs are as follows:

- · Fair value of common stock—See the subsection titled "Fair value of common stock" below.
- Expected term—The expected term represents the average period that our options granted are expected to be outstanding and is
  determined using the simplified method (based on the mid-point between the weighted-average vesting date and the end of the
  contractual term). We have very limited historical information to develop reasonable expectations about future exercise patterns and
  post-vesting employment termination behavior for our stock option grants.
- Expected volatility—Since we were a privately-held company until our IPO in May 2021 and have only a limited trading history for our common stock, the expected volatility was estimated based on the historical average volatility for comparable publicly traded biopharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, life cycle stage, or area of specialty. We will continue to apply this process until enough historical information regarding the volatility of our own stock price becomes available.
- Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the options.
- Expected dividend yield—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

We will continue to use judgment in evaluating the expected volatility, expected terms, and interest rates utilized for our stock-based compensation calculations on a prospective basis. Assumptions we used in applying the Black-Scholes option-pricing model to determine the estimated fair value of our stock options granted involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation could be materially different.

# Fair value of common stock

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

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

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

The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, we considered the following methods:

• **Option Pricing Method (OPM)**. Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the redeemable convertible preferred stock and common stock are inferred by

analyzing these options. This method is appropriate to use when the range of possible future outcomes is difficult to predict and thus creates highly speculative forecasts.

• **Probability-Weighted Expected Return Method (PWERM)**. The PWERM is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class. This method is generally most appropriate to use when the time to a liquidity event is short, making the range of possible future outcomes relatively easy to predict.

Based on our early stage of development and other relevant factors, we determined that the OPM was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock for valuations during 2019 and 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.

### Emerging growth company status

We are an emerging growth company, as defined in the 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. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years audited financial statements in this prospectus, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company under the JOBS Act until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenue of \$1.07 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.

#### Recent accounting pronouncements

See Note 2 to our audited financial statements included elsewhere in this prospectus 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.

# **Business**

# **Overview**

We are a late-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases. We expect to initiate multiple registration-enabling trials over the next 18 months. Our lead product candidate, atacicept, a self-administered fusion protein that blocks both BLyS and APRIL, is currently being evaluated for the treatment of IgAN in the Phase 2b ORIGIN trial, which we expect will complete enrollment in mid-2022 and report topline results in the fourth guarter of 2022. If these data are positive, we plan to seek an accelerated approval path in the United States from the FDA and in the European Union from the EMA while initiating a pivotal Phase 3 clinical trial in 2023. We plan to initiate a Phase 3 clinical trial of atacicept in LN, a severe renal manifestation of SLE, in the fourth quarter of 2022 based on positive feedback from the FDA's review of promising clinical results in a Phase 2 clinical trial of atacicept in high disease activity patients with SLE. In December 2021, we obtained worldwide, exclusive development and commercial rights from Amplyx, a wholly owned subsidiary of Pfizer, for MAU868, a potentially first-in-class monoclonal antibody to treat BKV infections. We believe MAU868 is the only 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. In an interim analysis of Phase 2 data in BK viremia among kidney transplant recipients, MAU868 was shown to be well tolerated and demonstrated a clinically significant reduction of virologic activity. We expect to share full results from the interim analysis in mid-2022 and expect to initiate a Phase 2b or Phase 3 clinical trial in 2023. We believe that our current pipeline programs, shown in Figure 1, leverage the deep expertise of the Vera Therapeutics team and have strong commercial synergies. We currently hold global rights to all of our pipeline programs.

# Figure 1: Vera therapeutics pipeline



# Atacicept in IgAN

IgAN is a serious and progressive autoimmune disease of the kidney that is driven by the production of immunogenic galactose-deficient IgA1 (Gd-IgA1) which is associated with increased risk of kidney-related morbidity and mortality. We estimate there are approximately 126,000 biopsy-confirmed IgAN patients in the United States, 136,000 in the European Union, and 130,000 in Japan. Up to 50% of patients diagnosed with IgAN develop 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 one treatment, TARPEYO (developed by Calliditas Therapeutics AB under the name Nefecon), a recently-approved reformulated steroid, has been approved for this indication, and the current standard of care continues to consist of off-label use of RAAS inhibitors, including ACE inhibitors and ARBs, and potentially steroids. We estimate the U.S. market opportunity for novel therapeutics in IgAN is approximately \$4.0 billion to \$8.0 billion annually, based on the disease prevalence and the segment of IgAN patients at high risk of progressing to ESRD. In Europe and Japan, we estimate the annual market opportunity for novel IgAN therapeutics to be \$1.0 billion and \$600 million, respectively.

Atacicept is a fusion protein self-administered as a subcutaneous injection once weekly that blocks both BLyS and APRIL, which stimulate B cells and plasma cells to produce autoantibodies contributing to certain autoimmune diseases. We believe that atacicept's mechanism has the potential to drive clinical success by measures designed to assess efficacy in IgAN and other immunologic diseases. BLyS inhibition has been clinically and commercially validated through the approval of Benlysta (belimumab) in both SLE and LN. Preclinical and clinical evidence supports that atacicept's mechanism of dual inhibition of BLyS and APRIL may provide improved clinical outcomes, measured by endpoints designed to assess efficacy, compared to inhibiting either signal alone. Atacicept has been shown in a clinical trial to reduce Gd-IgA1, which is central to the pathogenesis of IgAN, and therefore has the potential to be the first disease modifying therapy for IgAN due to its ability to act on core pathophysiology processes. As reported in a Phase 2a clinical trial of 16 patients conducted by Merck KGaA, Darmstadt, Germany, atacicept is the first and only molecule in development to demonstrate a 60% reduction in plasma Gd-IgA1 in a randomized controlled study in IgAN patients (75 mg dose, n=4 at 24 weeks), which we believe can be disease modifying.

We have worldwide, exclusive rights to atacicept from Ares, an affiliate of Merck KGaA, Darmstadt, Germany, pursuant to the Ares Agreement, which advanced atacicept in randomized, double-blind, placebo-controlled clinical trials for several autoimmune diseases in over 1,500 patients, in which it was well tolerated. In IgAN, Merck KGaA, Darmstadt, Germany, conducted a randomized, double-blind, placebo-controlled Phase 2a trial, known as JANUS. Results from the JANUS trial showed a dose-dependent effect of atacicept 25mg and 75mg weekly on serum Gd-IgA1, proteinuria and key biomarkers, including serum immunoglobulin levels. Atacicept was observed to be generally well tolerated. Specifically, the atacicept 75 mg dose arm demonstrated a 60% reduction in serum Gd-IgA1.

We are conducting a global, randomized, double-blind, placebo-controlled Phase 2b clinical trial in IgAN, which we refer to as ORIGIN. The ORIGIN trial is evaluating three subcutaneous weekly doses of atacicept (25 mg, 75 mg and 150 mg) and their impact on the reduction of proteinuria as the primary endpoint. A significant reduction in proteinuria, as measured by UPCR in a 24-hour urine collection, is associated with improved renal outcomes in patients with IgAN. UPCR is a surrogate endpoint endorsed by the FDA for primary glomerular diseases associated with significant proteinuria, including IgAN. The ORIGIN trial is powered to demonstrate a statistically significant difference between atacicept and placebo in decrease of proteinuria. Given the FDA's recent approval of TARPEYO, we believe this provides validation for the use of proteinuria as a surrogate for accelerated approval. Secondary endpoints include the difference in kidney function between treated and placebo patients as measured by estimated eGFR and reduction in Gd-IgA1. We are currently enrolling the Phase 2b ORIGIN trial and expect to enroll a total of 105 patients at multiple global sites and to report topline results in the fourth quarter of 2022.

### Atacicept in LN

Based on positive feedback from the FDA's review of promising clinical results in a Phase 2 clinical trial of atacicept in high disease activity patients with SLE, we are planning to initiate a Phase 3 clinical trial of



atacicept in fourth guarter 2022 as a potential treatment for patients with LN, a severe renal manifestation of SLE. We estimate that there are approximately 110,000 LN patients in the United States, 69,000 in the European Union, and 22,000 in Japan. We estimate the market for novel LN therapeutics annually to be approximately \$2.0 to \$5.0 billion, \$600 million and \$200 million in United States, Europe and Japan, respectively. Significant unmet need for improved efficacy persists for these patients despite the recent approval of the first two LN-specific therapies. Fewer than half of patients treated for LN have a complete response to therapy, and among patients without a complete response, over half will have non-functioning kidneys within five years. Benlysta (belimumab), a BlyS-only inhibitor, is one of the two therapies approved for patients with LN. Both BlyS and APRIL levels are increased in patients with SLE, suggesting that dual inhibition by atacicept may be more potent than blocking BLyS alone and has the benefit of targeting plasma cells in addition to B cells. Merck KGaA, Darmstadt, Germany previously initiated a randomized, double-blind, placebo-controlled Phase 2/3 clinical trial of atacicept in LN, the APRIL-LN trial, 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 subjects developing hypogammaglobulinemia with induction therapy (MMF and CS) which continued to worsen when initiating atacicept and subsequently two subjects 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 High Disease Activity patient segment (defined as Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) <sup>3</sup> 10 at screening), including reduction of renal flares, which we believe supports atacicept's applicability in LN. Because both preclinical and clinical evidence suggests atacicept's dual inhibition of BLyS and APRIL may provide improved clinical outcomes, measured by endpoints designed to assess efficacy, compared to inhibiting either signal alone, we believe there is a strong rationale to conduct a clinical trial of atacicept in LN.

Our Phase 3 randomized, double-blinded, placebo-controlled trial will evaluate the efficacy and safety of atacicept in subjects with LN. The clinical trial consists of a 52-week double-blind treatment period, followed by a 104-week open-label treatment period and a 26-week safety follow-up period. The trial will assess 150 mg of once weekly subcutaneous injections of atacicept versus placebo. The primary endpoint is complete renal response at 52 weeks. We plan to initiate patient screening for our Phase 3 clinical trial in LN in the fourth quarter of 2022.

# MAU868 in BK viremia among kidney transplant recipients

We are developing MAU868 as a potential treatment for BK viremia in kidney transplant recipients. While up to 90% of healthy adults have been infected with the BKV at some point in their lives, it remains latent in everyone except severely immunocompromised populations such as kidney transplant recipients. BKV is a polyoma virus that can cause 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 there are 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 BK viremia in kidney transplant recipients to be approximately \$700 million annually worldwide, with \$350 million, \$120 million, \$18 million, and \$50 million in peak sales generated in the United States, Europe, Japan, and China, respectively. 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.

MAU868 has been shown in an interim analysis of week 12 data from Cohort 1 and 2 of a Phase 2 clinical trial to be well tolerated and have reduction of virologic activity. We expect to share full Cohort 1 and Cohort 2 interim

analysis results in mid-2022. Given the overlap of patients with IgAN and BKV, we obtained worldwide, exclusive rights to develop, manufacture and commercialize MAU868 from Amplyx, a wholly owned subsidiary of Pfizer in December 2021.

#### 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 44,000 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. Based on primary market research with physicians and extensive secondary research, we estimate the market for a novel agent to treat BKV cystitis to be approximately \$550 million annually worldwide, with \$230 million, \$230 million, \$50 million, and \$7 million in peak sales generated in the United States, Europe, Japan, and China, respectively. We believe that MAU868 may represent an important future treatment option for these patients.

# Our business principles and strategy

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

- Develop disease modifying medicines to improve patients' lives. Our team seeks to bring transformative medical products to patients with severe immunological diseases, who often receive steroids for treatment. The non-specific immunologic effect of steroids, with known acute and chronic side effects, presents an important opportunity for innovation. We aim to develop and commercialize disease modifying drugs that target the source of disease, minimize side effects, and have high potential to meaningfully change standard medical care and improve patients' lives.
- Establish clear line-of-sight to successful products. We apply our deep drug development experience, scientific rigor, and disciplined decision making to establish clear line-of-sight along the full spectrum of drug development. We pursue biologic targets, product candidates, and disease indications with a de-risked profile and capital efficient development pathway, and optimize for high probability of clinical, regulatory, and commercial success.
- Build a leading biotech company that delivers innovative medicines to patients. We believe our team's expertise and our business culture are fundamental to our success. Our Research and Development team is led by experienced drug development executives with proven track records in clinical and commercial development who have led or been involved in the approvals of more than 12 medicines from leading companies, including Gilead Sciences and Genentech. We leverage our team's know-how with additional outsourced resources and enable focused clinical development of our product candidates with the goal of improving patients' lives.

These principles have guided us to the successful in-licensing of atacicept from Ares and obtaining the rights to MAU868 from Amplyx, in each case with worldwide rights for development and commercialization in all

indications. We take a gated-capital raise approach and scale product candidate investment and exposure in close step with key development milestones to ensure high return on development costs.

The near-term objectives to achieve our goal include:

- **Complete global development of atacicept in IgAN.** We are currently enrolling patients in the Phase 2b ORIGIN trial and expect to enroll a total of 105 patients at multiple global sites. We expect to report topline results from ORIGIN in the fourth quarter of 2022. If these data are positive, we plan to seek an accelerated approval path in the United States by the FDA and in the European Union by the EMA while initiating a pivotal Phase 3 clinical trial in 2023.
- **Complete global development of atacicept in LN.** We intend to initiate a Phase 3 clinical trial in the fourth quarter of 2022. LN is a frequent but devastating complication of SLE. The recent FDA approval of the anti-BLyS antibody, Benlysta (belimumab), provides clinical and regulatory precedent upon which to build our program. We believe that atacicept could offer a significant efficacy advantage for LN patients with its dual anti-APRIL and anti-BlyS mechanism.
- Complete global development of MAU868 in BK viremia in kidney transplant recipients and explore treatment of BK cystitis in HSCT patients. We expect to share full Cohort 1 and Cohort 2 interim analysis results from the ongoing Phase 2 clinical trial in kidney transplant recipients in mid-2022. We intend to initiate a Phase 2b or Phase 3 clinical trial in 2023.
- Build and scale organizational capabilities to support commercialization of atacicept and MAU868. Under the leadership of our experienced management team, we plan to build a specialized commercial organization to launch atacicept and MAU868 in the United States and other key markets, if approved. Within certain ex-U.S. markets, we may consider strategic collaborations for commercialization.
- Explore additional disease areas where atacicept holds significant therapeutic promise. By targeting APRIL and BLyS, atacicept's ability to reduce disease causing autoantibodies may provide clinical benefit. We intend to explore additional immunologic diseases where BLyS and APRIL are abnormally elevated, or where autoantibodies play an important role.
- Expand our pipeline by acquiring or in-licensing product candidates for immunologic diseases with unmet needs. We believe our expertise and track record will enable us to identify and acquire or in-license additional product candidates that represent opportunities to expand the potential value of our pipeline. We will leverage our lean clinical development operation to bring to market additional product candidates to address immunologic diseases.

# Management team

We were founded and are led by a team of experienced drug development professionals who have proven track records in clinical and commercial development and have led or been involved in the approvals of 10 medicines from Gilead Sciences. Inc. (Gilead) and Genentech, Inc. (Genentech), including numerous drugs within Gilead's multi-billion 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, Tad Thomas, Ph.D., who was formerly Associate Vice President, Technical Operations at Codexis, Inc. and held previous manufacturing leadership roles at Bayer HealthCare LLC and other biopharmaceutical companies; and Senior Vice President, Finance and Chief Accounting Officer, Joseph Young, who was formerly Senior Vice President, Finance and Treasurer at Plexxikon Inc. In conjunction with the Ares Agreement, we completed an approximately \$80.0 million Series C redeemable convertible preferred stock financing led by Abingworth LLP. Other investors included Sofinnova Investments, Longitude Capital, Fidelity Management & Research Company LLC, Surveyor Capital (a Citadel company), Octagon Capital, Kleiner Perkins, GV (formerly Google Ventures), and Alexandria Venture Investments.

# Intellectual property

As of December 31, 2021, our licensed patent portfolio related to atacicept contains approximately 15 issued U.S. patents, as well as foreign counterparts of a subset of these patents in several foreign countries, including countries within the European Patent Convention and the Eurasian Patent Organization. Our licensed patent portfolio related to atacicept also includes a pending PCT application and a counterpart Taiwanese application. 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 10 years in the European Union. Our licensed patent portfolio covering MAU868 includes three issued U.S. patents, a pending US application, as well as certain foreign counterparts of a subset of these patents granted in Australia, China, and Taiwan, and pending applications in other jurisdictions such as Canada, Mexico, Europe and Japan. In addition, there is a pending PCT application, and a counterpart application in Taiwan.

# Atacicept in IgAN

We are developing atacicept as a potential treatment for patients with IgAN, a disease with a high unmet medical need and limited treatment options available. IgAN is a serious and progressive autoimmune disease of the kidney, that is driven by the production of pathogenic Gd-IgA1. IgAN 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 plasma Gd-IgA1 in IgAN patients, suggesting atacicept targets the source of disease in these patients. Based on these encouraging results, we are currently 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 expect to report topline results in the fourth quarter of 2022, and if positive, we plan to seek an accelerated approval path in the United States by the FDA and in the European Union by the EMA while initiating a pivotal Phase 3 clinical trial in 2023. We believe that atacicept has the potential to be the best-in-class and the leading B cell-targeted therapy for IgAN. 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

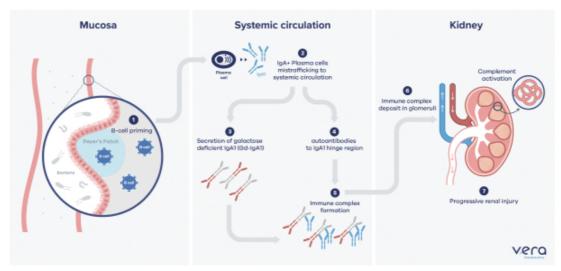
estimated to be over \$40.0 billion annually in the United States. Despite this high level of morbidity, the current standard of care consists of off-label use of RAAS inhibitors, including ACE inhibitors and ARBs, and potentially steroids.

### Pathophysiology of IgAN

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

As shown in Figure 2 below, a multi-step process leads to the ultimate development of progressive renal injury.

Figure 2: IgAN pathophysiology—overview



- B cells, which mature into plasma cells, are abnormally primed in the Peyer's patch region of the ileum of the intestines, potentially due to a combination of genetic predisposition and environmental, bacterial or dietary factors. BLyS promotes B cell maturation and survival, increasing the number of disease causing B cells.
  - APRIL, a factor important for plasma cell survival, becomes upregulated, resulting in increased numbers of disease-causing plasma cells.
- APRIL increases the number of plasma cells and increases antibody class switching, which is a mechanism that changes cells production from one immunoglobulin to another, causing an increase in the production of immunogenic Gd-IgA1. (See "Hit 1" in Figure 3 below.)
- The Gd-IgA1 antibodies are immunogenic when found in the systemic circulation, which triggers autoantibodies, or antibodies created by the body in response to a constituent of its own tissue. (See "Hit 2" in Figure 3 below.)

Autoantibodies against Gd-IgA lead to the formation of pathogenic immune complexes, or clusters of antibodies. (See "Hit 3" in Figure 3 below.)



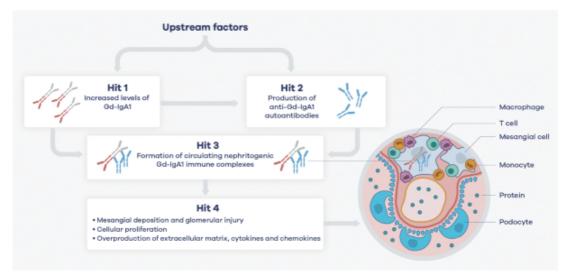


Pathogenic immune complexes are deposited and become trapped in the kidney's glomeruli and initiate an inflammatory response that damages the membranes, resulting in protein and blood leaking into the urine. (See "Hit 4" in Figure 3 below.)

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

Similarly, IgAN has also been described as having a multi-hit pathogenesis, as shown in Figure 3 below, and referenced in the steps 3-6 above.

# Figure 3: IgAN pathophysiology-downstream effects of elevated Gd-IgA1

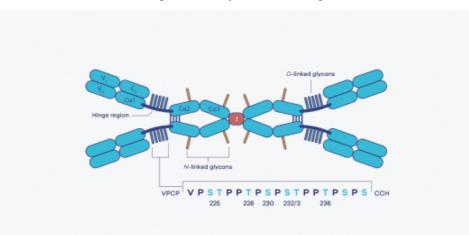


# Gd-IgA1 is central to the pathogenesis of IgAN

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 4 below. The hinge region is a stretch of amino acids in the IgA antibody. Circulating immune complex—containing Gd-IgA1 proteins have been shown to be the target antigens for IgG antibodies with specificity for the hinge region.



Figure 4: Components of Gd-IgA1



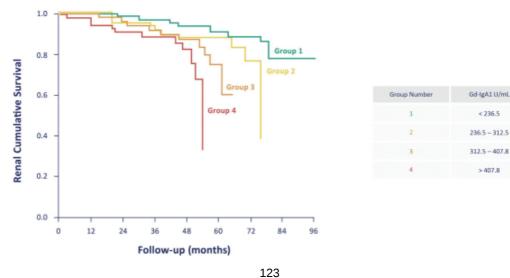
A histopathological hallmark of IgAN is deposition of Gd-IgA1 in the glomerular mesangium, either alone or in combination with IgG and/or immunoglobulin M (IgM). Sampling of the serum of subjects with IgAN has confirmed the presence of elevated levels of circulating immune complex-containing Gd-IgA1.

Clinical trials of patients with IgAN have correlated higher serum levels of Gd-IgA1 with greater severity of IgAN disease, suggesting that reduction in serum levels of Gd-IgA1 may slow disease progression. Compared with healthy subjects, patients with IgAN have an increase in the 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 5 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 end-stage renal disease or death.



< 236.5

> 407.8



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

# Disease burden, diagnosis, and predictors of disease progression

IgAN is a rare disease in the United States and European Union and is also the predominant cause of primary glomerulonephritis.

Patients with IgAN are diagnosed throughout life, but most commonly in the second and third decade. There are three common ways in which patients present:

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

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

# IgAN market opportunity

We estimate there are approximately 126,000 biopsy-confirmed IgAN patients in the United States, 136,000 in the European Union, and 130,000 in Japan, and that growth in the diagnosed prevalent population is due to overall population growth. Underlying genetic differences may contribute to the significantly higher rate in Japan. As therapies become commercially available, however, an increase in diagnosis rate or longer time to progression, due to better treatments, may increase the diagnosed population over time.

We estimate the U.S. market opportunity for novel therapeutics in IgAN is approximately \$4.0 billion to \$8.0 billion annually, based on the prevalence of the disease in the United States and the segment of IgAN patients at high risk of progressing to ESRD. In Europe and Japan, we estimate the annual market opportunity for novel IgAN therapeutics to be \$1.0 billion and \$600 million, respectively.

#### Current standard of care for IgAN patients

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

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

Treatment is selected based on perceived risk of progressive kidney disease, and clinical measures such as hematuria, proteinuria, and eGFR are used to monitor patients while on treatment. The current standard of care is seen as insufficient by physicians and patients; these treatment approaches have limited clinical efficacy and are not well tolerated. Approximately 50% of patients fail to achieve controlled UPCR on ACE inhibitors,

ARBS, or steroids. The use of steroids may cause significant side effects, including serious infections, high blood pressure, weight gain, diabetes, and osteoporosis. As such, there is a high unmet medical need for targeted therapies that impact the underlying disease pathophysiology and more tolerable, steroid-sparing treatment options for IgAN patients.

# Emerging therapies in development

There is only one agent approved for the treatment of IgAN, a reformulated steroid, 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 that has demonstrated a 60% reduction of Gd-IgA1 in IgAN patients, the upstream source of IgAN pathogenesis.

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

*Glucocorticoid receptor agonists.* Glucocorticoid receptor agonists are a well-known class of molecules that have broad antiinflammatory 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 glucocorticoid may improve renal survival. The glucocorticoid, budesonide, has been reformulated to concentrate steroid effects locally on the gut mucosa, theoretically suppressing the abnormal B-cell activity reducing systemic steroid toxicity. Currently in a Phase 3 clinical trial in IgAN, reformulated budesonide has demonstrated statistically meaningful reduction of proteinuria, though systemic steroid side effects have been observed in prior clinical trials and the ongoing Phase 3 clinical trial.

*ERAs.* Aberrant endothelin signaling is implicated in structural podocyte changes and increased mesangial proliferation in chronic kidney diseases, including IgAN. ERAs block endothelin-induced cell proliferation hence may reduce renal perfusion pressure and proteinuria. Since this mechanism of action works downstream of disease related immune activities, it is not expected to reduce Gd-IgA1 or the resulting immune complexes that cause the disease. Several ERAs, which have previously been approved for the treatment of pulmonary arterial hypertension and erectile dysfunction and make use of a vasodilatory effect, are currently in Phase 3 development and have been shown to reduce proteinuria in patients with IgAN. However, ERAs have been associated with edema, significant liver toxicity and increased risk of heart failure.

*Complement inhibitors.* Increased complement activation is commonly observed in patients with IgAN. It is hypothesized that immunecomplex deposition in glomeruli may contribute to complement activation, though the exact mechanism is not well understood. Several agents that inhibit complement activation are in clinical development for IgAN. Modest reduction of proteinuria has been observed in early clinical trials. As complement inhibition works downstream of immune complex formation, these agents are not expected to impact the upstream cause of disease and reduce Gd-IgA1 or the resulting immune complexes that cause inflammation and complement activation in the kidney.

*B-cell modulators.* B-cell modulators, including atacicept, are an important category of emerging therapies for IgAN. The disease causing Gd-IgA1 is predominantly produced by B cells and plasma cells. Therefore, control of B-cell activation may reduce production of Gd-IgA1 and the downstream formation of autoantibodies and immune complex. Interestingly, product candidates that modulate B cells through other single-target mechanisms, such as rituximab (CD20 alone), or blisibimod (BlyS alone), have been studied in patients with IgAN and have not shown a meaningful reduction of Gd-IgA1 and/or proteinuria. Preclinical models have shown that dual inhibition of BlyS and APRIL offers improved suppression of B cell activities than blocking BlyS or

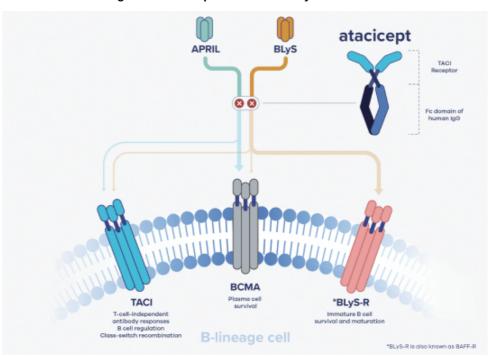
APRIL alone. Atacicept blocks both BlyS and APRIL, and has shown substantial reduction (60%) in Gd-IgA1. We believe that dual inhibition may also confer a potential dosing advantage versus APRIL only inhibition.

#### **Our solution: Atacicept**

Atacicept is a fusion protein that blocks both BLyS and APRIL, which play key roles in the upstream pathway that causes IgAN, and is dosed once weekly via a 1 mL subcutaneous injection. As a result, we believe atacicept has the potential to be the first disease modifying therapy for IgAN. Through an integrated analysis of randomized, double-blind, placebo-controlled clinical trials in over 1,500 patients to date, atacicept has a well-characterized clinical safety profile. In a Phase 2a clinical trial in patients with IgAN, atacicept substantially reduced Gd-IgA1 and demonstrated a clinically meaningful reduction in proteinuria and stable eGFR parameters at week 24. We are currently enrolling patients in the Phase 2b ORIGIN trial, and we expect to report topline results in the fourth quarter of 2022.

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

Atacicept is a fully humanized fusion protein that impacts the B-cell pathway, which has well characterized implications in immunologic diseases. Specifically, as shown in Figure 6 below, atacicept contains the soluble TACI receptor that binds to the cytokines BLyS and APRIL. These cytokines are members of the tumor necrosis factor family that promote B-cell survival and autoantibody production associated with IgAN and other immunologic diseases. Dual blockade of BlyS and APRIL by TACI has been shown to be more potent than blocking BLyS alone or APRIL alone and has the benefit of targeting long-lived plasma cells, in addition to B cells, thus reducing autoantibody production, including Gd-IgA1, IgA, IgG and IgM. Therefore, atacicept's mechanism acts directly on the source of IgAN, which we believe will significantly mitigate the downstream effects of the disease.





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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 7 below.

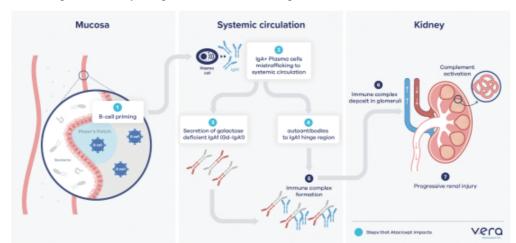


Figure 7: Atacicept impact on IgAN pathogenesis

- Atacicept blocks BLyS, a factor important for B cell survival and maturation, resulting in reduced numbers of disease-causing B cells.
- 2 Atacicept blocks APRIL, a factor important for Plasma cell survival, resulting in reduced numbers of disease-causing plasma cells.

3 Reductions in plasma cells and in antibody class switching to IgA reduces production of immunogenic Gd-IgA.

Reductions in B cells, plasma cells, and Gd-IgA1 work together to cause a reduction in production of autoantibodies to Gd-IgA1.

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

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

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

Atacicept's disease modifying mechanism addresses the upstream processes that cause IgAN, while most other molecules in development act downstream. Therefore, we believe that the clinical outcomes of atacicept, measured by measures designed to assess efficacy and durability will be favorable to 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 ZymoGenetics, Inc. in 2001 and licensed on an exclusive basis to Ares in 2008. It was advanced by Merck KGaA, Darmstadt, Germany, in clinical trials for several autoimmune disease, including rheumatoid arthritis (RA), multiple sclerosis, SLE, and IgAN, and in totality studied in double-blind placebo-controlled clinical trials in over 1,500 subjects 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.

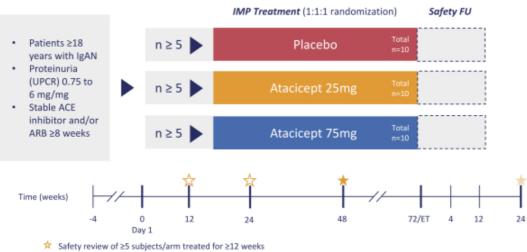
In the Phase 2a JANUS trial conducted by Merck KGaA, Darmstadt, Germany in patients with IgAN, atacicept (25 mg and 75 mg doses) reduced Gd-IgA1 by 60% in IgAN patients. Atacicept has been the first molecule observed to reduce Gd-IgA1, the presumed upstream source of the disease, by this magnitude in IgAN patients. The 150 mg dose was not studied in the JANUS trial. A clinically meaningful reduction in proteinuria and stable eGFR parameters was observed at week 24 for both the 25 mg and 75 mg doses. The clinically significant and robust reduction in Gd-IgA1 provides important corroborative evidence of the potential benefit of atacicept for patients with IgAN. Based on this encouraging data, we are conducting the Phase 2b ORIGIN trial in IgAN to test 25 mg, 75 mg and 150 mg of atacicept with endpoints of proteinuria, eGFR and Gd-IgA1 planned from week 12 though week 96.

We believe atacicept has the potential to be the first disease modifying therapy for IgAN. We believe the large and established clinical data set for atacicept provides a competitive advantage for us versus other emerging and approved therapies in development, many of which are either earlier in development and have clinical profiles that are not as well characterized or are characterized by the well-known acute and chronic side effects of corticosteroids that limit their medical use.

#### Phase 2a JANUS trial of atacicept in patients with IgAN

The Phase 2a JANUS trial was a randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of atacicept in IgAN. The trial enrolled 16 subjects with IgAN and persistent proteinuria who were on a stable and optimized dose of ACEi and/or ARB. The JANUS trial design is shown in Figure 8 below and the baseline patient characteristics shown in Figure 9 below. Results showed a dose dependent effect of atacicept 25mg and 75mg weekly on proteinuria as well as key biomarkers including serum immunoglobulin levels, and Gd-IgA1, and atacicept was observed to be generally well tolerated. The JANUS trial was terminated earlier than planned due to Ares' decision to deprioritize the program and therefore the sample size was truncated to 16 subjects, the 150 mg dose arm was not enrolled, and there was limited long-term follow up after week 24. Trial termination was not related to safety or efficacy. Due to the small sample size of JANUS, the results should be interpreted with caution.

# Figure 8: Phase 2a JANUS trial design



Primary analysis at week 48 (1º endpoint: Safety)

Final analysis at end of study

#### Figure 9: Phase 2a JANUS trial baseline characteristics

	Placebo (n=5)	Atacicept 25 mg (n=6)	Atacicept 75 mg (n=5)	Total (n=16)
Age, mean±SD				
n(%)	5 (100.0)	6 (100.0)	5 (100.0)	16 (100.0)
Mean±SD	46 ±3.1	41 ±16.9	43 ±8.7	43 ±11.1
Median	47	36	42	44
Q1; Q3	46; 48	26; 64	38; 49	36; 49
Min; Max	41; 49	24; 64	32; 54	24; 64
Sex, n (%)				
Male	4 (80.0)	1 (16.7)	3 (60.0)	8 (50.0)
Female	1 (20.0)	5 (83.3)	2 (40.0)	8 (50.0)
Race, n (%)				
White	4 (80.0)	5 (83.3)	2 (40.0)	11 (68.8)
Asian	1 (20.0)	1 (16.7)	1 (20.0)	3 (18.8)
Other	0	0	2 (40.0)	2 (12.5)

# Atacicept dose-related effects within target weekly dose ranges

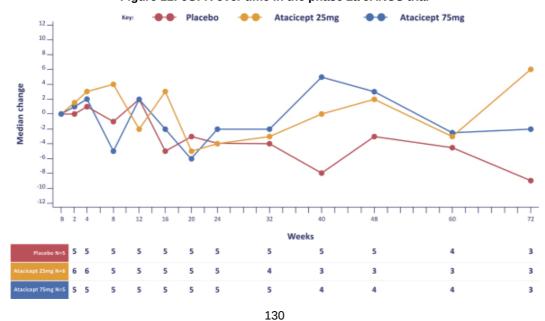
A clinically meaningful reduction in proteinuria parameters was observed at week 24 in the atacicept group. The median percent change for UPCR and total protein by 24-hour urine collection decreased from baseline to week 24 for the atacicept 25 mg and 75 mg groups and increased for the placebo group, as shown in Figure 10 below.



Figure 10: Proteinuria at week 24 in the phase 2a JANUS trial

After week 24, a persistent reduction in UPCR and total protein by 24-hour urine collection was observed in the atacicept 25 mg group. The results for the 75 mg group after week 24 were inconclusive, however, because of confounding factors related to low subject numbers and changes in co-morbid disease and treatments, such as diabetes and hypertension, that affected four of the five subjects. All five subjects showed an initial decrease of proteinuria parameters. The one subject without trial management issues after week 24 showed a persistent reduction in UPCR and total protein at weeks 48 and 72.

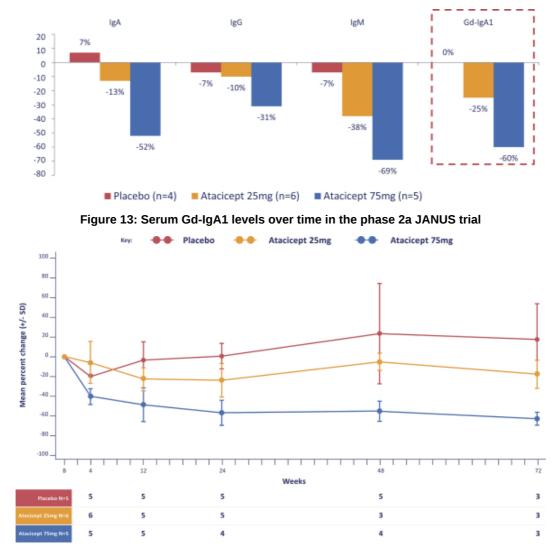
As seen in Figure 11 below, atacicept also showed stable eGFR for greater than one year versus expected 25% decline, as was shown in the placebo arm.



#### Figure 11: eGFR over time in the phase 2a JANUS trial

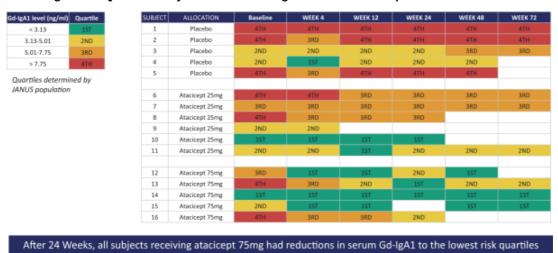
Atacicept 75 mg also showed a 60% reduction of Gd-IgA1 at 24 weeks, the largest magnitude in reduction of any molecule in a randomized controlled study in IgAN patients, and dose-dependent reduction in serum IgA, IgG and IgM, as shown in Figure 12 below. Clear dose-dependent reductions of serum Gd-IgA1 were observed over the 72-week period studied (as shown in Figure 13 below), with atacicept 75 mg reducing Gd-IgA1 significantly (60%) and durably.





New analysis of these results initially divided JANUS trial patients into four equal groups according to the quartiles of serum Gd-IgA1 distribution at baseline. Quartile level was then assessed at each timepoint. This additional analysis showed that atacicept decreased serum Gd-IgA1 levels by up to two quartiles. As shown in Figure 14 below, the largest effect was seen in the atacicept 75mg arm where after 24 weeks all study patients had reductions in serum Gd-IgA1 to the lowest risk quartiles, which is associated with the most favorable renal survival.

Additionally, the serum Gd-IgA1 quartiles determined from a separate cohort of 150 IgAN patients from the University of Leicester were applied to the 16 JANUS patients' quartile level assessment and confirmed that attacicept 75mg reduced serum Gd-IgA1 to the lowest quartiles at each measured timepoint. These new analyses were presented at the American Society of Nephrology Kidney Week 2021.



#### Figure 14: Quartile analysis of serum Gd-IgA1 levels from the phase 2a JANUS trial

As the number of subjects included in the Phase 2a JANUS trial in IgAN for atacicept 25 mg and 75 mg was limited, further investigation of these doses is warranted in a larger cohort, while also evaluating the safety and efficacy of atacicept 150 mg in IgAN, to ensure the optimal dose of atacicept is selected for a Phase 3 clinical trial.

# Atacicept safety and tolerability profile in the JANUS trial

Atacicept 25 mg and 75 mg weekly were observed to be generally well tolerated in the Phase 2a JANUS trial, with treatment-emergent adverse events (TEAEs) shown in Figure 15 below. Among the 11 atacicept treated patients, there was no TEAE leading to death and only one patient in the 25 mg weekly cohort discontinued treatment due to injection site pruritus. Most TEAEs were graded as mild and were related to injection site events such as injection site bruising and erythema. The one severe TEAE event of cervical spinal stenosis was reported by a patient in the 25 mg weekly cohort during the safety follow-up period, and was deemed not drug related.

### Figure 15: Overview of treatment-emergent adverse events by severity in the phase 2a JANUS trial

Number of Subjects with:	Placebo n=5 (100%) n (%)	Atacicept 25 mg n=6 (100%) n (%)	Atacicept 75 mg n=5 (100%) n (%)	Total n=16 (100%) n (%)
Mild TEAEs	5 (100.0)	6 (100.0)	3 (60.0)	14 (87.5)
Moderate TEAEs	2 (40.0)	5 (83.3)	1 (20.0)	8 (50.0)
Severe TEAEs	0 (0.0)	1 (16.7)	0 (0.0)	1 (6.3)
TEAEs leading to treatment discontinuation	0 (0.0)	1 (16.7)	0 (0.0)	1 (6.3)
TEAEs with fatal outcome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)



# Atacicept safety and tolerability profile: Integrated analysis

Though there was a limited number of patients in the JANUS trial, in an integrated safety analysis in clinical trials of over 1,500 patients in a number of indications atacicept was well tolerated, shown in Figure 16 below. Serious 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 us versus other approved and emerging therapies in development, many of which lack extensive safety data.

#### Figure 16. Integrated safety analysis: Summary of treatment-emergent adverse events > 5% in any arm, by dose

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

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

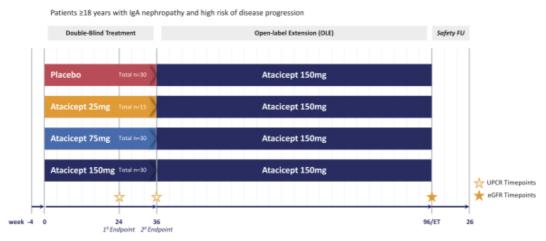
In the most recent atacicept Phase 2 SLE clinical trial, ADDRESS II, the frequencies of treatment-emergent adverse events were infections and infestations were similar among atacicept 75 mg, 150 mg and placebo. There was no correlation between infections and reduced levels of IgG, IgM, or IgA or reduced naïve B cell or plasma cell numbers. No association was found between decreases in IgG and risk of serious or severe infection.

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

# Ongoing phase 2b ORIGIN clinical trial design

ORIGIN, our ongoing Phase 2b randomized, double-blinded, placebo-controlled, dose-ranging trial, will evaluate the efficacy and safety of atacicept in subjects 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 will assess multiple doses (25 mg, 75 mg and 150 mg) of once weekly 1 mL subcutaneous injections of

atacicept versus placebo on impact of renal function as measured by proteinuria. The primary endpoint is change from baseline in UPCR at 24 weeks based on 24-hour urine collection, with a secondary endpoint of UPCR at 36 weeks. Other endpoints include change from baseline in UPCR at 12, 48, 96 weeks, change from baseline in eGFR at 12, 24, 36, 48, 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 17. Phase 2b ORIGIN trial design

UPCR is an accepted surrogate primary endpoint for clinical trials in IgAN, which allows for a faster path to commercialization than rate of change/slope in GFR, which is measured after two years. The recommendation for usage of this surrogate endpoint was put forward by the ASN, partnering with the FDA under the auspices of the Kidney Health Initiative, and the EMA, and has now been implemented in five Phase 3 clinical trials in IgAN and in the one FDA approval 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.

We are currently enrolling the Phase 2b ORIGIN trial and expect to enroll a total of 105 patients at multiple global sites. We expect to complete enrollment by mid-2022 and report topline results from ORIGIN in the fourth quarter of 2022. If these data are positive, we plan to seek an accelerated approval path in the United States by the FDA and in the European Union by the EMA while initiating a pivotal Phase 3 clinical trial in 2023.

# Atacicept in LN: A severe renal manifestation of SLE

Based on discussions with the FDA following the review of positive Phase 2 data in SLE, we are planning to initiate a Phase 3 clinical trial of atacicept in fourth quarter 2022 as a potential treatment for patients with LN, a severe renal manifestation of SLE. We estimate that there are approximately 110,000 LN patients in the United States, 69,000 in the European Union, and 22,000 in Japan. Significant unmet need for improved efficacy persists for these patients despite the recent approval of the first two LN-specific therapies. Fewer than half of patients treated for LN have a complete response to therapy, and among patients without a complete response, over half will have non-functioning kidneys within five years. Benlysta (belimumab), a BlyS-only inhibitor, is one of the two therapies approved for patients with LN. Both BlyS and APRIL levels are increased in patients with SLE, suggesting that dual inhibition by atacicept may be more potent than blocking BLyS alone and has the benefit of targeting plasma cells in addition to B cells. Merck KGaA, Darmstadt, Germany previously

initiated a randomized, double-blind, placebo-controlled Phase 2/3 clinical trial of atacicept in LN, the APRIL-LN trial, aimed to evaluate the efficacy and safety of atacicept at 150 mg twice weekly for four weeks—then weekly—in patients with active LN. However, this trial was terminated early due to three subjects developing hypogammaglobulinemia with induction therapy (MMF and CS) which continued to worsen when initiating atacicept and subsequently two subjects developed pneumonia. In a prior Phase 2 clinical trials of atacicept in SLE also conducted by Merck KGaA, Darmstadt, Germany, despite missing its primary endpoint of improved SLE responder index 4 (SRI- 4) at week 24, in the broader SLE study population, atacicept achieved positive clinical data on multiple measures within the prespecified High Disease Activity patient segment, including reduction of renal flares, which we believe supports atacicept's applicability in LN. Because both preclinical and clinical evidence suggests atacicept's dual inhibition of BLyS and APRIL may provide improved clinical outcomes, measured by endpoints designed to assess efficacy, compared to inhibiting either signal alone, we believe there is a strong rationale to conduct a clinical trial of atacicept in LN.

# Pathophysiology of LN

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

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

### LN disease burden and diagnosis

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

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

LN patients are segmented in Class 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, 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 18 below, LN typically develops early in the disease course, though the rate of SLE patients that develop LN increases over time.

# Figure 18: LN progression



# LN market opportunity

According to the Centers for Disease Control and Prevention, there are approximately 322,000 people living with SLE in the United States. Approximately half of individuals living with SLE develop LN within 15 years of their initial diagnosis, as shown in Figure 18 above.

We estimate that there are approximately 110,000 LN patients in the United States, 69,000 in the European Union, and 22,000 in Japan at present. In the United States, higher prevalence rates occur in the heterogeneous population, as both SLE and LN occur more frequently among non-Caucasian 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 ± corticosteroids or cylophosphamide (CYC) ± corticosteroids in the first line of treatment, switching to either CYC or MMF in the second line, whichever was not administered first line. Third line induction therapy has generally consisted of rituximab for Class III-V patients. For induction therapy of Class V LN patients, patients typically receive MMF ± steroids in the first line, a calcineurin inhibitor in the second line, and rituximab for third line. Maintenance therapy, which typically consists of MMF, azathioprine (AZA), or hydroxychloroquine (HCQ), is typically prescribed to well controlled patients after any line of induction to reduce flares. Immunosuppressive therapy is unlikely to be beneficial for Class VI, or advanced sclerosing LN.

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

# Recently approved and emerging therapies in development

Until recently, there were no approved therapies for the treatment of LN. In December 2020, the FDA approved Benlysta (belimumab), an anti-BLyS antibody, for treatment of adult patients with active LN who are receiving

standard therapy. In January 2021, the FDA approved Lupkynis (voclosporin), a calcineurin inhibitor, to be used in combination with a background immunosuppressive therapy regimen for adult patients with active LN. Clinical guidelines on how these two medicines may be incorporated into standard of care remain to be updated. In addition to Benlysta (belimumab) and Lupkynis (voclosporin), there are several other cytokine inhibitors and complement inhibitors in development for LN.

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

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

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

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

# **Our solution: Atacicept**

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

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

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

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

**Preclinical evidence indicates that dual inhibition of BLyS and APRIL is superior to either BLyS or APRIL alone.** Animal models of kidney disease have confirmed that atacicept reduces plasma cell numbers and reduces autoantibodies more effectively than BLyS and APRIL antibodies given individually. In a mouse model of collagen-induced arthritis, soluble atacicept inhibited development of collagen-specific antibodies and

reduced the incidence of the disease better than BLyS (also known as BAFF) agents alone. In a mouse model of SLE, soluble atacicept decreased the number of B cells, increased survival time and reduced severity of disease symptoms. Furthermore, in a mouse model of SLE, atacicept administered after onset of autoimmunity decreased the number of bone marrow plasma cells and slowed down further formation of autoantibodies. Atacicept prevented renal damage during a 12-week treatment period regardless of autoantibody levels, while BLyS-only inhibitor did not. Atacicept also decreased established plasma cells in an immunization model better than single inhibitors of BLyS or APRIL.

In patients with active SLE, targeting BLyS and APRIL (atacicept) appears to have improved clinical outcomes, measured by endpoints designed to assess efficacy, compared to BLyS alone (Benlysta (belimumab)). While Atacicept and Benlysta (belimumab) have not been studied head-to-head in clinical trials, each has been studied in similar populations of patients with SLE, and results of a Phase 2 clinical trial of 150 mg of atacicept compared favorably to published reports on changes in symptom response 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 by SRI-4 at 24 weeks was approximately 39% (25% placebo, 64% atacicept 75 mg, 65% atacicept 150 mg, both p=0.005). For Benlysta (belimumab), in a Phase 3 clinical trial of SLE patients, a published analysis of patients with HDA and serologically active disease, clinical efficacy for Benlysta (belimumab) 10 mg/kg showed a difference between treatment and placebo by SRI-4 at 24 weeks of approximately 12%. However, as this data is based on a cross-trial comparison and not a head-to-head clinical trial, such data may not be directly comparable due to differences in study protocols, conditions and patient populations. Accordingly, cross-trial comparisons may not be reliable predictors of the relative efficacy or other benefits of atacicept compared to other product candidates that may be approved or that are in development.

In SLE, atacicept consistently demonstrated improved clinical outcomes, measured by endpoints designed to assess efficacy, in SLE patients with HDA (SLEDAI-2K <sup>3</sup>10) versus placebo across additional clinical measures and consistent across all SRI cut-offs, as well as using the separate clinical assessment, 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, we believe an improved clinical benefit may be observed in patients with LN.

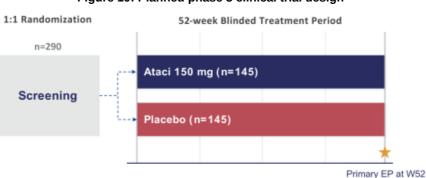
# Prior clinical development of atacicept in LN

Merck KGaA, Darmstadt, Germany conducted a randomized, double-blind, placebo-controlled Phase 2/3 clinical trial of atacicept in LN, the APRIL-LN trial, aimed to evaluate the efficacy and safety of atacicept in patients with active LN. As per trial protocol, patients initiated high-dose CS (the lesser of 0.8 mg/kg/day or 60 mg/day prednisone) and mycophenolate mofetil 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 subjects developed decreases in the 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 reduced; two subjects developed severe hypogammaglobulinemia, defined as IgG <3 g/L, and pneumonia. These two subjects 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.

# Planned phase 3 clinical trial design

Our Phase 3 randomized, double-blinded, placebo-controlled trial will evaluate the efficacy and safety of atacicept in subjects with lupus nephritis. The clinical trial consists of a 52-week double-blind treatment period, followed by a 104-week open-label treatment period and a 26-week safety follow-up period. The trial, as shown in Figure 19 below, will assess 150 mg of once weekly subcutaneous injections of atacicept versus placebo. The primary endpoint is complete renal response at 52 weeks. We plan to initiate patient screening for our Phase 3 clinical trial in LN in the fourth quarter of 2022.



# Figure 19: Planned phase 3 clinical trial design

# 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 subjects with SLE in the Phase 2 APRIL-SLE and ADDRESS II trials. In these trials, autoantibody titers were significantly reduced, and prespecified and post hoc analyses revealed prevention of flare and reduction of active disease with atacicept treatment, despite the fact that the primary endpoints in these trials were not met.

In ADDRESS II, SLE subjects with HDA (SLEDAI-2K <sup>3</sup> 10) had an increase in SLE Responder Index (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 attaccept 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 placebocontrolled trials of atacicept 150 mg compared to placebo, were reviewed by FDA via end-of-phase 2 communication and scientific advice communication with EMA, prior to Merck KGaA, Darmstadt, Germany terminating the SLE program and the IgAN program for business strategy reasons.

# Phase 2 SLE clinical trial in patients with SLE for 24 weeks

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

Atacicept demonstrated consistent reductions in IgG, IgA, and IgM serum levels, and reductions in anti-dsDNA antibodies, as well as improvements in serum C3 and C4 levels, as shown in Figure 20 below.

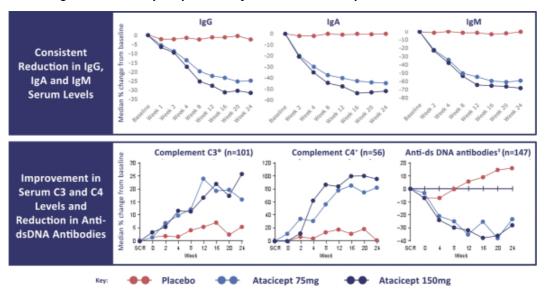


Figure 20: Atacicept impact on key biomarkers in the phase 2 ADDRESS II trial

Though atacicept missed its primary endpoint of SRI-6 reduction versus placebo in all comers, in a pre-specified analysis within 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) by SRI-6 versus placebo, flare risk reduction, and serologic marker normalization. SRI-6 response is defined as <sup>3</sup>6-point reduction in the SELENA-SLEDAI score, and 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.

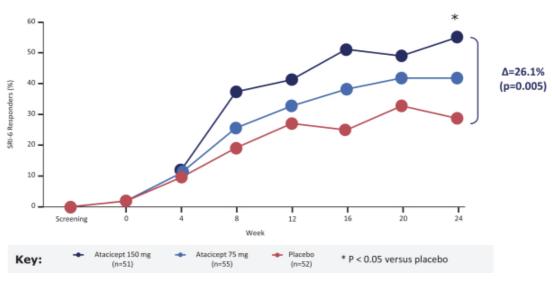


Figure 21: SRI-6 response among HDA patients in the phase 2 ADDRESS II trial

Also, among this HDA patient segment, significantly more patients on the atacicept 150 mg arm reached LDA, as measured by SLEDAI-2K <= 2, as shown in Figure 22 below.

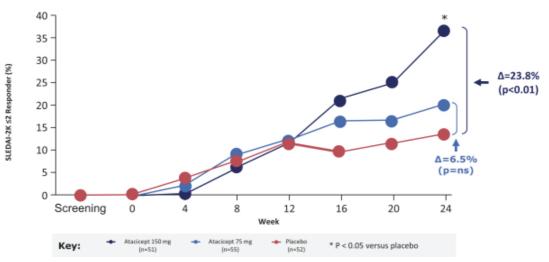
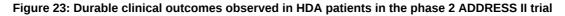
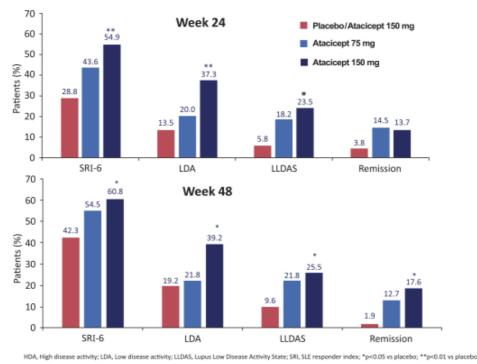


Figure 22: HDA patients reaching LDA in the phase 2 ADDRESS II trial

Furthermore, Figure 23 below demonstrates the durable clinical outcomes observed in the HDA segment: more patients reached LDA by multiple measures at both week 24 and week 48. Significantly more patients treated with atacicept 150 mg once weekly versus placebo demonstrated clinical improvement (as shown by SRI-6), achieved LDA, and remission.



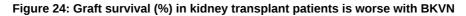


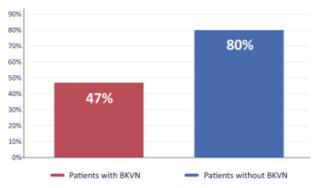


We believe that the clinical outcomes, measured by endpoints designed to assess efficacy, demonstrated on multiple measures within the HDA segment of the SLE population in the ADDRESS II trial—and a favorable tolerability profile observed in ADDRESS II, as well as the integrated safety analysis in over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

# MAU868 in BK viremia among kidney transplant recipients

We are developing MAU868 as a potential treatment for BK viremia in kidney transplant recipients. While up to 90% of healthy adults have been infected with the 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 24, BKVN is a leading cause of allograft loss, a devastating outcome for kidney transplant recipients.





Currently, there are no approved treatment options for BK viremia or BKVN. In mid-2022, we expect to share full Cohort 1 and Cohort 2 results from the Phase 2 trial conducted by Amplyx, and initiate a Phase 2b or Phase 3 clinical trial in 2023. We believe that MAU868 has the potential to become standard of care for the treatment of BK viremia in order to prevent devastating consequences such as BKVN.

# Pathophysiology of BK virus in kidney transplant

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

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

# BKVN disease burden and diagnosis

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

Most institutions monitor for BK in both the urine, through PCR and urinalysis, and plasma, via PCR. It is common practice to screen kidney transplant recipients for BK viremia via PCR test monthly at 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 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.

Based on primary market research with physicians and extensive secondary research, we estimate the market for a novel agent to treat BK viremia to be approximately \$700 million annually worldwide, with \$350 million, \$120 million, \$18 million, and \$50 million in peak sales generated in the United States, Europe, Japan, and China, respectively. There may also be potential for usage in additional patient segments, such as prophylaxis in high risk patients.

## Current standard of care for kidney transplant patients with BK viremia

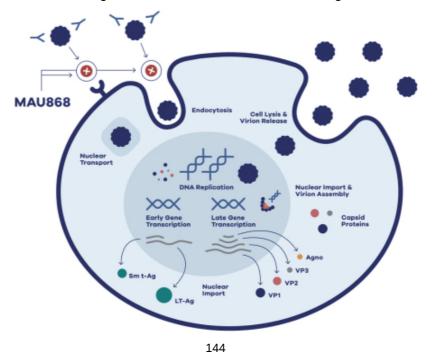
Currently, there is no approved treatment specific to BKV. Upon detection of BK viremia, physicians first line of defense is to reduce immunosuppression with the goal of restoring CD4+ and CD8+ T cell immunity without causing acute rejection. Initial modification will typically consist of lowering MMF 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 IVIG, leflunomide, and cidofovir, are occasionally used—but all have limited data and both leflunomide and cidofovir have serious safety concerns. After development of BKVN, patients have limited options and may continue to receive antivirals or IVIG. Physicians are not satisfied with current treatment options for BKV and highlight that there is a significant unmet need for a viable therapy.

# Emerging therapies in development

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

# Our solution: MAU868 / scientific rationale

MAU868 is a human monoclonal antibody (IgG1/I 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 25. MAU868 neutralizes all four serotypes of BKV at sub-nanomolar concentrations and has a high barrier to resistance *in vitro* (resistant isolates of BKV were not selected *in vitro* at any of the concentrations of MAU868 investigated). MAU868 is being developed for the treatment of BKV disease in kidney transplant recipients (BKV nephropathy) and being considered for hematopoietic cell transplant 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 25: MAU868 blocks BK virion binding

# **Clinical development of MAU868**

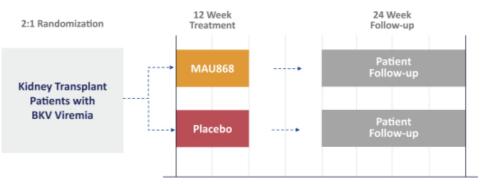
#### Phase 1

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

# Ongoing phase 2

A Phase 2 randomized, double-blind, placebo-controlled clinical trial designed to assess the safety, tolerability, and efficacy of MAU868 for the treatment of allograft-threatening BKV infection in kidney (or kidney-pancreas) transplant recipients is ongoing. Up to 36 patients with BK viremia will participate in 1 of 3 sequential cohorts. As shown in Figure 26, each cohort was designed to randomize approximately 12 patients (8 to MAU868 and 4 to placebo), for which Cohort 1 (1350 mg IV approximately every 28 days for a total of 4 doses) and Cohort 2 (6750 mg IV on Day 1, 1350 mg IV every 28 days for 3 additional doses) have completed dosing.

The primary objective of the clinical trial is to assess the safety and tolerability of MAU868, with secondary objectives to assess the impact of MAU868 on BKV related outcomes. MAU868 has been shown in an interim analysis of week 12 data from Cohort 1 and 2 of a Phase 2 study to be well-tolerated and showed a greater proportion of subjects with decrease in BK plasma viral load versus placebo. We expect to share Cohort 1 and Cohort 2 interim analysis results from the ongoing Phase 2 clinical trial in kidney transplant recipients in mid-2022.



## Figure 26: MAU868 phase 2 clinical trial design

#### Future clinical trials

We intend to initiate a Phase 2b or Phase 3 clinical trial in 2023.

# 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 and 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 have 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 screened for currently until symptoms of cystitis occur, but this is likely to change once physicians have an effective treatment available.

An estimated 44,000 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.

Based on primary market research with physicians and extensive secondary research, we estimate the market for a novel agent to treat BKV cystitis to be approximately \$550 million annually worldwide, with \$230 million, \$230 million, \$50 million, and \$7 million in peak sales generated in the United States, Europe, Japan, and China, respectively.

# Current standard of care for BKV cystitis in HSCT patients

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

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

## Emerging therapies in development

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

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

# Exclusive license agreement with Ares Trading S.A.

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

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

In consideration for the rights granted under the Ares Agreement, we issued 22,171,553 shares of our Series C redeemable convertible preferred stock to Ares at the time of the initial closing of our Series C redeemable convertible preferred stock financing in October 2020, representing ownership of approximately 10% on a fully diluted basis. As additional consideration under the Ares Agreement, we paid Ares \$25.0 million upon delivery and initiation of the transfer of specified information and supply of drug product and drug substance and we are required to pay Ares aggregate milestone payments of up to \$176.5 million upon the achievement of specified BLA filing or regulatory approvals in the United States, Europe and Japan (the first of which consists of a \$15.0 million payment upon filing of the BLA), and aggregate milestone payments of up to \$515 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 the Amplyx Agreement with Amplyx, a wholly-owned subsidiary of Pfizer Inc.

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

In partial consideration for the Asset Acquisition, we made an upfront initial payment of \$5.0 million to Amplyx. In addition, we are also obligated to make certain milestone payments to Amplyx in an aggregate amount of up to \$7.0 million based on certain regulatory milestones. Further, we are required to pay Amplyx low single digit percentage royalties based on net sales on a country-by-country and product-by-product basis.

MAU868 is subject to the Novartis License, which was assigned to us by Amplyx. Pursuant to the terms of the Novartis License, we obtained a worldwide, exclusive license from Novartis to develop, manufacture and commercialize MAU868, subject to certain retained rights for research and development by Novartis, provided that Novartis may not develop or sell products incorporating monoclonal antibody targeting BKV and treating BKV disease within a certain period. We will be solely responsible for all research, development, regulatory, manufacturing and commercialization activities of MAU868. Pursuant to the Novartis License, we are obligated to make certain milestone payments to Novartis in an aggregate amount of up to \$69.0 million based on certain clinical development, regulatory and sales milestones. Further, we are required to pay Novartis mid- to high-single digit percentage royalties based on net sales on a country-by-country and product-by-product basis. Unless terminated earlier, the Novartis License will remain in effect with respect to each MAU868 product until the expiration of the royalty term for such product. We may terminate the Novartis License for convenience with 60 days' prior written notice. We or Novartis may terminate the Novartis License for the other party's uncured material breach. Novartis may terminate the Novartis License for our insolvency. Upon termination, any license granted by Novartis to us will terminate.

# Intellectual property

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

As of December 31, 2021, 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 15 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, New Zealand, Ukraine, Singapore, South Korea, South Africa, and countries within the European Patent Convention and the Eurasian Patent Organization. The issued patents are expected to expire between 2022 and 2029, with patents covering the composition of matter of atacicept expiring in 2022.

In regard to atacicept, we in-license a patent family that includes one issued U.S. patent with claims covering a method of purifying atacicept and over 10 foreign patents granted in various jurisdictions including Australia, China, Europe, Israel, and Mexico. The U.S. patent is expected to expire in 2028 and the foreign patents are expected to expire in 2027. We also in-license a patent family that includes one issued U.S. patent with claims covering a formulation of atacicept and six foreign patents granted in various jurisdictions such as Australia, Canada, China, and Europe. The U.S. patent is expected to expire in 2029, without taking into account any patent term extension, and the foreign patents are expected to expire in 2028. There is also a pending PCT application and a counterpart Taiwanese application directed to treatment of IgAN and proteinuria. Once nationalized, patents that issue in this family are expected to expire in 2041.

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

Our patent portfolio covering MAU868 includes three issued U.S. patents with claims covering the composition of matter of MAU868, and methods of neutralizing BKV or JC virus as well as methods of treating or reducing the likelihood of BKV or JC virus associated disorders. The U.S. patents are expected to expire in 2036. Corresponding foreign counterparts are granted in Australia, China, and Taiwan, and pending in other jurisdictions such as Canada, Mexico, Europe and Japan. The foreign patents are expected to expire in 2036.

In addition, an application directed to dosing regimens for MAU868 is pending as a PCT application and is also pending in Taiwan. Once nationalized, patents that issue in this family are expected to expire in 2041.In addition to patents, we may rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors, and non-solicitation, confidentiality, and invention assignment agreements with our employees and consultants. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we

enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties, such agreements will not be breached, or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. For more information, see "Risk factors—Risks related to our intellectual property."

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

# Manufacturing and supply

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

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

Atacicept is manufactured following cGMPs using a process that is similar to that used routinely for production of monoclonal antibodies.

The atacicept drug product is available as a ready-to-use injection solution in a prefilled syringe (PFS) at strengths of 25 mg/mL, 75 mg/mL, or 150 mg/mL of trial drug. Each atacicept PFS is designed to deliver a 1 mL solution of drug product. The drug product formulation is composed of atacicept as the active substance, a sugar as a stabilizing agent, and sodium acetate as a buffer. 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 will be used to initiate the Phase 2b ORIGIN trial. Additionally, we will acquire 6 kg of atacicept drug substance. As part of the Ares Agreement, in the first quarter of 2022, Ares will convert the 6 kg of drug substance into drug product to supply both the ongoing Phase 2b ORIGIN trial and to support our future clinical trials through the first quarter in 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 2777 unlabeled vials and work-in-process expected to yield approximately 5300 vials with release targeted for March 2022. These materials will support both the completion of the ongoing Phase 2 clinical trial and initiation of a future clinical trial.

# **Commercialization plans**

# Atacicept

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

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

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

# **MAU868**

We estimate the worldwide market opportunity for novel therapeutics addressing the BKV across both kidney transplant recipients and HSCT patients to be approximately \$1 billion in annual revenues, based on our assumptions, secondary research, and primary market research with physicians. We plan to prioritize the development of MAU868 for the treatment of BK viremia in kidney transplant, which has strong commercial synergies with our plans for atacicept. We believe that the prescribing physicians for MAU868 in renal transplant, if approved, will be a subset of the IgAN treating physicians, and plan to conduct an assessment of call point overlap. The launch of this indication, if prior to the atacicept launch, would require a smaller specialty commercial infrastructure build focused on educating and engaging treating physicians, including transplant nephrologists, partnering with kidney transplant organizations, and ensuring market access for patients. If prior to the atacicept launch, we would plan to leverage this infrastructure for eventual atacicept sales and marketing activities.

Through the Amplyx Agreement, we obtained worldwide rights to the development and commercialization of MAU868 in all indications. Similar to our plans with atacicept, we intend to commercialize MAU868 ourselves in the United States and other key markets, if approved. We also may consider strategic collaborations to facilitate commercialization in certain ex-U.S. markets.

# Competition

The biotechnology and pharmaceutical industries are characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. This is also true for the development and commercialization of treatments for immunologic diseases. Though we believe that our focus, experienced team, scientific knowledge, and intellectual property provide us with competitive advantages, we face competition from a number of sources, including large and small biopharmaceutical companies, universities, and other research institutions.

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

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

# Atacicept in IgAN

Despite a high level of morbidity for IgAN, the current standard of care consists of off-label use of RAAS inhibitors, including ACE inhibitors and ARBs, and potentially steroids. Atacicept, if and when approved and successfully commercialized, may compete with these existing approaches and with any new therapies that may become available in the future. Among emerging therapies, we consider our most direct competitors with respect to atacicept in IgAN to be the recently approved reformulated steroid from Calliditas Therapeutics AB, programs in Phase 3 clinical development: Novartis, Omeros Corporation, Travere Therapeutics, Inc., and Chinook Therapeutics Inc., and the following companies with programs in Phase 2 of clinical development: Chinook Therapeutics Inc., Alnylam Pharmaceuticals Inc., Apellis Pharmaceuticals, Inc., Reata Pharmaceuticals, Inc., RemeGen Co., Ltd., Visterra, Inc., Ionis Pharmaceuticals, Inc., Alexion, and DiaMedica Therapeutics, Inc. There is also a potential that SGLT2 inhibitors, including AstraZeneca's Farxiga, which has been approved for chronic kidney disease in April 2021 and Boehringer's jardiance, which is undergoing Phase 3 clinical development, will be approved broadly for chronic kidney disease and used in IgAN.

# Atacicept in LN

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

Pharmaceuticals, Inc., AstraZeneca, Alexion, Omeros Corporation, Kezar Life Science Inc., Bristol Myers Squibb, Boehringer, and Novartis Pharmaceuticals Corporation, each of which have programs in Phase 2 clinical development.

#### **MAU868**

There are currently no anti-BKV therapies approved, either in the kidney transplant or HSCT setting. The standard of care in both settings is to reduce immunosuppression as a first line, and potentially to offer IVIG in kidney transplant recipients or antivirals with limited clinical evidence, including leflunomide and cidofovir, in either setting. There are few industry sponsored programs in development for these indications; we consider our most direct competitor to be Allovir's multi-virus specific T-cell therapy, Posoleucel, which is in a Phase 2 clinical trial for BK viremia in kidney transplant recipients, a Phase 3 clinical trial for treatment of virus-associated cystitis, and a Phase 2 clinical trial in multi-virus prevention following allogeneic HSCT.

# **Government regulation**

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

# Regulatory approval in the United States

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

Our investigational medicines and any future investigational medicines must be approved by the FDA pursuant to a BLA before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical laboratory and animal studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practices (GLP) requirements;
- submission to the FDA of an Investigational New Drug Application (IND), which must become effective before human clinical trials may begin;

- approval of the protocol and related documents by an IRB or independent ethics committee at each clinical trial site before each clinical trial may be commenced;
- performance of adequate and well controlled human clinical trials in accordance with applicable IND regulations, GCP requirements
  and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- preparation of and submission to the FDA of a BLA for marketing approval that includes sufficient evidence of establishing the safety, purity, and potency of the proposed biological product for its intended indication, including from results of nonclinical testing and clinical trials;
- · payment of any user fees for FDA review of the BLA;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the biologic, or components thereof, will be produced to assess compliance with current cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- satisfactory completion of any potential FDA audits of the clinical trial sites that generated the data in support of the BLA to assure compliance with GCPs and integrity of the clinical data;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA;
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee; and
- compliance with any post-approval requirements, including a REMS, where applicable, and post- approval studies required by the FDA as a condition of approval.

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

#### Preclinical studies

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

Prior to beginning the first clinical trial with a product candidate in the United States, an IND must be submitted to the FDA and the FDA must allow the IND to proceed. An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA allowance that such investigational product may be administered to humans in connection with such trial. Such authorization must be secured prior to interstate shipment and administration. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND sponsor must also submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical

data or literature and plans for clinical trials, among other things, to the FDA as part of an IND. Some long-term preclinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

# **Clinical trials**

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

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

Some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee (DSMB). This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study.

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

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

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

 Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose

of these clinical trials is to assess the metabolism, pharmacokinetics, pharmacologic action, side effect tolerability, safety of the product candidate, and, if possible, early evidence of effectiveness.

- Phase 2 clinical trials generally involve studies in disease-affected patients to evaluate proof of concept and/or determine the dosing regimen(s) for subsequent investigations. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to
  demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of
  the product and provide an adequate basis for product labeling. In most cases, the FDA requires two adequate and well-controlled
  Phase 3 clinical trials to demonstrate the efficacy of the biologic.

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

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

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

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

Phase 1, Phase 2, Phase 3 and other types of clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including non-compliance with regulatory requirements or a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients.

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

# FDA review processes

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

The cost of preparing and submitting a BLA is substantial. Under the Prescription Drug User Fee Act (PDUFA), each BLA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved BLA is also subject to an annual program fee.

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

Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of an original BLA for a new molecular entity and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process can be extended by FDA requests for additional information or clarification.

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

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

After the FDA evaluates a BLA, it will issue either an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter generally outlines the

deficiencies in the BLA and may require additional clinical data, additional pivotal clinical trial(s) and/or other significant and timeconsuming requirements related to clinical trials, preclinical studies or manufacturing in order for FDA to reconsider the application. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. The FDA has committed to reviewing such resubmissions in two or six months, depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

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

# Orphan drug designation

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

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

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

# Expedited development and review programs

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

Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor of a new biologic candidate can request the FDA to designate the candidate for a specific indication for fast track status concurrent with, or after, the submission of the IND for the candidate. The FDA must determine if the biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's BLA before the application is complete. This "rolling review" is available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval.

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

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

Accelerated approval may be granted for products that are intended to treat a serious or life-threatening condition and that generally provide a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Use of the accelerated approval pathway entails submission of a BLA with the surrogate or intermediate clinical endpoint data while continuing to conduct the trial(s) to completion and is contingent on a sponsor's agreement to

complete and/or conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval, but may expedite the development or approval process.

# Additional controls for biologics

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

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

# **Combination products**

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

FDA is divided into various branches, or Centers, by product type. Different Centers typically review drug, biologic, or device applications. In order to review an application for a combination product, FDA must decide which Center should be responsible for the review. FDA regulations require that FDA determine the combination product's primary mode of action, or PMOA, which is the single mode of a combination product that provides the most important therapeutic action of the combination product. The Center that regulates that portion of the product that generates the PMOA becomes the lead evaluator. If there are two independent modes of action, neither of which is subordinate to the other, FDA makes a determination as to which Center to assign the product based on consistency with other combination products raising similar types of safety and

effectiveness questions or to the Center with the most expertise in evaluating the most significant safety and effectiveness questions raised by the combination product. When evaluating an application, a lead Center may consult other Centers but still retain complete reviewing authority, or it may collaborate with another Center, by which the Center assigns review of a specific section of the application to another Center, delegating its review authority for that section. Typically, FDA requires a single marketing application submitted to the Center selected to be the lead evaluator, although the agency has the discretion to require separate applications to more than one Center. We believe that our prefilled autoinjector would have a biologic PMOA.

## Pediatric information

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

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

#### Post-approval requirements

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

Adverse event reporting and submission of periodic safety summary reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects a biologic product's manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of product nead quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with required regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

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

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- · fines, warning or other enforcement-related letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- · product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

# U.S. marketing exclusivity

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

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

# Regulatory approval in the European Union

The EMA is a decentralized scientific agency of the European Union. It coordinates the evaluation and monitoring of centrally authorized medicinal products. It is responsible for the scientific evaluation of applications for EU marketing authorizations, as well as the development of technical guidance and the

provision of scientific advice to sponsors. The EMA decentralizes its scientific assessment of medicines by working through a network of about 4,500 experts throughout the European Union, nominated by the Member States. The EMA draws on resources of over 40 national competent authorities of European Union Member States.

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

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU Good Laboratory Practice regulations;
- submission to the relevant national competent authorities of a clinical trial application (CTA) for each trial in humans, which must be
  approved by such national authorities and at least one independent ethics committee before the trial may begin in each country where
  patient enrollment is planned;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a marketing authorization application (MAA) which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced cGMP;
- · potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

# Preclinical studies

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

# **Clinical trials**

Pursuant to the Clinical Trials Directive 2001/20/EC, as amended (Clinical Trials Directive), a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, approval must be obtained from the national competent authority of each European Union Member State in which a clinical trial is planned to be conducted. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier and further supporting information prescribed by the Clinical Trials Directive and other applicable guidance documents including but not being limited to the clinical trial protocol. Furthermore, a clinical trial may only be started after an independent ethics committee has issued a favorable opinion on the CTA in that country.

In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive. The Regulation introduces an authorization procedure based on a single

submission via a single E.U. portal, an assessment procedure leading to a single decision, as well as transparency requirements (the proactive publication of clinical trial data in the E.U. database). It is expected that the new Regulation will apply following confirmation of full functionality of the Clinical Trials Information System (CTIS), the centralized EU portal and database for clinical trials foreseen by the Regulation, through an independent audit, currently expected to occur in December 2021.

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

# **Review and approval**

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

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

Under the centralized authorization procedure, the Committee for Medicinal Products for Human Use (CHMP) serves as the scientific committee that renders opinions about the safety, efficacy and quality of human medicinal products on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national drug authority, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the CHMP acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP is required to issue an opinion within 210 days of receipt of a valid application, though the clock is stopped if it is necessary to ask the applicant for clarification or further supporting data. Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days. The process is complex and involves extensive consultation with the regulatory authorities of Member States and a number of experts. Once the procedure is completed, a European Public Assessment Report is produced. If the CHMP concludes that the quality, safety and efficacy of the medicinal product is sufficiently proven, it adopts a positive opinion. The CHMP's opinion is sent to the European Commission, which uses the opinion as the basis for its decision whether or not to grant a marketing authorization. The European Commission's decision is issued within 67 days of receipt of the CHMP's recommendation. If the opinion is negative, information is given as to the grounds on which this conclusion was reached.

After a drug has been authorized and launched, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review. Sanctions may be imposed for

failure to adhere to the conditions of the marketing authorization. In extreme cases, the authorization may be revoked, resulting in withdrawal of the product from sale.

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

#### Conditional approval and accelerated assessment

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

When an application is submitted for a marketing authorization in respect of a drug for human use which is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure pursuant to Article 14(9) of Regulation (EC) 726/2004. Under the accelerated assessment procedure, the CHMP is required to issue an opinion within 150 days of receipt of a valid application, subject to clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment. We believe that some of the disease indications in which our product candidates are currently being or may be developed in the future qualify for this provision, and we will take advantage of this provision as appropriate.

#### Period of authorization and renewals

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

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

# Orphan drug designation

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

Regulation (EC) 847/2000 sets out provisions for the implementation of the criteria for the designation of orphan drugs. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a 10-year period of market exclusivity, which means that no similar medicinal product can be authorized in the same indication. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify continued market exclusivity. In addition, derogation from market exclusivity may be granted on an individual basis in very select cases, such as with consent from the marketing authorization holder, inability to supply sufficient quantities of the authorized product or demonstration of "clinically relevant superiority" by a similar medicinal product. Medicinal products designated as orphan drugs pursuant to Regulation (EC) 141/2000 are eligible for incentives made available by the European Union and by the Member States to support research into, and the development and availability of, orphan drugs.

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

# European and United Kingdom data collection and processing

The collection, use, disclosure and other processing of health-related and other personal information about clinical trials participants and other individuals in Europe is governed by the GDPR (and in the UK, is governed by the European Union (Withdrawal) Act 2018 and the UK Data Protection Act 2018 (UK GDPR)). The GDPR and UK GDPR require companies to give detailed disclosures about how they collect, use and share personal

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

# Marketing

Much like the Anti-Kickback Statute prohibition in the United States, as described below, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the E.U. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of European Union member states and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

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

# Brexit and the regulatory framework in the United Kingdom

In June 2016, the electorate in the UK voted in favor of leaving the EU (commonly referred to as "Brexit"). Thereafter, in March 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty and the UK formally left the EU on January 31, 2020. A transition period began on February 1, 2020, during which EU pharmaceutical law remained applicable to the UK, which ended on December 31, 2020. Since the regulatory framework in the UK covering the quality, safety and efficacy of medicinal products, clinical trials, marketing authorization, commercial sales and distribution of medicinal products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the UK, as UK legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the UK in the long-term. The MHRA, the UK medicines and medical devices regulator, has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now the transition period is over, which will be updated as the UK's regulatory position on medicinal products evolves over time.

# International regulation

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

# Other healthcare laws and regulations and legislative reform

# Healthcare laws and regulations

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

- The federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, Affordable Care Act), to a stricter standard such that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.
- Federal civil and criminal false claims laws, such as the False Claims Act, which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims.



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

If our operations are found to be in violation of any of these laws or any other current or future healthcare laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages,

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

## Legislative reform

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

For example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In 2010, the U.S. Congress enacted the Affordable Care Act, which included changes to the coverage and reimbursement of drug products under government healthcare programs such as:

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

- established a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- · created a licensure framework for follow-on biologic products.

There have been executive, judicial and congressional challenges to certain aspects of the Affordable Care Act as well as efforts to repeal or replace certain aspects of the Affordable Care Act. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and will remain 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. It is possible that the ACA 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, will remain in effect through 2031 with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, absent additional congressional action. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. If government spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA, to continue to function at current levels, which may impact the ability of relevant agencies to timely review and approve research and development, manufacturing and marketing activities, which may delay our ability to develop, market and sell any product candidates we may develop. In addition, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our anticipated product revenues.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020, providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been

delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, the CMS issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the Most Favored Nation model interim final rule. 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. No legislation or administrative actions have been finalized to implement these principles. 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

# Environmental, health and safety laws and regulations

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

# Pharmaceutical coverage, pricing and reimbursement

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

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

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

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

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. There is no uniform policy for coverage and reimbursement in the United States and, as a result, coverage and reimbursement can differ significantly from payor to payor. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, which decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often, but not always, follow the CMS's decisions regarding coverage and reimbursement. It is difficult to predict what third-party payors will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Further, one payor's determination to provide coverage and adequate reimbursement for a product does not assure that other payors will also provide coverage and adequate reimbursement for that product. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates. There can be no assurance that our product candidates will be considered medically necessary or cost-effective. Therefore, it is possible that any of our product candidates, even if approved, may not be covered by third-party payors or the reimbursement limit may be so restrictive that we cannot commercialize the product candidates profitably.

Reimbursement agencies in Europe may be more restrictive than payors in the United States. In Europe, pricing and reimbursement schemes vary widely from country to country. For example, some countries provide that products may be marketed only after an agreement on reimbursement price has been reached. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Other countries require the completion of additional health technology assessments that compare the cost- effectiveness of a particular product candidate to currently available therapies. In addition, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product, may adopt a system of direct or indirect controls on the profitability of the company placing the product on the market or monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. Furthermore, many countries in the European Union have increased the amount of discounts required on pharmaceutical products, and these efforts could continue as countries attempt to manage healthcare

expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, and prescription products in particular, has become increasingly intense. As a result, there are increasingly higher barriers to entry for new products. There can be no assurance that any country that has reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. Accordingly, the reimbursement for any products in Europe may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

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

# Employees and human capital resources

As of December 31, 2021, we had a total of 17 full-time employees and approximately 20 consultants on a part-time basis. We have in the past, and may in the future, retain additional expert consultants if required in connection with our plans. We are not a party to any collective bargaining agreements.

Attracting, hiring, 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 *teamwork*, *accountability*, and *empathy* for patients to enhance the working environment for our current employees and to attract our desired candidates.

# Facilities

We have recently leased and are occupying 4,945 square feet of office space at 8000 Marina Boulevard in Brisbane, California though November 30, 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 to Vaxart, Inc. through September 30, 2025.

# COVID-19 impact on facilities

We are operating through a blend of in-person and virtual work to align with local COVID-19 guidelines, which we believe meets our operational needs as a late-stage biotechnology company.

# 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.

# Management

# Executive officers, key employees and directors

The following table sets forth information regarding our executive officers, key employees and directors, including ages as of December 31, 2021.

Name	Age	Position
Executive Officers:		
Marshall Fordyce, M.D.	48	President, Chief Executive Officer and Director
Celia Lin, M.D.	47	Chief Medical Officer
Joanne Curley, Ph.D.	53	Chief Development Officer
Sean Grant	37	Chief Financial Officer
Other Key Employees		
Lauren Frenz	36	Chief Business Officer
Tom Doan	50	Senior Vice President, Development Operations
Joseph Young	50	Senior Vice President, Finance and Chief Accounting Officer
Tad Thomas, Ph.D.	62	Senior Vice President and Head of Product Development and Manufacturing
Non-Employee Directors:		
Kurt von Emster, C.F.A.(2)(3)	54	Chairperson of the Board of Directors
Andrew Cheng, M.D., Ph.D.(1)(2)	54	Director
Beth Seidenberg, M.D.(3)	64	Director
Maha Katabi, Ph.D., C.F.A.(1)(2)	48	Director
Patrick Enright(1)	59	Director
Scott Morrison(3)	64	Director
Kimball Hall	55	Director

(1) Member of the compensation committee.

(2) Member of the nominating and corporate governance committee.

(3) Member of the audit committee.

# **Executive officers**

*Marshall Fordyce, M.D.* is our founder and has served as our President and Chief Executive Officer and as a member of our board of directors since May 2016. From April 2011 to July 2016, Dr. Fordyce held a number of senior leadership roles at Gilead Sciences, Inc. (Gilead), a biotechnology company, including Director of Clinical Research and Senior Director of Clinical Research, where he was responsible for leading teams in clinical translation, development and commercialization of new treatments. In April 2012, Dr. Fordyce joined the Albert and Mary Lasker Foundation, a foundation supporting biomedical research, as a non-executive director and continues in that role. Dr. Fordyce received a B.A. in medical anthropology from Harvard University and an M.D.



from Harvard Medical School. Our board of directors believes that Dr. Fordyce is qualified to serve on our board of directors due to his extensive experience in the biotechnology industry in senior leadership roles, as well as the perspective and experience he brings as our President and Chief Executive Officer.

*Celia Lin, M.D.* has served as our Chief Medical Officer since February 2021. From August 2015 to February 2021, Dr. Lin was Senior Medical Director at Genentech. She was responsible for late stage development and regulatory approval for a novel product in an orphan disease. She also served as Global Development Lead for a BTK inhibitor in multiple sclerosis, and led other programs including monoclonal antibodies, bispecifics, and complement inhibitors in various therapeutic areas such as respiratory, allergy, nephrology, infectious disease and inflammation. Dr. Lin previously served as Medical Director in Clinical Development and Medical Affairs at Amgen, from April 2012 to August 2015, leading teams and activities related to the approval and commercialization of two osteoporosis therapies. Dr. Lin is a board certified physician. Prior to joining industry, she was on faculty at UCSF. She received her B.S. from UCLA and her M.D. from University of Rochester School of Medicine. She trained in internal medicine at Boston Medical Center and in rheumatology at UCLA and Washington University in St. Louis where she also was a post-doctoral fellow.

*Joanne Curley, Ph.D.* has served as our Chief Development Officer since March 2020. From June 2005 until March 2020, Dr. Curley held a number of senior leadership roles at Gilead, a biotechnology company, including Senior Director, Project and Portfolio Management and Vice President, Project and Portfolio Management, where she was responsible for developing products from research through regulatory approval. From 2002 to 2005, Dr. Curley served as a staff scientist at Nektar Therapeutics, a pharmaceutical company. Dr. Curley has served as a member of the board of directors of VistaGen Therapeutics, Inc., a biopharmaceutical company, since April 2021. Dr. Curley received a B.Sc. in physics and chemistry from Trinity College, Ireland, a Ph.D. in polymer science and engineering from the University of Massachusetts, Amherst, and did a post-doctorate at Massachusetts Institute of Technology and Harvard Medical School focused on long-acting biodegradable formulations.

*Sean Grant* has served as our Chief Financial Officer since July 2021. Mr. Grant previously served as Vice President of Corporate Strategy and Business Development for CareDx, Inc., a biotechnology company, from May 2020 to June 2021. His responsibilities included leading mergers and acquisitions, venture investments and partnerships across diagnostics and therapeutics. Prior to joining CareDx, Mr. Grant served as Vice President in the Investment Banking Healthcare Division at Citigroup Global Capital Markets from July 2015 to March 2020. At Citigroup, Mr. Grant specialized in public and private capital raising as well as mergers and acquisitions for leading life science companies. Mr. Grant received a B.A. in Government and International Politics from George Mason University and an M.B.A. from the Johns Hopkins University Carey Business School.

# Other key employees

*Lauren Frenz* has served as our Chief Business Officer since April 2020. Ms. Frenz previously served as our Senior Vice President of Corporate Strategy and Finance from August 2017 to April 2020. From June 2012 to July 2017, Ms. Frenz served in positions of increasing responsibility at Gilead, a biotechnology company, in the US Sales & Marketing and Global Commercial Planning & Operations organizations in multiple therapeutic areas. At Gilead, she most recently led healthcare provider marketing for multiple blockbuster HIV therapies. Prior to Gilead, Ms. Frenz worked at SVB Leerink, an investment bank specializing in healthcare and life sciences, in their Strategic Advisory Group, devising business development, commercial, and portfolio management strategies for biotech and pharmaceutical companies. Ms. Frenz received an M.B.A. from Harvard Business School and an A.B. in psychology with a certificate in neuroscience from Princeton University.

*Tom Doan* has served as our Senior Vice President, Development Operations since March 2020. From April 2007 to March 2020, Mr. Doan held a number of senior leadership roles at Gilead, a biotechnology company, where he was responsible for clinical operations for multiple successful drug market filings and approvals, including most recently Executive Director, Clinical Operations, Therapeutic Area Head, Inflammation/Respiratory. From October 2003 until April 2007, Mr. Doan served as Clinical Trial Manager and Senior Clinical Trial Manager, BioOncology, at Genentech, a biotechnology company. From September 1999 until October 2003, Mr. Doan served as Clinical Research Manager and Clinical Research Associate, at Cato Research, LLC, a clinical research organization. Mr. Doan received a B.S. in Fisheries Biology from Humboldt State University.

**Joseph Young** has served as our Senior Vice President, Finance since March 2021 and our Chief Accounting Officer since May 2021. From April 2006 to July 2020, Mr. Young held a number of senior leadership roles at Plexxikon Inc., a biotechnology company, and whollyowned subsidiary of Daiichi-Sankyo Co., Ltd. since its acquisition of Plexxikon in 2011, including most recently Senior Vice President, Finance and Treasurer, where he was responsible for all accounting, finance and treasury operations, in addition to oversight of other business functions. From August 2005 to April 2006, Mr. Young served as Associate Director, Internal Controls Compliance at VaxGen, Inc., a biotechnology company. From February 1999 to August 2005, Mr. Young held management roles at Cerus Corporation, a biotechnology company, including most recently Controller. From October 1994 to January 1999, Mr. Young was an auditor at Ernst & Young LLP. Mr. Young received a B.A. in Business-Economics from the University of California, Los Angeles and an M.B.A. from the University of California, Berkeley—Haas School of Business, and is a Certified Public Accountant (inactive status).

*Tad Thomas, Ph.D.* has served as our Senior Vice President and Head of Product Development and Manufacturing since April 2021. From March 2019 to April 2021, Dr. Thomas served as Associate Vice President, Technical Operations at Codexis, Inc., a biotechnology company, where he was responsible for overseeing preclinical development for biotherapeutic products and management of external contract manufacturing partnerships. From July 2013 to March 2019, Dr. Thomas served as Director and Global Lead, Biologics Process Transfer and Launch at Bayer HealthCare LLC, a pharmaceutical and life sciences company, where he was responsible for leading manufacturing site process transfers of clinical phase projects and leading the teams that drafted the Quality (CMC) sections of the successful marketing applications for Kovaltry and Jivi. Dr. Thomas received a B.A. in Biochemistry from the University of California, Berkeley, a Ph.D. in Biochemistry & Biophysics from the University of California, Davis, and completed a post-doctoral fellowship at the Harvard Medical School and Brigham and Women's Hospital.

# Non-employee directors

*Kurt von Emster, C.F.A.* has served on our board of directors since October 2020. Mr. von Emster currently serves as Managing Partner at Abingworth LLP, a venture capital firm, where he has been employed as a Partner since January 2015. Mr. von Emster has served as a member of the board of directors of Tizona Therapeutics, Inc., a biotechnology company, since December 2020, Launch Therapeutics, Inc., a biotechnology company, since August 2021, Orbus Therapeutics, Inc., a pharmaceutical company, since July 2020, SFJ Pharmaceuticals, Inc., a specialty pharmaceutical company, since April 2020, Jasper Therapeutics, Inc., a biotechnology company, since August 2021, orbus Therapeutical vaccine company, since July 2015, and CymaBay Therapeutics, Inc., a biotechnology company, since April 2009. Mr. von Emster previously served on the board of directors of the following companies: Trishula Therapeutics, Inc. from December 2020 to December 2021, CRISPR Therapeutics, Inc. from March 2015 to June 2019, Kesios Therapeutics Ltd. from November 2015 to January 2017, Cytos Biotechnology AG from November 2012 to January 2016 (merged and renamed Kuros Biosciences AG in January 2016), Aurinia Pharmaceuticals Inc. from February 2014 to March 2015, Facet Biotech Corporation (acquired by Abbott Laboratories in April 2010) from

February 2009 to April 2010, and Somaxon Pharmaceuticals, Inc. (acquired by Pernix Therapeutics Holdings, Inc. in March 2013) from August 2005 to March 2013. In addition, Mr. von Emster co-founded venBio LLC, a health-care focused investment firm, in 2009, and served as Partner until 2014. Prior to that, Mr. von Emster was General Partner at MPM Capital, Inc., a biotechnology private equity firm, from 2000 to 2009. Mr. von Emster was also a Biotechnology and Healthcare Analyst and Portfolio Manager at Franklin Templeton Group from 1989 to 2000. Mr. von Emster received a B.S. in Business and Economics from the University of California, Santa Barbara and is a Chartered Financial Analyst (C.F.A.). Our board of directors believes that Mr. von Emster's experience in the biotechnology industry, as well as his experience as a member on the boards of directors of multiple companies in the industry, qualifies him to serve on our board of directors.

Andrew Cheng, M.D., Ph.D. has served as a member of our board of directors since May 2017. Dr. Cheng has served as the President and Chief Executive Officer, as well as a director, of Akero Therapeutics, Inc., a biotechnology company, since September 2018. In August 2019, Dr. Cheng joined Arbutus Biopharma Corporation, a biopharmaceutical company, as a non-executive director and continues in that role. Before joining Akero, Dr. Cheng was at Gilead, a biotechnology company, as Chief Medical Officer from March 2018 to September 2018, Executive Vice President from February 2015 to September 2018, and Senior Vice President from February 2009 to February 2015. From April 2018 to November 2018, Dr. Cheng served on the board of directors of Syntimmune, Inc., a biotechnology company, which was acquired by Alexion Pharmaceuticals Inc. Dr. Cheng holds a B.A. in biology from the Johns Hopkins University and an M.D. and Ph.D. in cellular and molecular biology from Columbia University College of Physicians and Surgeons. He completed his internal medicine residency at UCLA and was board certified in internal medicine. Our board of directors believes that Dr. Cheng is qualified to serve as a member of our board of directors due to his extensive experience in clinical development across multiple therapeutic areas.

**Beth Seidenberg, M.D.** has served as a member of our board of directors since June 2016. Dr. Seidenberg is a founding Managing Director of Westlake Village BioPartners, a venture capital firm, a position she has held since September 2018. Dr. Seidenberg has been a Partner at Kleiner Perkins, a venture capital firm, since May 2005, where she primarily focuses on life sciences investing. Prior to joining Kleiner Perkins, Dr. Seidenberg was the Senior Vice President, Head of Global Development and Chief Medical Officer at Amgen, a biotechnology company. In addition, Dr. Seidenberg was a senior executive in research and development at Bristol Myers Squibb Company, a biopharmaceutical company, and Merck & Co., Inc. Dr. Seidenberg has served on the board of directors of Atara Biotherapeutics, Inc. since August 2012. Dr. Seidenberg has served on the board of directors of Progyny, Inc. since May 2010. From February 2008 until September 2019 she served on the board of directors of Epizyme, Inc., from June 2011 to February 2019 she served on the board of directors of Atara BioSciences, Inc. Dr. Seidenberg received a B.S. from Barnard College and an M.D. from the University of Miami School of Medicine and completed her post-graduate training at the Johns Hopkins University, George Washington University and the National Institutes of Health. Our board of directors believes that Dr. Seidenberg is qualified to serve on our board of directors because of her extensive experience in the life sciences industry as a senior executive and venture capitalist, as well as her training as a physician.

*Maha Katabi, Ph.D.* has served as a member of our board of directors since October 2020. Dr. Katabi is a General Partner at Sofinnova Investments, a venture capital firm, since March 2020. She joined Sofinnova as a Partner in April 2019. Prior to joining Sofinnova, Dr. Katabi was a founding Managing Partner at Oxalis Capital, a venture capital firm, from August 2018 until April 2019. From September 2008 until January 2018, Dr. Katabi was a Partner, Private Equity at Sectoral Asset Management, an investment advisor exclusively focused on the global healthcare sector. She was the portfolio manager of a family of funds investing in small cap and private biotech companies She held these positions since July 2012, and joined Sectoral in 2008 as Investment Manager. Prior to joining Sectoral in 2008, Dr. Katabi was a Vice President at Ventures West from 2004 to

2008, where she focused on early-stage venture investments in the life sciences industry. She started her venture capital career in 1999 with T2C2 Capital Bio, a seed fund focused on university start-ups. Dr. Katabi has served as a member of the board of directors of several private companies, and currently serves as a director of Aerovate Therapeutics, Inc., Gyroscope Therapeutics Limited, Northsea Therapeutics B.V., Quanta Therapeutics, Inc., and Sofinnova Investments, Inc. She received a Ph.D. in Pharmacology in 1999 at McGill University and her CFA charter in 2011. Our board of directors believes that Dr. Katabi is qualified to serve on our board of directors due to her experience as a biopharmaceutical and biotechnology public and private company investor.

**Patrick Enright** has served on our board of directors since October 2020. Since July 2007, Mr. Enright has served as a Managing Director of Longitude Capital, a venture capital firm, of which he is a co-founder. From 2002 through 2006, Mr. Enright was a Managing Director of Pequot Ventures, a venture capital investment firm, where he co-led the life sciences investment practice. Mr. Enright currently serves on the boards of Aptinyx Inc. (APTX), Jazz Pharmaceuticals plc (JAZZ) and other private companies as well as the National Venture Capital Association (NVCA). Selected prior board memberships include Aimmune Therapeutics, Inc. (AIMT, acquired by Nestlé), Esperion Therapeutics, Inc. (ESPR) and Vaxcyte (PCVX). Mr. Enright received a B.S. in Biological Sciences from Stanford University and an M.B.A. from the Wharton School of the University of Pennsylvania. Our board of directors believes that Mr. Enright is qualified to serve on our board of directors due to his experience serving on the board of directors of clinical-stage biotechnology companies and his investment experience in the life sciences industry.

**Scott Morrison** has served on our board of directors since April 2020. From 1996 to December 2015, Mr. Morrison was a partner with Ernst & Young LLP, a public accounting firm, where he also served as U.S. Life Sciences Leader from 2002 to December 2015. Mr. Morrison has served on the board of directors of Corvus Pharmaceuticals Inc., a biopharmaceutical company, since December 2015, IDEAYA Biosciences, Inc., a biotechnology company, since July 2018, Audentes Therapeutics, Inc., a biotechnology company, from December 2015 through its sale to Astellas Pharma Inc. on January 15, 2021, Global Blood Therapeutics, Inc., a biopharmaceutical company, since December 2015, Escape Bio, Inc., a biotechnology company, since October 2020, and Zai Lab Limited, a biotechnology company, since October 2021. Mr. Morrison has also held roles on the boards of directors of numerous other life sciences industry organizations. Mr. Morrison has previously served on the boards of directors of the Life Sciences Foundation, the California Life Sciences Association, the Biotech Institute and the Emerging Companies Section of the Biotechnology Innovation Organization. He holds a B.S. in Business Administration from the University of California, Berkeley and is a certified public accountant (inactive). Our board of directors believes that Mr. Morrison's 40 years of experience serving life sciences companies and in public accounting as well as many years of governance experience qualifies him to serve on our board of directors.

*Kimball Hall* has served on our board of directors since December 2021. Since December 2020, Ms. Hall has served as President and Chief Operating Officer of Abzena Holdings (US), LLC, a privately owned Contract Development and Manufacturing Organization. She also serves as a member of Abzena's board of directors and first joined as Chief Operating Officer in October 2019. Since January 2016, prior to joining Abzena, Ms. Hall held several executive positions at Genentech, Inc., a member of the Roche family. She served as a member of the Genentech Executive Committee and was Senior Vice President, Global Head of Drug Substance Manufacturing. Prior to joining Genentech, Ms. Hall spent 16 years at Amgen, a biotechnology company. Ms. Hall received a B.S. in microbiology from the University of Washington. Our board of directors believes that Ms. Hall is qualified to serve on our board of directors given her extensive experience as an executive in the pharmaceutical and biotechnology sectors.

## **Family relationships**

There are no family relationships among any of our executive officers or directors.

## Composition of our board of directors

Our business and affairs are organized under the direction of our board of directors, which currently consists of eight members with no vacancies. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

All members of our board of directors, other than Ms. Hall, were elected under the provisions of our Amended and Restated Voting Agreement entered into in October 2020. Under the terms of this Voting Agreement, the stockholders party to the Voting Agreement agreed how to vote their respective shares in the election of our directors. This Voting Agreement terminated upon the closing of our IPO.

Our board of directors may establish the authorized number of directors from time to time by resolution. In accordance with our amended and restated certificate of incorporation, our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

- the Class I directors are Dr. Fordyce, M.D., Dr. Seidenberg, M.D., and Ms. Hall, and their terms will expire at the annual meeting of stockholders to be held in 2022;
- the Class II directors are Mr. von Emster, Dr. Katabi Ph.D., and Mr. Enright, and their terms will expire at the annual meeting of stockholders to be held in 2023; and
- the Class III directors are Dr. Cheng M.D., Ph.D. and Mr. Morrison, and their terms will expire at the annual meeting of stockholders to be held in 2024.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

## **Director independence**

Under the listing requirements and rules of the Nasdaq Stock Market LLC (Nasdaq Listing Rules), a majority of our directors must be independent directors.

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning her or his background, employment and affiliations, including family relationships, our board of directors has determined that Dr. Cheng, M.D., Ph.D., Dr. Seidenberg, M.D., Mr. von Emster, Dr. Katabi, Ph.D., Mr. Enright, Mr. Morrison and Ms. Hall do not have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Nasdaq Listing Rules. Our board of directors has determined that Dr. Fordyce, by virtue of his position as our President and Chief Executive Officer, is not independent under applicable rules and regulations of the U.S. Securities and Exchange Commission (SEC) and the Nasdaq Listing Rules. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in the section titled "Certain relationships and related person transactions."

## Committees of our board of directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee has adopted a written charter that satisfies the application rules and regulation of the SEC and the Nasdaq Listing Rules, which are posted on our website at www.veratx.com. Information contained on, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

### Audit committee

Our audit committee currently consists of Mr. Morrison, Mr. von Emster and Dr. Seidenberg M.D., each of whom our board of directors has determined satisfies the independence requirements under the Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Exchange Act. With respect to Mr. von Emster specifically, our board of directors has determined that he is independent even though he falls outside the "safe harbor" definition set forth in Rule 10A- 3(e)(1)(ii) under the Exchange Act. Mr. von Emster has not accepted directly or indirectly any consulting, advisory or other compensatory fee from us, and while he is a Managing Partner of Abingworth LLP, he shares, but does not control, voting and investment power over the shares held by Abingworth Bioventures 8 LP, which is an affiliate of Abingworth LLP and owns in excess of 10% of our outstanding common stock prior to this public offering. As a result of this facts and circumstances analysis, our board of directors has determined in good faith that Mr. von Emster is not an "affiliated person" of us who would fail to satisfy the applicable independence requirements for audit committee members. The chair of our audit committee is Mr. Morrison, who our board of directors has determined is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control and financial-statement audits, and to oversee our independent registered accounting firm. Specific responsibilities of our audit committee include:

- · helping our board of directors oversee our corporate accounting and financial reporting processes;
- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management
  and the independent accountants, our interim and year-end operating results;
- · developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- monitoring and assessing, and overseeing the reporting of, any material cybersecurity breaches and associated risks;
- reviewing related person transactions;

- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving, or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

## Compensation committee

Our compensation committee currently consists of Mr. Enright, Dr. Katabi, Ph.D., and Dr. Cheng, M.D., Ph.D. The chair of our compensation committee is Mr. Enright. Our board of directors has determined that each member of the compensation committee is independent under the Nasdaq Listing Rules and as a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate. Specific responsibilities of our compensation committee include:

- reviewing and approving the compensation of our chief executive officer, other executive officers and senior management, and
  overseeing the development and performance of our officers and our succession planning;
- · reviewing and recommending to our board of directors the compensation paid to our directors;
- · reviewing employee diversity and inclusion initiatives;
- · reviewing and approving the compensation arrangements with our executive officers and other senior management;
- · administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending and terminating, incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans and any other compensatory arrangements for our executive officers and other senior management;
- · reviewing, evaluating and recommending to our board of directors succession plans for our executive officers; and
- reviewing and establishing general policies relating to compensation and benefits of our employees.

#### Nominating and corporate governance committee

Our nominating and corporate governance committee consists of Mr. von Emster, Dr. Katabi, Ph.D., and Dr. Cheng, M.D., Ph.D. The chair of our nominating and corporate governance committee is Mr. von Emster. Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the Nasdaq Listing Rules, a non-employee director, and free from any relationship that would interfere with the exercise of his or her independent judgment.

Specific responsibilities of our nominating and corporate governance committee include:

 identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our board of directors;

- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- instituting plans or programs for the continuing education of our board of directors and orientation of new directors;
- · developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the board of directors' performance, including committees of the board of directors and management.

## Code of business conduct and ethics

We maintain a written Code of Business Conduct and Ethics that applies to all our employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Business Conduct and Ethics is posted on our website at www.veratx.com. We intend to disclose on our website any future amendments of our Code of Business Conduct and Ethics or waivers that exempt any principal executive officer, principal accounting officer or controller, persons performing similar functions or our directors from provisions in the Code of Business Conduct and Ethics. Information contained on, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

## Compensation committee interlocks and insider participation

None of the members of our compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last calendar year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

## Non-employee director compensation

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the year ended December 31, 2021 to each of our non-employee directors who served on our board of directors during 2021:

Name	Fees earned or paid in cash (\$)	Option awards (\$)(1)(2)	Total (\$)
Beth Seidenberg, M.D.	26,563	66.836	93,398
			,
Andrew Cheng, M.D., Ph.D.	27,500	66,836	94,336
Scott Morrison	31,250	66,836	98,086
Maha Katabi, Ph.D.	30,000	66,836	96,836
Kurt von Emster	47,813	66,836	114,648
Kimball Hall(3)	1,944	313,120	315,064
Patrick Enright	28,125	66,836	94,961

(1) The amounts disclosed represent the aggregate grant date fair value of the stock options granted to our non-employee directors during fiscal year 2021 under our 2021 Plan, computed in accordance with FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the stock options are set forth in Note 9 to our unaudited condensed financial statements for the nine months ended September 30, 2021, included elsewhere in this prospectus. This amount does not reflect the actual economic value that may be realized by the named executive officer.

- (2) The aggregate number of shares underlying outstanding options to purchase our Class A common stock held by our non-employee directors was 286,529, as follows: 78,968 by Dr. Seidenberg; 78,968 by Dr. Cheng; 78,968 by Mr. Morrison; 9,925 by Dr. Katabi; 9,925 by Mr. von Emster; 19,850 by Ms. Hall; and 9,925 by Mr. Enright.
- (3) Ms. Hall was appointed as a member of our board of directors effective as of December 10, 2021.

We have reimbursed and will continue to reimburse all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings. Marshall Fordyce, M.D., our President and Chief Executive Officer, was also a director as of December 31, 2021, but did not receive any additional compensation for his service as a director. See the section titled "Executive compensation" for more information regarding the compensation earned by Dr. Fordyce.

During the year ended December 31, 2021, each of the following individuals served on our board of directors as non-employee directors: Kurt von Emster, Maha Katabi, Ph.D., Patrick Enright, Andrew Cheng, M.D., Ph.D., Beth Seidenberg, M.D., Scott Morrison, and Kimball Hall. Other than as set forth above, none of our non-employee directors earned any compensation in the year ended December 31, 2021 or held any equity awards as of December 31, 2021.

Our board of directors adopted a non-employee director compensation policy in May 2021 that is applicable to all of our non-employee directors. This compensation policy provides that each such non-employee director will receive the following compensation for service on our board of directors:

- an annual cash retainer of \$35,000; and an additional annual cash retainer of \$30,000 for services as non-executive chairperson of our board of directors;
- an additional annual cash retainer of \$7,500, \$5,000 and \$4,000 for service as a member of the audit committee, compensation committee and the nominating and corporate governance committee, respectively;
- an additional annual cash retainer of \$7,500, \$5,000 and \$4,000 for service as chair of the audit committee, compensation committee and the nominating and corporate governance committee, respectively;
- an initial option grant to purchase 19,850 shares of our Class A common stock on the date of each such non-employee director's appointment to our board of directors; and
- an annual option grant to purchase 9,925 shares of our Class A common stock on the date of each of our annual stockholder meetings.

Each of the option grants described above will be granted under our 2021 Plan, the terms of which are described in more detail below under the section titled "Executive compensation—Equity benefit plans—2021 Equity incentive plan." Each such option grant will vest and become exercisable subject to the director's continuous service to us through the earlier of the first anniversary of the date of grant or the next annual stockholder meeting. The term of each option will be 10 years, subject to earlier termination as provided in the 2021 Plan.

## **Executive compensation**

Our named executive officers for the year ended December 31, 2021, consisting of our principal executive officer and the next two most highly compensated executive officers, were:

- · Marshall Fordyce, M.D., our President, Chief Executive Officer and Director;
- Sean Grant, our Chief Financial Officer; and
- Celia Lin, M.D., our Chief Medical Officer.

## Summary compensation table

The following table presents all of the compensation awarded to, earned by, or paid to our named executive officers during the fiscal years indicated below.

Name and principal position	Fiscal year	Salary (\$)	Bonus (\$)(1)	Stock awards (\$)(2)	Option awards (\$)(3)	Non-equity incentive plan compensation (\$)(4)	All other compensation (\$)	Total (\$)
Marshall Fordyce, M.D.	2021	479,099			770,343	236,259	_	1,485,701
President and Chief Executive Officer	2020	360,000	—	316,323	2,441,982	108,000	—	3,226,305
Sean Grant Chief Financial Officer(5)	2021 2020	189,487 —	60,000 —		1,765,026	67,858 —		2,082,371
Celia Lin, M.D. Chief Medical Officer(6)	2021 2020	361,205	150,000	_	797,776 —	134,616		1,443,597 —

(1) Mr. Grant was paid a lump sum advance of \$60,000 that will be earned if he remains continuously employed by us through July 12, 2022 or, if earlier, through the date on which his employment terminates for any reason other than termination for cause or his resignation without good reason (each as defined in his offer letter). Dr. Lin was paid a lump sum hiring bonus of \$150,000 subject to the signing of her offer letter.

- (2) In October 2020, in connection with the closing of our Series C redeemable convertible preferred stock financing, 49,636 outstanding shares of our Class A common stock held by Dr. Fordyce were amended to be subject to a 12 month vesting period. The amounts disclosed represent the value of such amendment, computed in accordance with FASB ASC Topic 718.
- (3) The amounts disclosed represent the aggregate grant date fair value of the awards granted to our named executive officers during fiscal years 2020 and 2021 under our 2017 and 2021 Plan, respectively, computed in accordance with FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the stock options are set forth in Note 9 to our unaudited condensed financial statements for the nine months ended September 30, 2021, included elsewhere in this prospectus. This amount does not reflect the actual economic value that may be realized by the named executive officer.
- (4) The amounts disclosed represent performance bonuses earned in 2020 and 2021, but paid in the beginning of 2021 and 2022, respectively. Mr. Grant's and Dr. Lin's bonuses were pro-rated to reflect each of their partial years of service.
- (5) Mr. Grant has served as our Chief Financial Officer since July 2021.

(6) Dr. Lin has served as our Chief Medical Officer since February 2021.

## Narrative to the summary compensation table

Our board of directors reviews compensation annually for all employees, including our named executive officers. In making compensation determinations, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our company.

Our board of directors has historically determined our named executive officers' compensation and has typically reviewed and discussed management's proposed compensation with our chief executive officer for all executives other than our chief executive officer. Based on those discussions and its discretion, our board of directors then



approved the compensation of each named executive officer. The compensation committee determines our executive officers' compensation and follows this process, but generally the compensation committee itself, rather than our board of directors, approves the compensation of each named executive officer.

## Annual base salary

Base salaries for our named executive officers are initially established through arm's-length negotiations at the time of the named executive officer's hiring, taking into account such named executive officer's qualifications, experience, the scope of his or her responsibilities and competitive market compensation paid by other companies for similar positions within the industry and geography. Base salaries are reviewed periodically, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. In making decisions regarding salary increases, we may also draw upon the experience of members of our board of directors with executives at other companies. The 2021 annual base salaries for our named executive officers are set forth in the table below.

Name	2021 base salary
Marshall Fordyce, M.D.(1)	\$ 525,000
Sean Grant	\$ 400,000
Celia Lin, M.D.(2)	\$ 429,200

(1) Dr. Fordyce's base salary increased from \$400,000 to \$525,000 on May 13, 2021.

(2) Dr. Lin's base salary increased from \$370,000 to \$429,200 on May 13, 2021.

## Outstanding equity awards as of December 31, 2021

The following table presents the outstanding equity incentive plan awards held by each named executive officer as of December 31, 2021.

				O	ption awards(1)
Name	Grant date	Number of securities underlying unexercised options exercisable (#)	Number of securities underlying unexercised options unexercisable (#)	Option exercise price per share (\$)	Option expiration date
Marshall Fordyce, M.D.	01-16-2020(2)	2,319	3.350	2.32	01-15-2030
	12-16-2020(3)	276,803	830,409	2.90	12-15-2030
	05-13-2021(4)	_	110,038	11.00	05-12-2031
Sean Grant	07-13-2021(5)	_	180,000	14.87	07-12-2031
Celia Lin, M.D.	02-23-2021(6)	_	230,821	3.94	02-22-2031
	05-13-2021(7)		16,916	11.00	05-12-2031

(1) All of the option and stock awards granted prior to May 13, 2021 were granted under the 2017 Plan, the terms of which plan is described below under "—Equity benefit plans— 2017 Equity incentive plan." All of the option and stock awards granted on or subsequent to May 13, 2021 were granted under the 2021 Plan, the terms of which plan is described below under "—Equity benefit plans—2021 Equity incentive plan."

(2) One-third of the shares subject to the option award vest on January 10, 2021, and thereafter one-thirty-sixth of the shares subject to the option award vest on each monthly anniversary, subject to continuous service to us. Dr. Fordyce exercised this option with respect to 3,607 shares of Class A common stock in April 2021.

(3) One-fourth of the shares subject to the option award vest on December 16, 2021, and thereafter one-forty-eighth of the shares subject to the option award vest on each monthly anniversary, subject to continuous service to us. This option was conditioned on the cancellation of an option covering 12,945 shares granted to Dr. Fordyce on March 26, 2019 and an option covering 17,260 shares granted to Dr. Fordyce on February 7, 2018.

- (4) One-fourth of the shares subject to the option award vest on May 13, 2022, and thereafter one-forty-eighth of the shares subject to the option award vest on each monthly anniversary, subject to continuous service to us.
- (5) One-fourth of the shares subject to the option award vest on July 13, 2022, and thereafter one-forty-eighth of the shares subject to the option award vest on each monthly anniversary, subject to continuous service to us.
- (6) One-fourth of the shares subject to the option award vest on February 23, 2022, and thereafter one-forty-eighth of the shares subject to the option award vest on each monthly anniversary, subject to continuous service to us.
- (7) One-fourth of the shares subject to the option award vest on May 13, 2022, and thereafter one-forty-eighth of the shares subject to the option award vest on each monthly anniversary, subject to continuous service to us.

Options held by certain of our named executive officers are eligible for accelerated vesting under specified circumstances. Please see the subsection titled "-Employment, severance and change in control agreements" below for a description of such potential acceleration.

## Emerging growth company status

We are an "emerging growth company," as defined in the JOBS Act. As an emerging growth company we will be exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our chief executive officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

## **Pension benefits**

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during the fiscal year ended December 31, 2021.

## Nonqualified deferred compensation

Our named executive officers did not participate in, or earn any benefits under, a non-qualified deferred compensation plan sponsored by us during the fiscal year ended December 31, 2021.

## Employment, severance and change in control agreements

## Offer letters

Below are descriptions of our offer letters with our named executive officers. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with our named executive officers, please see the section titled "—Potential payments and benefits upon termination or change in control" below.

*Dr. Fordyce*. In December 2020, we and Dr. Fordyce entered into an offer letter that governs the current terms of Dr. Fordyce's employment with us. Pursuant to the agreement, Dr. Fordyce is entitled to an initial annual base salary of \$400,000, is eligible to receive an annual performance bonus with a target achievement of 40% of his base salary, as determined by our board of directors, and was granted an option exercisable for 1,141,733 shares of our Class A common stock (in addition to shares of our stock that Dr. Fordyce held at the time we entered into his offer letter). In May 2021, we and Dr. Fordyce entered into an amended and restated offer letter pursuant to which Dr. Fordyce's annual base salary increased to \$525,000 and his annual performance bonus target achievement increased to 50% of his base salary, as determined by our board of directors. In addition, Dr. Fordyce received a stock option covering 110,038 shares of our Class A common stock, at \$11.00 per share, which vest as follows: one-fourth of the shares subject to the option vest on May 13, 2022,

and thereafter one-forty-eighth of the shares subject to the option award vest on each monthly anniversary, subject to continuous service to us. Dr. Fordyce is also entitled to certain severance benefits, the terms of which are described below under the section titled "— Potential payments and benefits upon termination or change of control." Dr. Fordyce's employment is at will.

*Mr. Grant.* In July 2021, we and Mr. Grant entered in an offer letter that governs the current terms of Mr. Grant's employment with us. Pursuant to the agreement, Mr. Grant is entitled to an initial base salary of \$400,000, is eligible to receive an annual performance bonus with a target achievement of 40% of his base salary, based on our company's assessment of his performance and our company's attainment of written targeted goals as set by our company in its sole discretion. Mr. Grant was also paid a lump sum advance of \$60,000 that will be earned if he remains continuously employed by us through July 12, 2022 or, if earlier, through the date on which his employment terminates for any reason other than termination for cause or his resignation without good reason (each as defined below). In addition, Mr. Grant was granted a stock option covering 180,000 shares of our Class A common stock, at \$14.87 per share, which vest over a period of four years, with 25% of the shares vesting on July 13, 2022, and the remaining shares vesting in 36 equal monthly installments thereafter, in each case subject to Mr. Grant's continued employment through the applicable vesting dates. Mr. Grant is also entitled to certain severance benefits, the terms of which are described below under the section titled "—Potential payments and benefits upon termination or change of control." Mr. Grant's employment is at will.

*Dr. Lin.* In February 2021, we and Dr. Lin entered into an offer letter that governs the current terms of Dr. Lin's employment with us. Pursuant to the agreement, Dr. Lin is entitled to an initial annual base salary of \$370,000, is eligible to receive an annual performance bonus with a target achievement of 30% of her base salary, as determined by our board of directors, and was granted an option exercisable for 230,821 shares of our Class A common stock. Dr. Lin was also paid a lump sum hiring bonus of \$150,000. In May 2021, we and Dr. Lin entered into an amended and restated offer letter pursuant to which Dr. Lin's annual base salary increased to \$429,200 and her annual performance bonus target achievement increased to 40% of her base salary, as determined by our board of directors. In addition, Dr. Lin received a stock option covering 16,916 shares of our Class A common stock, at \$11.00 per share, which vest as follows: one-fourth of the shares subject to the option vest on May 13, 2022, and thereafter one-forty-eighth of the shares subject to the option award vest on each monthly anniversary, subject to continuous service to us. Dr. Lin is also entitled to certain severance benefits, the terms of which are described below under the section titled "—Potential payments and benefits upon termination or change of control." Dr. Lin's employment is at will.

### Potential payments and benefits upon termination or change of control

*Dr. Fordyce.* Pursuant to Dr. Fordyce's amended and restated offer letter, if (a) his employment is terminated without cause (as defined below), and other than as a result of his death or disability, or (b) he resigns for good reason (as defined below), then in addition to any amounts accrued and payable under the terms of our benefit plans through the date of termination, Dr. Fordyce will be entitled to receive severance in the form of 12 months of his then base salary, such amount to be paid in equal installments over a 12-month period after the date of termination, subject to applicable taxes and withholding, as well as up to 12 months of COBRA coverage. These severance benefits are conditioned upon Dr. Fordyce continuing to comply with his obligations under his proprietary information agreement and his delivery of a general release of claims in favor of the company that becomes effective and irrevocable within 21 days of the date of termination. Further, if within the three-month period immediately prior to or 12-month period that immediately follows a change of control (as defined below) Dr. Fordyce's employment is terminated without cause or for good reason, then (a) 100% of his then-unvested equity grants shall accelerate and become fully vested as of the termination date, (b) the amount of his cash severance and COBRA severance described above shall be increased from 12 months to 18 months and (c) he

shall receive additional cash severance in an amount equal to his target annual bonus for the year of such termination, to be paid in a single lump sum within 10 business days after the effective date of his release.

*Mr. Grant.* Pursuant to Mr. Grant's offer letter, if (a) his employment is terminated without cause (as defined below), and other than as a result of his death or disability, or (b) he resigns for good reason (as defined below), then in addition to any amounts accrued and payable under the terms of our benefit plans through the date of termination, Mr. Grant will be entitled to receive severance in the form of nine months of his then base salary, such amount to be paid in installments on the ordinary payroll dates, subject to applicable taxes and withholding, as well as up to nine months of COBRA coverage. These severance benefits are conditioned upon Mr. Grant continuing to comply with his obligations under his proprietary information agreement and his delivery of a general release of claims in favor of the company that becomes effective and irrevocable within 21 days of the date of termination. Further, if within the three-month period immediately prior to or 12-month period that immediately follows a change of control (as defined below) Mr. Grant's employment is terminated without cause or for good reason, then (a) 100% of his then-unvested equity grants shall accelerate and become fully vested as of the termination date, (b) the amount of his cash severance and COBRA severance described above shall be increased from nine months to 12 months and (c) he shall receive additional cash severance in an amount equal to his target annual bonus for the year of such termination, to be paid in a single lump sum within 10 business days after the effective date of his release.

*Dr. Lin.* Pursuant to Dr. Lin's amended and restated offer letter, if (a) her employment is terminated without cause (as defined below), and other than as a result of her death or disability, or (b) she resigns for good reason (as defined below), then in addition to any amounts accrued and payable under the terms of our benefit plans through the date of termination, Dr. Lin will be entitled to receive severance in the form of nine months of her then base salary, such amount to be paid in installments on the ordinary payroll dates, subject to applicable taxes and withholding, as well as up to nine months of COBRA coverage. These severance benefits are conditioned upon Dr. Lin continuing to comply with her obligations under her proprietary information agreement and her delivery of a general release of claims in favor of the company that becomes effective and irrevocable within 21 days of the date of termination. Further, if within the three-month period immediately prior to or 12-month period that immediately follows a change of control (as defined below) Dr. Lin's employment is terminated without cause or for good reason, then (a) 100% of her then-unvested equity grants shall accelerate and become fully vested as of the termination date, (b) the amount of her cash severance and COBRA severance described above shall be increased from nine months to 12 months and (c) she shall receive additional cash severance in an amount equal to her target annual bonus for the year of such termination, to be paid in a single lump sum within 10 business days after the effective date of her release.

For the purposes of Dr. Fordyce's, Mr. Grant's, and Dr. Lin's severance benefits, the following definitions apply:

• "cause" means (a) the officer's commission or conviction (including a guilty plea or plea of nolo contendere) of any felony or any other crime involving fraud, dishonesty or moral turpitude; (b) officer's commission or attempted commission of or participation in a fraud or act of dishonesty or misrepresentation against us; (c) willful and material breach of officer's duties to us; (d) willful damage to any of our property; (e) willful misconduct, or other willful violation of our policy that causes harm; or (f) officer's material violation of any written and fully executed contract or agreement between us and the officer, including without limitation, material breach of agreements relating to non-solicitation, nondisclosure and/or assignment of inventions, or material breach of any company policy, or of any statutory duty officer owes to us; provided, however, that in the event of subparagraph (f) above, we are required to provide written notice of such alleged violation and breach, and officer will have 30 days from receipt of such notice to cure. For purposes of this definition of Cause, no act, or failure to act, on officer's part shall be considered "willful" unless it is done, or omitted to be done, by officer intentionally and without reasonable belief that officer's action or omission was in the best interests of the company.

- "change of control" means (a) any consolidation or merger of the company with or into any other corporation or other entity or person, or any other corporate reorganization, other than any such consolidation, merger or reorganization in which the stockholders of the company immediately prior to such consolidation, merger or reorganization, continue to hold a majority of the voting power of the surviving entity (or, if the surviving entity is a wholly owned subsidiary, its parent) immediately after such consolidation, merger or reorganization; (b) any transaction or series of related transactions to which the company is a party in which in excess of 50% of our voting power is transferred; provided that the foregoing shall not include any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by us or our indebtedness is cancelled or converted or a combination thereof; or (c) a sale, lease, exclusive license or other disposition of all or substantially all of our assets.
- "good reason" means any of the following actions, if taken by us without officer's prior written consent: (a) a material reduction in officer's base salary, which we and officer agree is a reduction of at least 10% of officer's base salary (unless pursuant to a salary reduction program applicable generally to our similarly situated employees); (b) a material reduction in officer's duties (including responsibilities and/or authorities) (with respect to Dr. Fordyce, as our President and Chief Executive Officer), provided, however, that a change in job position (including a change in title) shall not be deemed a "material reduction" in and of itself unless officer's new duties are materially reduced from the prior duties; (c) relocation of officer's principal place of employment to a place that increases officer's one-way commute by more than 50 miles as compared to officer's then-current principal place of employment immediately prior to such relocation, provided that if officer works remotely during any period in which officer's regular principal place of business at a company office is closed, then neither officer's relocation to remote work or back to the office from remote work will be considered a relocation from officer's principal place of employment for the purposes of this definition; or, with respect to Dr. Fordyce, (d) prior to a change of control, no longer being a member of our board of directors or reporting to our board of directors as Chief Executive Officer. In order to resign for good reason, officer must provide written notice to our board of directors, or with respect to Mr. Grant or Dr. Lin, our Chief Executive Officer, within 30 days after each occurrence of the event giving rise to good reason setting forth the basis for officer's resignation, allow us at least 30 days from receipt of such written notice to cure such event, and if such event is not reasonably cured within such period, officer must resign from all positions officer then holds with the company not later than 30 days after the expiration of the cure period.

## Other compensation and benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental and vision, in each case on the same basis as all of our other employees. We pay the premiums for the medical, disability, accidental death and dismemberment insurance for all of our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers.

## Equity benefit plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain and motivate employees, consultants and directors, and encourages them to devote their best efforts to our business and financial success. The principal features of our equity incentive plans and our 401(k) plan are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which, other than the 401(k) plan, are filed as exhibits to the registration statement of which this prospectus is a part.

## 2021 Equity incentive plan

Our board of directors has adopted, and our stockholders have approved, our 2021 Plan. Our 2021 Plan became effective on May 13, 2021.

*Awards.* Our 2021 Plan provides for the grant of incentive stock options (ISOs) within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (Code), to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to our employees, directors and consultants and any of our affiliates' employees and consultants.

*Authorized shares*. Initially, the maximum number of shares of our Class A common stock that may be issued under our 2021 Plan will not exceed 4,405,336 shares of our Class A common stock, which is the sum of (i) 2,212,335 new shares, plus (ii) an additional number of shares up to a maximum of 2,193,001 shares, which number consists of shares of our Class A common stock subject to outstanding stock options or other stock awards granted under our 2017 Plan that, on or after our 2021 Plan became effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. In addition, the number of shares of our Class A common stock reserved for issuance under our 2021 Plan will automatically increase on January 1<sup>st</sup> of each year for a period of 10 years, beginning on January 1, 2022 and continuing through January 1, 2031, in an amount equal to (1) 5% of the total number of shares of our Class A common stock outstanding on December 31<sup>st</sup> of the immediately preceding year, or (2) a lesser number of shares determined by our board of directors no later than the date of any such increase. The maximum number of shares of our Class A common stock that may be issued on the exercise of ISOs under our 2021 Plan is 13,216,008 shares.

Shares subject to stock awards granted under our 2021 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares will not reduce the number of shares available for issuance under our 2021 Plan. Shares withheld under a stock award to satisfy the exercise, strike or purchase price of a stock award or to satisfy a tax withholding obligation will not reduce the number of shares available for issuance under our 2021 Plan. If any shares of our Class A common stock issued pursuant to a stock award are forfeited back to or repurchased or reacquired by us (i) because of a failure to meet a contingency or condition required for the vesting of such shares; (ii) to satisfy the exercise, strike or purchase price of a stock award; or (iii) to satisfy a tax withholding obligation in connection with a stock award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under our 2021 Plan.

*Plan administration.* Our board of directors, or a duly authorized committee of our board of directors, administers our 2021 Plan. Our board of directors may delegate to one or more of our officers the authority to (i) designate employees (other than officers) to receive specified stock awards; and (ii) determine the number of shares subject to such stock awards. Under our 2021 Plan, our board of directors has the authority to determine stock award recipients, the types of stock awards to be granted, grant dates, the number of shares subject to each stock award, the fair market value of our Class A common stock, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

Under our 2021 Plan, our board of directors also generally has the authority to effect, with the consent of any materially adversely affected participant, (i) the reduction of the exercise, purchase, or strike price of any outstanding option or stock appreciation right; (ii) the cancellation of any outstanding option or stock appreciation right and the grant in substitution therefore of other awards, cash, or other consideration; or (iii) any other action that is treated as a repricing under generally accepted accounting principles.

Stock options. ISOs and NSOs are granted under stock option agreements adopted by the administrator. The administrator will determine the exercise price for stock options, within the terms and conditions of our 2021 Plan, except the exercise price of a stock option generally will not be less than 100% of the fair market value of our Class A common stock on the date of grant. Options granted under our 2021 Plan will vest at the rate specified in the stock option agreement as will be determined by the administrator.

The administrator will determine the term of stock options granted under our 2021 Plan, up to a maximum of 10 years. Unless the terms of an optionholder's stock option agreement, or other written agreement between us and the recipient, provide otherwise, if an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death, or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of Class A common stock issued upon the exercise of a stock option will be determined by the administrator and may include (i) cash, check, bank draft or money order; (ii) a broker-assisted cashless exercise; (iii) the tender of shares of our Class A common stock previously owned by the optionholder; (iv) a net exercise of the option if it is an NSO; or (v) other legal consideration approved by the administrator.

Unless the administrator provides otherwise, options or stock appreciation rights generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the administrator or a duly authorized officer, an option may be transferred pursuant to a domestic relations order, official marital settlement agreement, or other divorce or separation instrument.

*Tax limitations on ISOs.* The aggregate fair market value, determined at the time of grant, of our Class A common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the term of the ISO does not exceed five years from the date of grant.

*Restricted stock unit awards.* Restricted stock unit awards are granted under restricted stock unit award agreements adopted by the administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the recipient, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

*Restricted stock awards.* Restricted stock awards are granted under restricted stock award agreements adopted by the administrator. A restricted stock award may be awarded in consideration for cash, check, bank

draft or money order, past or future services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The administrator will determine the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of Class A common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock appreciation rights. Stock appreciation rights are granted under stock appreciation right agreements adopted by the administrator. The administrator will determine the purchase price or strike price for a stock appreciation right, which generally will not be less than 100% of the fair market value of our Class A common stock on the date of grant. A stock appreciation right granted under our 2021 Plan will vest at the rate specified in the stock appreciation right agreement as will be determined by the administrator. Stock appreciation rights may be settled in cash or shares of our Class A common stock or in any other form of payment as determined by our board of directors and specified in the stock appreciation right agreement.

The administrator will determine the term of stock appreciation rights granted under our 2021 Plan, up to a maximum of 10 years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability, or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate upon the termination date. In no event may a stock appreciation right be exercised beyond the expiration of its term.

*Performance awards*. Our 2021 Plan permits the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. 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, our Class A common stock.

The performance goals may be based on any measure of performance selected by our board of directors. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates, or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by our board of directors at the time the performance award is granted, our board will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of our Class A common stock 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 Class A common stockholders; (ix) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are

required to be expensed under generally accepted accounting principles; and (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

Other stock awards. The administrator is permitted to grant other awards based in whole or in part by reference to our Class A common stock. The administrator will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

*Non-employee director compensation limit.* The aggregate value of all compensation granted or paid to any non-employee director with respect to any calendar year, including awards granted and cash fees paid by us to such non-employee director, will not exceed \$750,000 in total value, except such amount will increase to \$1,000,000 for the first year for newly appointed or elected non-employee directors.

*Changes to capital structure.* In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under our 2021 Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of ISOs, and (iv) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

*Corporate transactions.* In the event of a corporate transaction (as defined below), unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the administrator at the time of grant, any stock awards outstanding under our 2021 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full (or, in the case of performance awards with multiple vesting levels depending on the level of performance, vesting will accelerate at 100% of the target level if the award is not assumed) to a date prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction), and such stock 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 persons other than current participants will terminate if not exercised (if applicable) at or prior to the affective time of the corporate transaction), and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction); and (ii) any such stock awards will terminate if not exercised (if applicable) prior to the

In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the participant would have received upon the exercise of the stock award, over (ii) any per share exercise price payable by such holder, if applicable. In addition, any escrow, holdback, earn out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of our Class A common stock.

Under our 2021 Plan, a "corporate transaction" is generally the consummation of (i) a sale or other disposition of all or substantially all of our assets; (ii) a sale or other disposition of at least 50% of our outstanding

securities; (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation; or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our Class A common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

*Change in control.* Stock awards granted under our 2021 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control (as defined below) as may be provided in the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

Under our 2021 Plan, a "change in control" is generally (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; (iii) a sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction; or (iv) when a majority of our board of directors becomes comprised of individuals who were not serving on our board of directors on the date of the underwriting agreement related to this offering, or the incumbent board, or whose nomination, appointment, or election was not approved by a majority of the incumbent board still in office.

*Plan amendment or termination.* Our board of directors has the authority to amend, suspend, or terminate our 2021 Plan at any time, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2021 Plan. No stock awards may be granted under our 2021 Plan while it is suspended or after it is terminated.

## 2017 Equity incentive plan

Our board of directors adopted the 2017 Plan and our stockholders approved the 2017 Plan in February 2017. The 2017 Plan is the successor to and continuation of the PNA Innovations, Inc. 2011 Stock Plan. The 2017 Plan provided for the grant of ISOs, NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards and other awards to our employees, directors and consultants or our affiliates. ISOs may be granted only to our employees or employees of our affiliates.

In May 2021, upon the effective date of the 2021 Plan, the 2017 Plan was terminated. However, any outstanding awards granted under the 2017 Plan remain outstanding, subject to the terms of the 2017 Plan and award agreements, until such outstanding options are exercised or until any awards terminate or expire by their terms.

*Authorized shares.* We can no longer grant awards under our 2017 Plan. As of December 31, 2021, options to purchase 2,191,563 shares were outstanding.

*Plan administration.* Our board or a duly authorized committee of our board administers our 2017 Plan and the awards granted under it. The administrator has the power to modify outstanding awards under our 2017 Plan. The administrator has the authority to reprice any outstanding option with the consent of any adversely affected participant.

*Corporate transactions.* Our 2017 Plan provides that in the event of certain specified significant corporate transactions, as defined under our 2017 Plan, our board may (1) arrange for the assumption, continuation or

substitution of an award by a successor corporation, or the acquiring corporation's parent company; (2) arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation, or the acquiring corporation's parent company; (3) accelerate the vesting, in whole or in part, of the award and provide for its termination prior to the transaction if not exercised prior to the effective time of the corporate transaction; (4) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us; (5) cancel or arrange for the cancellation of the award prior to the transaction in exchange for a cash payment, if any, determined by the board; or (6) make a payment in such form as determined by the board of directors equal to the excess, if any, of the per share amount (or value of property per share) payable to holders of Class A common stock over the per share exercise price under the applicable award. The administrator is not obligated to treat all awards or portions of awards, even those that are of the same type, in the same manner.

In the event of a change in control, as defined under our 2017 Plan, awards granted under our 2017 Plan will not receive automatic acceleration of vesting and exercisability, although this treatment may be provided for in an award agreement.

*Transferability*. Our board may impose limitations on the transferability of ISOs, NSOs and stock appreciation rights as the board will determine. Absent such limitations, a participant may not transfer awards under our 2017 Plan other than by will, the laws of descent and distribution or as otherwise provided under our 2017 Plan.

*Plan amendment or termination.* Our board has the authority to suspend or terminate our 2017 Plan at any time, provided that such action will not impair a participant's rights under such participant's outstanding award without his or her written consent. As described above, our 2017 Plan will be terminated upon the effective date of the 2021 Plan and no future awards will be granted under the 2017 Plan following such termination.

## 2021 Employee stock purchase plan

Our board of directors has adopted, and our stockholders have approved, our ESPP. Our ESPP became effective on May 13, 2021. The purpose of our ESPP is to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. Our ESPP includes two components. One component is designed to allow eligible U.S. employees to purchase our Class A common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. The other component permits the grant of purchase rights that do not qualify for such favorable tax treatment in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the U.S. while complying with applicable foreign laws.

*Share reserve.* The ESPP authorizes the issuance of 220,251 shares of our Class A common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our Class A common stock reserved for issuance will automatically increase on January 1<sup>st</sup> of each year for a period of 10 years, beginning on January 1, 2022 and continuing through January 1, 2031, by the lesser of (i) 1% of the total number of shares of our Class A common stock outstanding on December 31 of the immediately preceding year; and (ii) 440,502 shares, except before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii).

Administration. Our board of directors administers our ESPP and may delegate its authority to administer our ESPP to our compensation committee. Our ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our Class A common stock on specified dates during such offerings. Under our ESPP, our board of directors is permitted to specify offerings with durations of not more than 27 months and to specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our Class A common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

*Payroll deductions.* Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, will be eligible to participate in our ESPP and to contribute, normally through payroll deductions, up to a maximum percentage of their earnings (as defined in our ESPP) for the purchase of our Class A common stock under our ESPP. Unless otherwise determined by our board of directors, Class A common stock will be purchased for the accounts of employees participating in our ESPP at a price per share equal to the lesser of (i) 85% of the fair market value of a share of our Class A common stock on the first day of an offering; or (ii) 85% of the fair market value of a share of purchase.

*Limitations.* Employees may have to satisfy one or more of the following service requirements before participating in our ESPP, as determined by our board of directors: (i) being customarily employed for more than 20 hours per week; (ii) being customarily employed for more than five months per calendar year; or (iii) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee will be permitted to purchase shares under our ESPP at a rate in excess of \$25,000 worth of our Class A common stock (based on the fair market value per share of our Class A common stock at the beginning of an offering) for each calendar year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under our ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

*Changes to capital structure.* Our ESPP provides that in the event there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, our board of directors will make appropriate adjustments to: (i) the class(es) and maximum number of shares reserved under our ESPP; (ii) the class(es) and maximum number of shares by which the share reserve may increase automatically each year; (iii) the class(es) and number of shares subject to, and purchase price applicable to, outstanding offerings and purchase rights; and (iv) the class(es) and number of shares that are subject to purchase limits under ongoing offerings.

*Corporate transactions.* Our ESPP provides that in the event of a corporate transaction (as defined below), any then-outstanding rights to purchase our stock under our ESPP may be assumed, continued, or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our Class A common stock within 10 business days before such corporate transaction, and such purchase rights will terminate immediately after such purchase.

Under our ESPP, a "corporate transaction" is generally the consummation of (i) a sale or other disposition of all or substantially all of our assets; (ii) a sale or other disposition of at least 50% of our outstanding securities; (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation; or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our Class A common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Amendment or termination. Our board of directors has the authority to amend or terminate our ESPP, except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

## 401(k) Plan

We maintain a 401(k) plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees are able to defer eligible compensation up to certain Code limits, which are updated annually. We have the ability to make matching and discretionary contributions to the 401(k) plan. Currently, we do not make matching contributions or discretionary contributions to the 401(k) plan. The 401(k) plan is intended to be qualified under Section 401(a) of the Code, with the related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan are deductible by us when made, and contributions and earnings on those amounts are not generally taxable to the employees until withdrawn or distributed from the 401(k) plan.

## Limitations on liability and indemnification

Our amended and restated certificate of incorporation contains provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation authorizes us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding.

We believe that these amended and restated certificate of incorporation and amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

## Rule 10b5-1 plans

Our directors, officers and key consultant may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our Class A common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades under parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they do not possess of material nonpublic information, subject to compliance with the terms of our insider trading policy. During the first 90 days from this offering, the sale of any shares under such plan would be subject to the lock-up agreement that the director or officer has entered into with the underwriters.

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## Certain relationships and related person transactions

Other than compensation arrangements for our directors and executive officers, which are described elsewhere in this prospectus, below we describe transactions since January 1, 2019 and each currently proposed transaction in which:

- · the amounts involved exceeded or will exceed \$120,000; and
- any of our directors, executive officers or holders of more than 5% of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

## Participation in our initial public offering

Certain of our 5% stockholders and their affiliates purchased an aggregate of 3,883,078 shares of our Class A common stock in our IPO at the public offering price and on the same terms as the other purchasers in such offering and not pursuant to any pre-existing contractual rights or obligations. The following table sets forth the number of shares of our Class A common stock purchased by our then 5% stockholders and their affiliates, and the aggregate purchase price paid for such shares.

Name	Shares of class A common stock purchased	-	Igregate cash urchase price
Longitude Venture Partners IV, L.P.(1)	909,090	\$	9,999,990
Fidelity Management & Research Company LLC(2)	884,394		9,728,334
Abingworth Bioventures 8 LP(3)	772,727		8,499,997
Sofinnova Venture Partners X LP(4)	727,272		7,999,992
Surveyor Capital Management(5)	589,595		6,485,545
Total		\$	42,713,858

(1) Patrick Enright is a managing member of Longitude Capital Partners IV, LLC, the general partner of Longitude Venture Partners IV, L.P. and a member of our board of directors.

(2) Entities affiliated with Fidelity Management & Research Company LLC collectively beneficially own more than 5% of our outstanding capital stock.

(3) Kurt von Emster, C.F.A., is a managing partner at Abingworth Bioventures 8 LP and a member of our board of directors.

(4) Maha Katabi, Ph.D., is a general partner at Sofinnova Venture Partners X, L.P. and a member of our board of directors.

(5) Surveyor Capital Management is an affiliate of Citadel Multi-Strategy Equities Master Fund Ltd., the beneficial owner of more than 5% of our outstanding capital stock.

## 2020 convertible promissory note financing

From March 2020 to May 2020, we issued and sold convertible promissory notes (2020 Notes) in the aggregate principal amount of approximately \$5.6 million. The 2020 Notes accrued interest at a rate of 4% per annum. The aggregate principal amount and interest on the then-outstanding 2020 Notes converted into shares of our Series C convertible preferred stock (Series C preferred stock) in October 2020 in connection with our Series C convertible preferred stock financing (Series C preferred stock financing). Upon the closing of our IPO in May 2021, all shares of our Series C preferred stock converted into 15,774,013 shares of our Class A common stock.

The following table sets forth the principal amount and accrued interest of 2020 Notes purchased by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

Participants(1)	Principal amount and interest of 2020 notes
KPCB Holdings, Inc.(2)	\$ 3,073,314.91
GV 2019, L.P.(3)	\$ 2,048,876.44
Andrew K. Cheng, as Trustee of the Andrew Cheng 2010 Trust UA 10-26-2010(4)	\$ 101,928.43
James W. Fordyce, as Trustee of the James W. Fordyce 2005 Revocable Trust(5)	\$ 102,081.84
Walton, Mitchell & Co., Inc.(6)	\$ 102,060.21
BNY Mellon N.A., as Trustee of the Trust U/D/T William L. Mellon DTD 6/29/35 for James M. Walton(7)	\$ 10,182.74

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the caption "Principal stockholders."

(2) Beth Seidenberg, M.D., a member of our board of directors, is a partner of KPCB Holdings, Inc.

(3) Krishna Yeshwant, M.D., a member of our board of directors until October 2020, is a managing partner of GV 2019, L.P.

(4) Dr. Cheng is a member of our board of directors.

(5) Mr. Fordyce is an immediate family member of Dr. Fordyce, our President, Chief Executive Officer and a member of our board of directors.

(6) Mr. Walton, a member of our board of directors until October 2020, is affiliated with Walton, Mitchell & Co., Inc.

(7) Mr. Walton, a member of our board of directors until October 2020, is affiliated with BNY Mellon N.A., as Trustee of the Trust U/D/T William L. Mellon DTD 6/29/35 for James M. Walton.

## Series C preferred stock financing

In October 2020, we (1) issued and sold an aggregate of 168,756,599 shares of our Series C preferred stock at a purchase price of \$0.5918 per share, and (2) issued an aggregate of 11,404,246 shares of our Series C preferred stock upon conversion of the aggregate principal amount and interest on the then-outstanding 2020 Notes.

The following table summarizes the shares of our Series C preferred stock held by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

Participants(1)	Shares of series C preferred stock purchased for cash (#)		gregate cash ırchase price	Shares of series C preferred stock issued upon conversion of 2020 notes (#)
Abingworth Bioventures 8 LP(2)	25,346,400	\$14	,999,999.52	_
Entities affiliated with Fidelity(3)	25,346,400	\$14	,999,999.52	—
Longitude Venture Partners IV, L.P.(4)	25,346,400	\$14	,999,999.52	—
Sofinnova Venture Partners X, L.P.(5)	25,346,400	\$14	,999,999.52	_
Ares Trading S.A.(6)	22,171,553	\$	0(14)	
Citadel Multi-Strategy Equities Master Fund Ltd.(7)	16,897,600	\$ 9	9,999,999.68	_
GV 2019, L.P.(8)	3,379,520	\$ 1	,999,999.94	4,073,313
KPCB Holdings, Inc., as nominee(9)	3,379,520	\$ 1	,999,999.94	6,109,970
Andrew K. Cheng, as Trustee of the Andrew Cheng 2010 Trust UA 10-26-2010(10)	_		_	202,641
James W. Fordyce, as Trustee of the James W. Fordyce 2005 Revocable				
Trust(11)	253,464	\$	150,000	202,946
Walton, Mitchell & Co., Inc.(12)	84,488	\$	50,000	202,903
BNY Mellon N.A., as Trustee of the Trust U/D/T William L. Mellon DTD 6/29/35 for James M. Walton(13)	_		_	20,244

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the caption "Principal stockholders."

(2) Abingworth Bioventures 8 LP beneficially owns more than 5% of our outstanding capital stock. Kurt von Emster, C.F.A., is a managing partner at Abingworth Bioventures 8 LP and a member of our board of directors.

(3) Consists of (i) 631,285 shares of Series C preferred stock purchased by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund, (ii) 3,591,850 shares of Series C preferred stock purchased by Fidelity Mt. Vernon Street Trust: Fidelity 3,612,515 shares of Series C preferred stock purchased by Fidelity Growth Company Fund, (iii) 3,612,515 shares of Series C preferred stock purchased by Fidelity Growth Company Commingled Pool, (iv) 613,150 shares of Series C preferred stock purchased by Fidelity Select Portfolios: Biotechnology Portfolio, and (vi) 8,448,800 shares of Series C preferred stock purchased by Fidelity Select Portfolios: Biotechnology Portfolio, and (vi) 8,448,800 shares of Series C preferred stock purchased by Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund. These entities beneficially own more than 5% of our outstanding capital stock.

(4) Longitude Venture Partners IV, L.P. beneficially owns more than 5% of our outstanding capital stock. Patrick Enright is a managing member of Longitude Capital Partners IV, LLC, the general partner of Longitude Venture Partners IV, L.P. and a member of our board of directors.

(5) Sofinnova Venture Partners X, L.P. beneficially owns more than 5% of our outstanding capital stock. Maha Katabi, Ph.D., is a general partner at Sofinnova Venture Partners X, L.P. and a member of our board of directors.

(6) Ares Trading S.A. beneficially owns more than 5% of our outstanding capital stock.

(7) Citadel Multi-Strategy Equities Master Fund Ltd. beneficially owns more than 5% of our outstanding capital stock.

(8) Krishna Yeshwant, M.D., a member of our board of directors until October 2020, is a managing partner of GV 2019, L.P.

(9) Beth Seidenberg, M.D., a member of our board of directors, is a partner of KPCB Holdings, Inc.

(10) Dr. Cheng is a member of our board of directors

(11) Mr. Fordyce is an immediate family member of Dr. Fordyce, our President, Chief Executive Officer and a member of our board of directors.

(12) Mr. Walton, a member of our board of directors until October 2020, is affiliated with Walton, Mitchell & Co., Inc.

(13) Mr. Walton, a member of our board of directors until October 2020, is affiliated with BNY Mellon N.A., as Trustee of the Trust U/D/T William L. Mellon DTD 6/29/35 for James M. Walton.

(14) The shares of Series C preferred stock issued to Ares Trading S.A. were partial consideration for the license agreement entered into simultaneously with the sale and issuance of the Series C convertible preferred stock

## Employment agreements and stock option grants to directors and executive officers

We have entered into employment agreements with certain of our named executive officers, and granted stock options to our named executive officers and certain of our directors, as more fully described in the sections titled "Executive compensation" and "Management—Non-employee director compensation."

## License agreement

On October 29, 2020, we entered into the Ares Agreement, an exclusive worldwide license agreement with Ares, an affiliate of Merck KGaA, Darmstadt, Germany. Under the Ares Agreement, Ares granted us an exclusive license to certain patents and certain related know-how to research, develop, manufacture, use and commercialize throughout the world therapeutic products containing atacicept or any other compound that is covered by a claim of such patents. In consideration for the rights granted under the Ares Agreement, we issued to Ares an aggregate of 22,171,553 shares of Series C redeemable convertible preferred stock, we paid Ares \$25 million upon delivery and initiation of the transfer of specified information and materials and we are obligated to pay Ares certain clinical, regulatory and commercial milestone payments, sublicensing revenue payments and royalty payments on future sales of licensed products. Upon the closing of our IPO in May 2021, all shares of our Series C preferred stock converted into 15,774,013 shares of our Class A common stock. For more information regarding the license agreement see "Business—Exclusive license agreement with Ares Trading S.A."

## Consulting services agreement with Dr. Kotzin

In February 2021, we entered into a consulting services agreement with BLKotzin, Inc., an entity affiliated with our former director, Brian Kotzin, M.D., pursuant to which Dr. Kotzin provides certain consulting services to us. We pay Dr. Kotzin for his services at a rate of \$400 per hour up to a maximum of \$40,000 per year.

## Consulting services agreement with Dr. Ebens

In March 2021, we entered into a consulting services agreement with Allen Ebens, Ph.D., our former Chief Scientific Officer, pursuant to which Dr. Ebens provides certain consulting services to us. We pay Dr. Ebens for his services at a rate of \$350 per hour up to a maximum of \$300,000 per year. In addition, pursuant to the agreement, we granted Dr. Ebens an option covering 38,405 shares of our Class A common stock.

## Investors' rights agreement

In October 2020, we entered into a Second Amended and Restated Investors' Rights Agreement (Rights Agreement) with certain holders of more than 5% of our outstanding capital stock, including Abingworth Bioventures 8 LP, Ares Trading S.A., entities affiliated with Fidelity, Citadel Multi-Strategy Equities Master Fund Ltd., GV 2019, L.P., KPCB Holdings, Inc., Longitude Venture Partners IV, L.P. and Sofinnova Venture Partners X, L.P., and including certain affiliates of our directors.

The Rights Agreement granted to the holders of our outstanding redeemable convertible preferred stock certain rights, including certain registration rights with respect to the registrable securities held by them. See the section titled "Description of capital stock—Registration rights" for additional information. In addition, the Rights Agreement imposed certain affirmative obligations on us, including our obligation to, among other things, (i) grant each holder who holds shares of our redeemable convertible preferred stock with an aggregate original issue price of at least \$4.6 million (Major Investors), a right of first offer with respect to future sales of our equity, excluding the shares to be offered and sold in this offering, and grant certain information and

inspection rights to such Major Investors. Each of these obligations terminated in connection with the closing of our IPO in May 2021, except for the registration rights, as more fully described below in "Description of capital stock—Registration rights".

## Voting agreement

In October 2020, we entered into the Voting Agreement with certain holders of more than 5% of our outstanding capital stock, including Abingworth Bioventures 8 LP, Ares Trading S.A., entities affiliated with Fidelity, Citadel Multi-Strategy Equities Master Fund Ltd., GV 2019, L.P., KPCB Holdings, Inc., Longitude Venture Partners IV, L.P. and Sofinnova Venture Partners X, L.P., and including certain affiliates of our directors.

Pursuant to the Voting Agreement, each of Abingworth Bioventures 8 LP, Longitude Venture Partners IV, L.P. and Sofinnova Venture Partners X, L.P. formerly had the right to designate one member to be elected to our board of directors. See the section titled "Management—Composition of our board of directors." The Voting Agreement terminated by its terms in connection with the closing of our IPO in May 2021 and none of our stockholders have any continuing rights regarding the election or designation of members of our board of directors.

## **Right of first refusal and Co-Sale agreement**

In October 2020, we entered into a Second Amended and Restated Right of First Refusal and Co-Sale Agreement (Co-Sale Agreement) with certain holders of more than 5% of our outstanding capital stock, including Abingworth Bioventures 8 LP, Ares Trading S.A., entities affiliated with Fidelity, Citadel Multi-Strategy Equities Master Fund Ltd., GV 2019, L.P., KPCB Holdings, Inc., Longitude Venture Partners IV, L.P. and Sofinnova Venture Partners X, L.P., and including certain affiliates of our directors.

Pursuant to the Co-Sale Agreement, we formerly had a right of first refusal in respect of certain sales of securities by certain holders of our common stock and redeemable convertible preferred stock. To the extent we do not exercise such right in full, the investors party to the Co-Sale Agreement were granted certain rights of first refusal and co-sale in respect of such sale. The Co-Sale Agreement terminated in connection with the closing of our IPO in May 2021.

## Policies and procedures for transactions with related persons

We maintain a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the approval or ratification of our board of directors or our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds \$120,000 (or, if less, 1% of the average of our total assets in a fiscal year) and such person would have a direct or indirect interest, must be presented to our board of directors or our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our board of directors or our audit committee is to consider the material facts of the transaction, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

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# **Principal stockholders**

The following table sets forth information regarding beneficial ownership of our capital stock as of December 15, 2021 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our Class A common stock;
- · each of our directors;
- · each our of named executive officers; and
- · all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership before the offering is based on 20,968,376 shares of our Class A common stock outstanding and 309,238 shares of our Class B common stock outstanding as of December 15, 2021, including 4,137 shares of our unvested restricted Class A common stock subject to repurchase as of such date.

Applicable percentage ownership after the offering is based on assumed to be outstanding immediately after the closing of this offering, including shares of our unvested restricted Class A common stock subject to repurchase as of such date, and assuming no exercise by the underwriters of their option to purchase additional shares and no purchase of any shares of Class A common stock in this offering by the beneficial owners identified in the table below. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to options held by the person that are currently exercisable, or exercisable within 60 days of December 15, 2021. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Vera Therapeutics, Inc., 8000 Marina Boulevard, Suite 120, Brisbane, California 94005.

	Number of shares beneficially owned before the offering		Percentage of shares beneficially owned before the offering		shares beneficially owned after the offering	
Name of beneficial owner	Class A common stock	Class B common stock	Class A common stock	Class B common stock	Class A common stock	Class B common stock
5% Stockholders:	otook		010011	otoon		otoon
Abingworth Bioventures 8 LP(1)	2,960,231		14.1%			_
Entities affiliated with Fidelity(2)	3,071,896		14.7%			
Longitude Venture Partners IV, L.P.(3)	3,096,594	_	14.8%	_		_
Sofinnova Venture Partners X, L.P.(4)	2,914,776		13.9%	_		_
Ares Trading S.A.(5)	1,913,501	_	9.1%	_		_
Citadel Multi-Strategy Equities Master Fund Ltd.(6)	1,740,019	309,328	8.3%	100%		
KPCB Holdings, Inc., as nominee(7)	1,343,152	·	6.4%			—
Directors and Named Executive Officers:						
Marshall Fordyce, M.D.(8)	440,103	_	2.1%	_		_
Sean Grant	_	_	_	_		
Celia Lin, M.D.	_	_	_	_		_
Kurt von Emster, C.F.A.(1)	2,960,231	_	14.1%	_		_
Andrew Cheng, M.D., Ph.D.(9)	46,063	—	*	—		_
Beth Seidenberg, M.D.(7)(10)	1,368,084	—	6.5%	—		—
Maha Katabi, Ph.D.(4)	2,914,776	—	13.9%	—		_
Patrick Enright(3)	3,096,594	—	14.8%	—		—
Scott Morrison(11)	24,932	_	*	_		
Kimball Hall(12)	1,102	—	*	—		—
All directors and executive officers as a group (11 persons) (13)	10,905,905	_	51.0%	_		_

\* Represents beneficial ownership of less than 1%.

(1) Consists of 2,960,231 shares of Class A common stock held by Abingworth Bioventures 8, LP (ABV 8) and excludes options to purchase up to 9,925 shares of Class A common stock issued to Mr. von Emster which vest on the earlier of May 13, 2022 or the Company's 2022 annual meeting of stockholders. Abingworth Bioventures 8 GP LP (Abingworth GP) serves as the general partner of ABV 8. Abingworth General Partner 8 LLP serves as the general partner of ABV 8 (acting by its general partner Abingworth General Partner 8 LLP) has delegated to Abingworth LLP, all investment and vispositive power over the securities held by ABV 8. Mr. Von Emster is a member of the investment committee of Abingworth LLP, which approves investment and voting decisions by a super majority vote, and no individual member has the sole control or voting power over the shares held by ABV 8. Each of ABV 8, Abingworth LLP, Abingworth GP, Abingworth General Partner 8 LLP, and each member of the investment committee disclaims beneficial ownership of the shares held by ABV 8. The address for ABV 8 is c/o Abingworth LLP, 38 Jermyn Street, London, SW1Y 6DN, UK. The foregoing information was obtained from a Schedule 13D filed on May 18, 2021.

(2) Consists of 3,071,896 shares of Class A common stock beneficially owned, or that may be deemed to be beneficially owned, by FMR LLC, certain of its subsidiaries and affiliates, and other companies. Abigail P. Johnson is a Director, the Chairman, the Chief Executive Officer and the President of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B sotences have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company (FMR Co), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity

Funds' Boards of Trustees. The address of FMR LLC is 245 Summer Street, V13H, Boston, Massachusetts 02110. The foregoing information was obtained from a Schedule 13G filed on June 10, 2021.

- (3) Consists of 3,096,594 shares of Class A common stock held by Longitude Venture Partners IV, L.P. (LVP IV). Longitude Capital Partners IV, LLC (LCP IV), is the general partner of LVP IV and may be deemed to have voting and investment power over the shares held by LVP IV. Patrick Enright and Juliet Tammenoms Bakker are managing members of LCP IV and may be deemed to share voting and investment power over the shares held by LVP IV. Each of LCP IV, Ms. Bakker and Mr. Enright disclaims beneficial ownership of such shares except to the extent of their respective pecuniary interests therein. The address for this entity is 2740 Sand Hill Road, 2nd Floor, Menlo Park, CA 94025. The foregoing information was obtained from a Schedule 13D filed on May 27, 2021.
- (4) Consists of 2,914,776 shares of Class A common stock held by Sofinnova Venture Partners X, L.P. (SVP X). Sofinnova Management X, L.L.C. (SM X), is the general partner of SVP X. As such, each of James Healy, Maha Katabi and Michael Powell, the managing members of SM X, may be deemed to have shared voting and dispositive power over the shares owned by SVP X. The address for this entity is c/o Sofinnova Investments, 3000 Sand Hill Road, Building 4-Suite 250, Menlo Park, CA 94025. The foregoing information was obtained from a Schedule 13D filed on May 24, 2021.
- (5) Consists of 1,913,501 shares of Class A common stock held by Ares Trading S.A. The address for this entity is c/o Merck KGaA, Frankfurter Straße 250, 64293 Darmstadt, Germany, Attn: Alliance Management.
- (6) Consists of 1,715,149 shares of Class A common stock and 309,238 shares of Class B common stock held by Citadel Multi-Strategy Equities Master Fund Ltd. (Citadel). The Class B common stock is convertible into Class A common stock in Citadel's discretion but subject to the limitations described below under "Description of capital stock." Citadel Advisors LLC (Citadel Advisors) is the portfolio manager of Citadel. Citadel Advisors Holdings LP (CAH) is the sole member of Citadel Advisors. Citadel GP LLC (CGP) is the general partner of CAH. Kenneth Griffin owns a controlling interest in CGP. Mr. Griffin, as the owner of a controlling interest in CGP, may be deemed to have shared power to vote or direct the vote of, and/or shared power to dispose or to direct the disposition over, the shares held by Citadel. The foregoing should not be construed as an admission that Mr. Griffin or any of the Citadel related entities is the beneficial owner of any of our securities other than the securities actually owned by such person (if any). The address for this entity is 131 S Dearborn St, 32nd Floor, Chicago, IL 60603. The foregoing information was obtained from a Schedule 13G filed on May 28, 2021.
- (7) Consists of 1,298,695 shares of Class A common stock held by Kleiner Perkins Caufield & Byers XVI, LLC (KPCB XVI) and 44,457 shares of Class A common stock held by KPCB XVI Founders Fund, LLC (XVI Founders). All shares are held for convenience in the name of "KPCB Holdings, Inc., as nominee". The managing member of KPCB XVI is KPCB XVI Associates, LLC (KPCB XVI Associates). L. John Doerr, Beth Seidenberg, Randy Komisar, Theodore E. Schlein and Wen Hsieh, the managing members of KPCB XVI Associates, exercise shared voting and dispositive control over the shares held by KPCB XVI. Such managing members disclaim beneficial ownership of all shares held by KPCB XVI except to the extent of their pecuniary interest therein. The foregoing information was obtained from a Form 4 filed on May 13, 2021. The address for KPCB Holdings Inc. is c/o Kleiner Perkins Caufield & Byers, LLC, 2750 Sand Hill Road, Menlo Park, CA 94025.
- (8) Consists of (i) 133,793 shares of Class A common stock held directly by Dr. Fordyce and (ii) 306,310 shares of Class A common stock subject to options exercisable within 60 days of December 15, 2021 held by Dr. Fordyce.
- (9) Consists of (i) 17,488 shares of Class A common stock held by Dr. Cheng, as trustee of the Andrew Cheng 2010 Trust UA 10-26-2010 and (ii) 28,575 shares of Class A common stock subject to options exercisable within 60 days of December 15, 2021 held by Dr. Cheng.
- (10) Consists of 24,932 shares of Class A common stock subject to options exercisable within 60 days of December 15, 2021 held by Dr. Seidenberg.
- (11) Consists of 24,932 shares of Class A common stock subject to options exercisable within 60 days of December 15, 2021 held by Mr. Morrison.
- (12) Consists of 1,102 shares of Class A common stock subject to options exercisable within 60 days of December 15, 2021 held by Ms. Hall.
- (13) Consists of (i) 10,489,767 shares of Class A common stock beneficially owned by our current executive officers and directors, and (ii) 416,138 shares of Class A common stock subject to options exercisable within 60 days of December 15, 2021.

# **Description of capital stock**

## General

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws. Copies of these documents have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part.

Our authorized capital stock consists of 500,000,000 shares of Class A common stock, par value \$0.001 per share, 14,600,000 shares of Class B common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share. All of our authorized shares of preferred stock are undesignated.

## **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 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 will be 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, will be 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, removal of directors, director liability, vacancies on our board of directors, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

### Economic rights

Except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law, and other than the voting rights and conversion rights stated above, all shares of Class A common stock and Class B common stock will have the same rights and privileges and rank equally, share ratably, and be 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. See the section titled "Dividend policy" for further information.

*Liquidation Rights.* On our liquidation, dissolution, or winding-up, the holders of 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 our shares of 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.

#### Fully paid and non-assessable

In connection with this offering, our legal counsel will opine that the shares of our Class A common stock to be issued under this offering will be fully paid and non-assessable.

## **Preferred stock**

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.

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. 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 may adversely affect the market price of the Class A common stock and the voting and other rights of the holders of Class A common stock. We have no current plans to issue any shares of preferred stock.

## **Registration rights**

Certain holders of shares of our Class A common stock and Class B common stock are entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our amended and restated investors' rights agreement and are described in additional detail below. The registration of shares of our Class A common stock and Class B common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will expire no later than three years after the closing of our IPO.

## Demand registration rights

Certain holders of our Class A common stock and Class B common stock are entitled to certain demand registration rights. The holders of (i) 40% of these shares issued upon conversion of our Series C redeemable convertible preferred stock, or (ii) a majority of these shares, may request that we register all or a portion of their shares. We are not required to effect more than two registration statements which are declared or ordered effective. With respect to (ii), such request for registration must cover a majority of such shares then outstanding with an anticipated aggregate offering price that would exceed \$10 million. With certain exceptions, we are not required to effect the filing of a registration statement during the period starting with the date that is 60 days before the date of the filing of, and ending on a date 180 days following the effective date of the registration statement for this offering.

### Piggyback registration rights

In connection with this offering, certain holders of our Class A common stock and Class B common stock are entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering. In addition, in the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the holders of these shares will be entitled to certain piggyback registration rights allowing the holder to include their shares in such registration, subject to certain marketing and other limitations.

#### Form S-3 registration rights

Certain holders of Class A common stock and Class B common stock are entitled to certain Form S-3 registration rights. Holders of (i) shares issued upon conversion of our Series C redeemable convertible preferred stock with an aggregate original issue price of \$500,000, or (ii) 20% of these shares, can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 and, with respect to (ii), if the reasonably anticipated aggregate net proceeds of the shares offered would equal or exceed \$3 million. With respect to (ii), we will not be required to effect more than two registrations on Form S-3 within any 12-month period.

#### 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 to be in effect in connection with this offering

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 will be able to elect all of our directors. Our amended and

restated certificate of incorporation and our amended and restated bylaws provide for stockholder actions at a duly called meeting of stockholders or, before the date on which all shares of Class A common stock convert into a single class, by written consent. 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.

As described above in "Management—Composition of 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

When we have a class of voting stock that is either listed on a national securities exchange or held of record by more than 2,000 stockholders, we will be subject to Section 203 of the 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 (or, if and only if the Court of Chancery of the State of Delaware (or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our 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 against us or any of action against us or any of our current or former directors, officers, or other employees 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, 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 will 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.

Our amended and restated certificate of incorporation provides that the federal district courts of the United States of America 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 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.

## Limitations on liability and indemnification

See the section titled "Executive compensation-Limitations on liability and indemnification."

## **Exchange listing**

Our Class A common stock is listed on the Nasdaq Global Market under the symbol "VERA."

## Transfer agent and registrar

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

## Certain material U.S. federal income tax consequences to non-U.S. holders

The following is a summary of certain material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our Class A common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local or foreign tax laws, or any other U.S. federal tax laws. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the Internal Revenue Service (IRS), all as in effect on the date of this prospectus. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our Class A common stock pursuant to this offering and who hold our Class A common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to an individual non-U.S. holder in light of such non-U.S. holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to non-U.S. holders subject to special rules under the U.S. federal income tax laws, including:

- · certain former citizens or long-term residents of the United States;
- partnerships or other pass-through entities (and investors therein);
- "controlled foreign corporations";
- "passive foreign investment companies";
- corporations that accumulate earnings to avoid U.S. federal income tax;
- · banks, financial institutions, investment funds, insurance companies, brokers, dealers or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons who acquire our Class A common stock through the exercise of an option or otherwise as compensation;
- qualified foreign pension funds as defined in Section 897(I)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- · persons subject to the alternative minimum tax;
- · persons subject to special tax accounting rules under Section 451(b) of the Code;
- · persons that own or have owned, actually or constructively, more than 5% of our Class A common stock;
- · persons who have elected to mark securities to market; and

• persons holding our Class A common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our Class A common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Partnerships holding our Class A common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our Class A common stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR CLASS A COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.

### Definition of non-U.S. holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our Class A common stock that is not a "U.S. holder" or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. holder is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- · an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

### **Distributions on our Class A common stock**

As described under the section titled "Dividend policy," we do not anticipate declaring or paying, in the foreseeable future, any cash distributions on our capital stock. However, if we distribute cash or other property on our Class A common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's tax basis in our Class A common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our Class A common stock and will be treated as described under the section titled "—Gain on disposition of our Class A common stock" below.

Subject to the discussions below regarding effectively connected income, backup withholding and FATCA (as defined below), dividends paid to a non-U.S. holder of our Class A common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our withholding agent with a valid IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in

the case of entities), or other appropriate form, certifying such holder's qualification for the reduced rate. This certification must be provided to us or our withholding agent before the payment of dividends and must be updated periodically. In the case of a non-U.S. Holder that is an entity, Treasury Regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of the tax treaty, dividends will be treated as paid to the entity or to those holding an interest in the entity. If the non-U.S. holder holds our Class A common stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our withholding agent, either directly or through other intermediaries.

If a non-U.S. holder holds our Class A common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our Class A common stock are effectively connected with such holder's U.S. trade or business (and are attributable to such holder's permanent establishment or fixed base in the United States if required by an applicable tax treaty), the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent.

However, any such effectively connected dividends paid on our Class A common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

## Gain on disposition of our Class A common stock

Subject to the discussions below regarding backup withholding and FATCA (as defined below), a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our Class A common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if required by an
  applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United
  States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our Class A common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation (USRPHC) for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our Class A common stock, and our Class A common stock is not regularly traded on an established securities market during the calendar year in which the sale or other disposition occurs.

Determining whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We believe that we are not currently and we do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. Gain described in the third bullet point above will generally be subject to U.S. federal income tax in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

## Information reporting and backup withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the distributions on our Class A common stock paid to such holder and any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required because the distributions were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our Class A common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or certain other requirements are met, and if the payor does not have actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

## Withholding on foreign entities

Sections 1471 through 1474 of the Code, which are commonly referred to as FATCA, impose a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our Class A common stock and would have applied also to payments of gross proceeds from the sale or other disposition of our Class A common stock. The U.S. Treasury Department has released proposed regulations under FATCA providing for the elimination of the federal withholding tax of 30%

applicable to gross proceeds of a sale or other disposition of our Class A common stock. Under these proposed Treasury Regulations (which may be relied upon by taxpayers prior to finalization), FATCA will not apply to gross proceeds from sales or other dispositions of our Class A common stock.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our Class A common stock.

## Underwriting

We are offering the shares of Class A common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Cowen and Company, LLC and Evercore Group L.L.C. are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of Class A common stock listed next to its name in the following table:

	Number of
Name	Shares
J.P. Morgan Securities LLC	
Cowen and Company, LLC	
Evercore Group L.L.C.	
Total	

The underwriters are committed to purchase all the Class A common shares offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the Class A common shares directly to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to \$ per share from the public offering price. After the initial offering of the shares to the public, if all of the Class A common shares are not sold at the public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to additional shares of Class A common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares of Class A common stock are purchase shares in approximately the same proportion as shown in the table above. If any additional shares of Class A common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of Class A common stock less the amount paid by the underwriters to us per share of Class A common stock. The underwriting fee is \$ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per Share	\$	\$
Total	\$	\$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the SEC a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exercisable or exchangeable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, loan, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC, Cowen and Company, LLC and Evercore Group L.L.C. for a period of 90 days after the date of this prospectus, other than the shares of our common stock to be sold in this offering.

The restrictions on our actions, as described above, do not apply to certain transactions, including (i) the issuance of shares of common stock or securities convertible into or exercisable for shares of our common stock pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options (including net exercise) or the settlement of RSUs (including net settlement), in each case outstanding on the date of the underwriting agreement and described in this prospectus; (ii) grants of stock options, stock awards, restricted stock, RSUs, or other equity awards and the issuance of shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock (whether upon the exercise of stock options or otherwise) to our employees, officers, directors, advisors, or consultants pursuant to the terms of an equity compensation plan in effect as of the closing of this offering and described in this prospectus, provided that such recipients enter into a lock-up agreement with the underwriters; (iii) the issuance of up to 5% of the outstanding shares of our common stock, or securities convertible into, exercisable for, or which are otherwise exchangeable for, our common stock, immediately following the closing of this offering, in acquisitions or other similar strategic transactions, provided that such recipients enter into a lock-up agreement with the underwriters; or (iv) our filing of any registration statement on Form S-8 relating to securities granted or to be granted pursuant to an acquisition or similar strategic transaction.

Our directors and executive officers, and certain of our significant shareholders (such persons, the "lock-up parties") have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 90 days after the date of this prospectus (such period, the "restricted period"), may not (and may not cause any of their direct or indirect affiliates to), without the prior written consent of J.P. Morgan Securities LLC, Cowen and Company, LLC and Evercore Group L.L.C., (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other

securities which may be deemed to be beneficially owned by such lock-up parties in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant (collectively with the common stock, the "lock-up securities")), (2) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of lock-up securities, in cash or otherwise, (3) make any demand for, or exercise any right with respect to, the registration of any lock-up securities, or (4) publicly disclose the intention to do any of the foregoing. Such persons or entities have further acknowledged that these undertakings preclude them from engaging in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer (by any person or entity, whether or not a signatory to such agreement) of any economic consequences of ownership, in whole or in part, directly or indirectly, of any lock-up securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including: (i) transactions relating to the lock-up securities acquired in this offering or in open market transactions after the completion of this offering, provided that no filing under the Exchange Act or other public disclosure shall be required or shall be voluntarily made during the restricted period in connection with subsequent sales of Class A common stock or other securities acquired in such open market transactions during the restricted period, other than any required filing under Section 13 of the Exchange Act; (ii) transfers of lock-up securities by gift, including, without limitation, to a charitable organization, or by will or intestate succession to the legal representative, heir or beneficiary of the lock-up party or any family member, or to a trust whose beneficiaries consist exclusively of one or more of the lock-up party and/or a family member; provided, however, that such transfer is not for consideration: (iii) transfers or dispositions of the lock-up securities to a corporation, partnership, limited liability company or other entity, all of the beneficial ownership interests of which, in each case, are held by the lock-up party or any family member; (iv) transfers of the lock-up securities by operation of law pursuant to a qualified domestic order or other court order or in connection with a divorce settlement; (v) if the lock-up party is a corporation, partnership, limited liability company, trust or other business entity, distributions or transfers of the lock-up securities to (x) another corporation, partnership, limited liability company, trust or other business entity that is a direct or indirect affiliate (as defined in Rule 405 promulgated under the Securities Act) of the lock-up party, (y) any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the lock-up party or affiliates of the lock-up party (including, for the avoidance of doubt, where the lock-up party is a partnership, to its general partner or a successor partnership or fund, or any other funds man-aged by such partnership), or (z) limited partners, general partners, members, managers, managing members, stockholders or other equity holders of the lock-up party or of the entities described in the preceding clauses (x) and (y); (vi) transfers or dispositions of Class A common stock or Class B common stock to us as forfeitures (x) to satisfy tax withholding and remittance obligations of the lock-up party in connection with the vesting or exercise of equity awards granted pursuant to our equity incentive plans or (y) pursuant to a net exercise or cashless exercise by the stockholder of outstanding equity awards pursuant to our equity incentive plans; provided, however, that in each case, any such equity incentive plans exist as of the date of the underwriting agreement and are described in this prospectus; (vii) transfers of the lock-up securities pursuant to a change of control of the company (meaning the consummation of any bona fide third party tender offer, merger, consolidation or other similar transaction made to all holders of Class A common stock the result of which is that any "person" (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, becomes the beneficial owner (as defined in

Rules 13d-3 and 13d-5 of the Exchange Act) of more than 50% of the voting capital stock of the company) after this offering that has been approved by the independent members of our board of directors, provided, that in the event that such change of control is not completed, the lock-up securities owned by the lock-up party shall remain subject to the restrictions described herein; or (viii) transfers of the lock-up securities arising as a result of the termination of employment of the lock-up party to us pursuant to agreements that are in effect as of the date of the underwriting agreement for this offering and disclosed in the prospectus, under which we have the option to repurchase such lock-up securities or a right of first refusal with respect to transfers of such lock-up securities.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

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

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of Class A common stock in the open market for the purpose of preventing or retarding a decline in the market price of the Class A common stock while this offering is in progress. These stabilizing transactions may include making short sales of Class A common stock, which involves the sale by the underwriters of a greater number of shares of Class A common stock than they are required to purchase in this offering, and purchasing shares of Class A common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the Class A common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the Class A common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase Class A common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the Class A common stock or preventing or retarding a decline in the market price of the Class A common stock, and, as a result, the price of the Class A common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdag Stock Market, in the over-the-counter market or otherwise.

In addition, in connection with this offering certain of the underwriters (and selling group members) may engage in passive market making transactions in our Class A common stock on the Nasdaq Stock Market prior to the pricing and completion of this offering. Passive market making consists of displaying bids on the Nasdaq Stock Market no higher than the bid prices of independent market makers and making purchases at prices no higher than these independent bids and effected in response to order flow. Net purchases by a passive market

maker on each day are generally limited to a specified percentage of the passive market maker's average daily trading volume in the Class A common stock during a specified period and must be discontinued when such limit is reached. Passive market making may cause the price of our Class A common stock to be higher than the price that otherwise would exist in the open market in the absence of these transactions. If passive market making is commenced, it may be discontinued at any time.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

#### Canada

#### (A) Resale Restrictions

The distribution of the securities in Canada is being made only in the provinces of Ontario, Quebec, Alberta, British Columbia, Manitoba, New Brunswick and Nova Scotia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the securities in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the securities.

#### (B) Representations of Canadian Purchasers

By purchasing the securities in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the securities without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106—Prospectus Exemptions or Section 73.3(1) of the Securities Act (Ontario), as applicable,
- the purchaser is a "permitted client" as defined in National Instrument 31-103—Registration Requirements, Exemptions and Ongoing Registrant Obligations,
- · where required by law, the purchaser is purchasing as principal and not as agent, and
- · the purchaser has reviewed the text above under Resale Restrictions.

#### (C) Conflicts of Interest

Canadian purchasers are hereby notified that certain of the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105 – Underwriting Conflicts from having to provide certain conflict of interest disclosure in this document.

#### (D) Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

#### (E) Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

#### (F) Taxation and Eligibility for Investment

Canadian purchasers of the securities should consult their own legal and tax advisors with respect to the tax consequences of an investment in the securities in their particular circumstances and about the eligibility of the securities for investment by the purchaser under relevant Canadian legislation.

#### Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia (Corporations Act), has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

A. You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.



B. You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

#### European Economic Area

In relation to each Member State of the European Economic Area (each, a Relevant State), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which have been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant State at any time:

(a) to any legal entity which is a "qualified investor" as defined under Article 2 of the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression "offer to the public" in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

#### United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and

other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

#### Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong (SFO) and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong (CO) or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

#### Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (Securities Law) and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum (Addendum) to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

#### Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended) (FIEL), and the underwriters will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used

herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

#### Singapore

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the securities may not be circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (SFA), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the notes pursuant to an offer made under Section 275 of the SFA except:

- (i) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (ii) where no consideration is or will be given for the transfer;
- (iii) where the transfer is by operation of law;
- (iv) as specified in Section 276(7) of the SFA; or
- (v) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

#### Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

## Legal matters

Cooley LLP will pass upon the validity of the shares of our Class A common stock being offered in this prospectus. Goodwin Procter LLP will pass upon certain legal matters in connection with this offering.

## Experts

The financial statements of Vera Therapeutics, Inc. as of December 31, 2019 and 2020, and for each of the years in the two-year period ended December 31, 2020, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

## Where you can find additional information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of Class A common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our Class A common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

We also maintain a website at www.veratx.com. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our Class A common stock. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference.

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# Vera Therapeutics, Inc. Condensed balance sheets

(unaudited) (In thousands, except share data)

	Sep	otember 30 <u>,</u>	Dec	cember 31,	
		2021		2020	
Assets					
Current assets:					
Cash and cash equivalents	\$	86,191	\$	53,654	
Restricted cash, current		_		50	
Prepaid expenses and other current assets		3,569		557	
Total current assets		89,760		54,261	
Restricted cash, noncurrent		293		293	
Non-marketable equity securities		1,114			
Total assets	\$	91,167	\$	54,554	
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)					
Current liabilities:					
Accounts payable	\$	964	\$	909	
Restructuring liability, current		367		962	
Accrued expenses and other current liabilities		2,711		535	
Total current liabilities		4,042		2,406	
Restructuring liability, noncurrent		1,362		1,634	
Accrued and other noncurrent liabilities		286		286	
Total liabilities		5,690		4,326	
Commitments and contingencies (Note 12)					
Redeemable convertible preferred stock, \$0.001 par value; 0 and 182,772,372 shares authorized, issued and outstanding as of September 30, 2021 and December 31, 2020, respectively				139,576	
Stockholders' equity (deficit)					
Preferred stock, \$0.001 par value; 10,000,000 and 0 shares authorized as of September 30, 2021 and					
December 31, 2020, respectively; no shares issued and outstanding as of September 30, 2021 and					
December 31, 2020		—			
Class A common stock, \$0.001 par value; 500,000,000 and 273,986,920 shares authorized as of September 30,					
2021 and December 31, 2020, respectively; 20,968,376 and 355,296 shares issued and outstanding as of					
September 30, 2021 and December 31, 2020, respectively		21			
Class B non-voting common stock, \$0.001 par value; 14,600,000 and 21,593,607 shares authorized as of					
September 30, 2021 and December 31, 2020, respectively; 309,238 and 0 shares issued and outstanding as					
of September 30, 2021 and December 31, 2020, respectively Additional paid-in capital		192,665		2,099	
Additional paid-in capital		(107,209)		(91,447	
		85,477		(89,348	
Total stockholders' equity (deficit)	¢	,	¢		
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	\$	91,167	\$	54,554	

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

# Vera Therapeutics, Inc. Condensed statements of operations and comprehensive loss

(unaudited)

(In thousands, except per share data)

		N	line months ended September 30,
		2021	2020
Operating expenses:			
Research and development	\$	9,731	\$ 5,362
General and administrative		8,086	2,903
Restructuring costs			1,416
Total operating expenses		17,817	9,681
Loss from operations		(17,817)	(9,681
Other income (expense):			
Interest income		9	6
Interest expense			(151
Gain on issuance of convertible notes			63
Change in fair value of convertible notes			(775
Change in fair value of non-marketable equity securities		(645)	
Gain on sale of PNAi technology		2,691	
Total other income (expense)		2,055	(857
Net loss and comprehensive loss	\$	(15,762)	\$ (10,538
Net loss per share attributable to common stockholders, basic and diluted		\$ (1.46)	\$ (32.64
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	1(	),793,436	322,811

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

## Vera Therapeutics, Inc. Condensed statements of redeemable convertible preferred stock and stockholders' equity (Deficit) For the nine months ended September 30, 2021

(unaudited)

(in thousands, except share data)

	Redeemable convertible preferred stock		Class A	Class A common stock		scommon stock	Additional paid-in	Accumulated	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	(Deficit)
Balance 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		_	_	_	_	_	2,050	_	2,050
Net loss		—		_			_	(15,762)	(15,762)
Balances as of September 30, 2021	_	_	20,968,376	21	309,238	_	192,665	(107,209)	85,477

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

## Vera Therapeutics, Inc. Condensed statements of redeemable convertible preferred stock and stockholders' equity (Deficit) For the nine months ended September 30, 2020

(unaudited)

(in thousands, except share data)

	Redeemable convertible preferred Additional stock Common stock paid-in Accumulated									sto	Total ckholders'
	Shares	Amount	Shares	Amount		capital defic		deficit	t defic		
Balance as of December 31, 2019	14,015,773	\$40,095	322,007	\$ —	\$	1,486	\$	(38,034)	\$	(36,548)	
Issuance of common stock upon											
exercise of options	_	_	4,045	_		23				23	
Stock-based compensation	_	_	_	_		188				188	
Net loss		—	—	—		—		(10,538)		(10,538)	
Balances as of September 30, 2020	14,015,773	40,095	326,052	_		1,697		(48,572)		(46,875)	

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

## Vera Therapeutics, Inc. Condensed statements of cash flows (unaudited) (in thousands)

Nine months ended September 30, 2021 2020 Cash flows from operating activities Net loss \$ (15,762) \$(10,538) Adjustments to reconcile net loss to net cash used in operating activities: Depreciation, amortization and accretion 144 893 Impairment loss on property and equipment and intangible asset 1,185 Stock-based compensation 2,050 188 Restructuring payments (875) (88) Non-cash interest expense on convertible notes 125 Issuance costs for convertible notes 24 Gain on issuance of convertible notes (63) Gain on sale of PNAi technology (2,691)Change in fair value of convertible notes 775 Change in fair value of non-marketable equity securities 645 Changes in operating assets and liabilities: Prepaid expense and other current assets (3,012) (6) Accounts payable 55 (3)Accrued and other current liabilities 2,176 264 Other liabilities (183) Net cash used in operating activities (17, 270)(7, 427)Cash flows from investing activities Proceeds from sale of PNAi technology 796 \_\_\_\_ Purchase of property and equipment (99) 796 Net cash provided by (used in) investing activities (99) Cash flows from financing activities Proceeds from exercise of stock options 550 23 Proceeds from issuance of convertible notes 5,602 Proceeds from issuance of Class A common stock upon initial public offering, net of underwriting discounts and commissions 51,176 Payment of offering costs related to initial public offering (2,765)Payment issuance costs related to convertible promissory notes (24)Payment on capital lease obligations (112)Net cash provided by financing activities 48.961 5.489 Net increase (decrease) in cash and cash equivalents and restricted cash 32.487 (2,037)Cash, cash equivalents and restricted cash, beginning of period 53,997 3,558 Cash, cash equivalents and restricted cash, end of period \$ 86,484 \$ 1,521 Reconciliation of cash and cash equivalents and restricted cash to the balance sheets Cash and cash equivalents \$ 86,191 \$ 1,451 Restricted cash 293 70 Total cash and cash equivalents and restricted cash \$ 86,484 \$ 1,521 Supplemental disclosure of cash flow information Cash paid for interest \$ \$ 21 Reclassification of redeemable convertible preferred stock into common stock upon initial public offering \$139,576 \$ Non-marketable equity securities received as partial proceeds from sale of PNAi technology \$ 1,759 \$ Lease assignment 136 \$ \$

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

# Vera Therapeutics, Inc. Notes to unaudited condensed financial statements

(Amounts in thousands, except share and per share data)

## 1. Organization and description of the business

## Description of business

Vera Therapeutics, Inc., (the "Company") is a late-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases. The Company is headquartered in South San Francisco, California and was incorporated in May 2016 in Delaware. In 2017, the Company acquired all of the outstanding shares of PNA Innovations, Inc. ("PNAi"), which was based in Woburn, Massachusetts.

## 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 unaudited condensed 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 \$48,411 from the IPO, after deducting underwriting discounts and commissions of \$3,852, and offering costs of \$2,765. Prior to the completion of the IPO, all shares of redeemable convertible preferred stock then outstanding were converted into 15,464,775 shares of Class A common stock and 309,238 shares of Class B common stock.

#### Liquidity

Since inception, the Company has been primarily performing research and development activities, establishing and maintaining its intellectual property, hiring personnel and raising capital to support and expand these operations. The Company has incurred recurring net operating losses since its inception and had an accumulated deficit of \$107,209 as of September 30, 2021. The Company had cash and cash equivalents of \$86,191 as of September 30, 2021, and has not generated positive cash flow from operations. The Company has funded its operations primarily through the issuance of common stock, redeemable convertible preferred stock and convertible notes.

Management believes that the Company's cash and cash equivalents as of September 30, 2021, will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance

date of these unaudited condensed financial statements. While the Company believes that its current cash and cash equivalents are adequate to meet its needs for the next 12 months, the Company will need to raise additional capital in order to achieve its longer-term business objectives.

## 2. Basis of presentation and significant accounting policies

#### Basis of presentation

The accompanying unaudited condensed 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 interim financial reporting. The U.S. dollar is the Company's functional and reporting currency.

#### Unaudited interim condensed financial statements

The accompanying condensed balance sheet as of September 30, 2021, and condensed statements of operations and comprehensive loss, condensed statements of cash flows, and condensed statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the nine months ended September 30, 2021 and 2020, are unaudited. The balance sheet as of December 31, 2020, was derived from the audited financial statements as of and for the year ended December 31, 2020. The unaudited condensed financial statements have been prepared on a basis consistent with the audited annual financial statements as of and for the year ended December 31, 2020 and in the opinion of management, reflect all adjustments consisting solely of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2021, and the condensed results of its operations and its cash flows for the nine months ended September 30, 2021, are also unaudited. The condensed results of operations for the nine months ended September 30, 2021, are also unaudited. The condensed results of operations for the nine months ended September 30, 2021, are also unaudited. The condensed results of operations for the nine months ended September 30, 2021, are also unaudited. The condensed results of operations for the nine months ended September 30, 2021, are also unaudited. The condensed results of operations for the nine months ended September 30, 2021, are also unaudited. The condensed results of operations for the nine months ended September 30, 2021, are also unaudited. The condensed results of operations for the nine months ended September 30, 2021, are also unaudited. The condensed results of operations for the nine months ended September 30, 2021, are also unaudited. The condensed results of operations for the nine months ended September 30, 2021, are also unaudited. The condensed results of operations for the nine months ended September 30, 2021, are also unaudited in conjunction with the Company's

#### Emerging growth company status

The Company is an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (1) is no longer an emerging growth company or (2) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these unaudited condensed 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 unaudited condensed 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 unaudited condensed financial statements and the reported amounts of expenses during the reporting period. Management estimates that affect the reported amounts of assets and liabilities include the accrual of research and development expenses, restructuring liabilities, fair value of common stock and stock-based compensation expense, and the valuation allowance for deferred tax assets. The Company evaluates and adjusts its estimates and assumptions on an ongoing basis using historical experience and other factors. Actual results could differ materially from those estimates.

#### Deferred offering costs

Deferred offering costs consisting of legal, accounting and filing fees relating to the IPO are capitalized. The deferred offering costs were offset against the Company's IPO proceeds upon the closing of the IPO.

#### 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 and cash equivalents. 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 and cash equivalents to the extent recorded in the balance sheet. The Company has not experienced any losses on its deposits of cash and cash equivalents.

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's product candidates require approvals from the U.S. Food and Drug Administration and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed, or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company.

#### Impact of the COVID-19 pandemic

The COVID-19 pandemic continues to evolve. The extent of the impact of the COVID-19 pandemic on the Company's business, operations, and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on the Company's development activities, planned clinical trial enrollment, future trial sites, contract research organizations, third-party manufacturers, and other third parties with whom the Company does business, as well as its impact on regulatory authorities and the Company's key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, the Company is conducting business as usual, with necessary or advisable modifications to employee travel and with the Company's employees working remotely. The Company will continue to actively monitor the evolving situation related to the COVID-19 pandemic and may take further actions that alter the Company's operations, including those that may be required by federal, state or local authorities, or that the Company determines are in the best interests of its employees and other third parties with whom the Company does business. At this point, the extent to which the COVID-19 pandemic may affect the Company's business,

operations and development timelines and plans, including the resulting impact on expenditures and capital needs, remains uncertain.

#### 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 and as collateral for a credit card, which are classified within current and non-current assets on the condensed balance sheets.

#### **Comprehensive loss**

Comprehensive loss consists of net loss and other gains and losses affecting redeemable convertible preferred stock and stockholders' equity (deficit) that, under U.S. GAAP, are excluded from net loss. The Company has no items of other comprehensive loss for the nine months ended September 30, 2021 and 2020. As such, net loss equals comprehensive loss.

#### 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.

#### 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.

#### Redeemable convertible preferred stock

The Company records all shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The carrying value of the Company's redeemable convertible preferred

stock is adjusted to reflect dividends if and when declared by the Company's board of directors. No dividends have been declared by the board of directors since inception. The Company classifies its redeemable convertible preferred stock separate from total stockholders' equity (deficit), as the redemption of such stock is not solely under the control of the Company.

#### Stock-based compensation

The Company recognizes compensation expense based on estimated fair values for all stock-based payment awards made to the Company's employees, nonemployee directors and consultants that are expected to vest. The valuation of stock option awards is determined at the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the Company to make assumptions and judgements about the inputs used in the calculations, such as the fair value of the common stock, expected term, expected volatility of the Company's common stock, risk-free interest rate and expected dividend yield. The valuation of restricted stock awards is measured by the fair value of the Company's 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.

The fair value of the shares of common stock underlying the stock options has historically been 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.

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

The Company did not record an income tax provision for the nine months ended September 30, 2021 and 2020 as net operating losses have been incurred since inception. The net deferred tax assets generated from net operating losses are fully offset by a valuation allowance.

#### 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.

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

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, adjusted for outstanding shares that are subject to repurchase.

Diluted net loss per share is computed by giving effect to all potentially dilutive securities outstanding for the period using the treasury stock method or the if-converted method based on the nature of such securities. For periods in which the Company reports net losses, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, because potentially dilutive shares are not assumed to have been issued if their effect is anti-dilutive.

#### Leases

The Company leases office and laboratory space under operating leases and laboratory equipment under capital leases. Leases for which the Company assumes substantially all risks and rewards incidental to ownership of the leased assets are classified as capital leases. The leased assets and the corresponding lease liabilities (net of interest charges) are recognized on the balance sheet as property and equipment, based on the cost of the equipment, and borrowings, respectively, at the inception of the related lease. Each lease payment is apportioned between the reduction of the outstanding lease liability and the related interest expense. The interest expense is recorded on a basis that reflects a constant periodic rate of interest on the outstanding finance lease liability.

Leases for which substantially all risks and rewards incidental to ownership are retained by the lessors are classified as operating leases. Payments made under operating leases (net of any incentive received from the lessors) are recorded on a straight-line basis over the period of the lease.

#### **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.

#### Fair value option

The convertible notes issued in 2020, for which the Company elected the fair value option, are accounted for at fair value on a recurring basis with changes in fair value recognized in the statement of operations and comprehensive loss. Interest accrued on the convertible notes was recorded to interest expense during the periods in which the convertible notes were outstanding.

#### 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.

The carrying amounts of the Company's cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair value due to their short-term nature.

Money market funds are highly liquid investments that are actively traded. The pricing information for the Company's money market funds are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

The Company's non-marketable equity securities (Note 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 September 30, 2021, and December 31, 2020, the Company held \$84,810 and \$52,301, respectively, in money market funds with no unrealized gains or losses.

#### Recently adopted accounting pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* The standard simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The Company adopted this standard as of January 1, 2021. The adoption of this standard did not have a material impact on its unaudited condensed financial statements.

On June 20, 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, to reduce cost and complexity and to improve financial reporting for share-based payments issued to nonemployees (for example, service providers, external legal counsel, suppliers, etc.). This includes allowing for the measurement of awards at the grant date and recognition of awards with performance conditions when those conditions are probable, both of which are

earlier than under current guidance for nonemployee awards. The Company adopted this standard as of January 1, 2020 on a retrospective basis. The adoption of this standard did not have a material impact on its unaudited condensed financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which amends ASC 820, Fair Value Measurement. This standard modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. The Company adopted this standard as of January 1, 2020 on a retrospective basis. The adoption of this standard did not have a material impact on its unaudited condensed financial statements.

#### Recently issued accounting pronouncements

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. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. 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 existing guidance for operating leases today. The Company intends to use the modified retrospective approach to adopt this standard effective January 1, 2022. Additionally, the Company intends to use the package of available practical expedients, which allows it to (i) not reassess whether any expired or existing contracts are or contain leases; (ii) not reassess the lease classification for expired or existing leases; and (iii) not reassess the treatment of initial direct costs for any existing leases. The Company is currently evaluating the impact this standard will have on its financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The objective of the standard is to provide information about expected credit losses on financial instruments at each reporting date and to change how other-than temporary impairments on investment securities are recorded. The guidance is effective for the Company beginning on January 1, 2023, with early adoption permitted. The Company is currently evaluating the impact the standard may have on its financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40). This standard simplifies the accounting for convertible debt instruments and convertible preferred stock by removing the existing guidance in ASC 470-20 that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. ASU 2020-06 is effective for the Company for annual reporting periods, and interim reporting periods within those annual periods, beginning after December 15, 2023, and early adoption is permitted. The Company is currently evaluating the impact this standard will have on its financial statements and related disclosures.

## 3. Other financial statement information

#### Prepaid expense and other current assets

Prepaid expenses and other current assets consist of the following.

	Sept	ember 30, 2021	Decei	nber 31, 2020
Prepaid insurance	\$	1,837	\$	27
Prepaid contract costs		889		_
Deposits		57		86
Receivables on exercise of options		—		52
Other		786		392
Total prepaid expenses and other current assets	\$	3,569	\$	557

#### Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following.

	Septer	September 30,		mber 31,
	-	2021		2020
Accrued payroll	\$	1,051	\$	405
Related party payable		994		
Accrued expenses and other		666		130
Total accrued expenses and other current liabilities	\$	2,711	\$	535

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 11).

### 4. Neubase asset sale

On January 27, 2021, the Company entered into an asset purchase agreement with NeuBase Therapeutics, Inc. ("NeuBase"), whereby the Company agreed to sell all assets relating to its investment in PNAi, including all inventory, machinery, intellectual property, goodwill, and licenses, and NeuBase agreed to assume certain related liabilities. The sale of the Company's investment in PNAi closed on April 26, 2021. The Company received \$796 in cash and 308,635 shares of NeuBase common stock, with a fair market value of \$1,759 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 were placed in escrow to secure certain obligations under the asset purchase agreement. In connection with the sale, the Company also assigned certain leases for research and laboratory equipment to NeuBase (see Note 13). The Company recognized a gain of \$2,691 on the sale of assets to NeuBase.

As of September 30, 2021, there were 54,070 shares eligible for release from escrow. Per the terms of the agreement, the shares may be released from escrow upon the execution of a joint instruction letter.

### 5. Non-marketable equity securities

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

The Company recorded a cumulative net unrealized loss of \$645 in other expense for the nine months ended September 30, 2021. The carrying value is measured as the total initial cost, less the cumulative net unrealized loss. The carrying value of the non-marketable equity securities as of September 30, 2021, is summarized below.

Initial cost as of April 26, 2021	\$1,759
Change in fair value	(645)
Balance as of September 30, 2021	\$1,114

## 6. Convertible notes

In March 2020, the Company issued convertible notes to certain existing investors of the Company for cash. The principal amount of the convertible notes was \$5,000 in the aggregate with a fixed accrued interest rate of 4% per annum. The convertible notes were either due on or after December 31, 2020, or upon a change of control of the Company, unless earlier converted. No principal or interest was payable prior to maturity as the convertible notes and any accrued interest would automatically convert upon a qualified financing event at a conversion price equal to 85% of the price per share of the qualified financing. Holders also had the option to convert their notes to shares of Series B redeemable convertible stock at a conversion price equal to \$4.2926 per share on the maturity date or upon a change of control of the Company, if no qualified financing occurred prior to such date.

Due to certain embedded features within the convertible notes, the Company elected to account for the convertible notes under the fair value option.

In April and May 2020, the Company issued additional convertible notes to certain existing investors of the Company for cash. The principal amount of the convertible notes was \$602 in the aggregate with the same terms as the convertible notes issued in March 2020.

In October 2020, the outstanding principal and accrued interest of \$134, were automatically converted into 11,404,246 shares of the Company's Series C redeemable convertible preferred stock in connection with the closing of the Company's Series C redeemable convertible preferred stock financing (see Note 7) at a conversion price of \$0.5030 per share, which was 85% of the \$0.5918 original issuance price of the Series C redeemable convertible preferred stock.

## 7. Redeemable convertible preferred stock

As of December 31, 2020, the Company's redeemable convertible preferred stock consisted of the following balances.

	Issue price per share	Shares authorized	Shares issued and outstanding	Carrying value	Aggregate liquidation preference
Series Seed	\$1.01	1,010,456	1,010,456	\$ 1,789	\$ 1,020
Series Seed-1	1.92	1,787,640	1,787,640	3,718	3,430
Series A	2.15	6,120,111	6,120,111	12,851	13,136
Series B	4.29	5,097,566	5,097,566	21,737	21,882
Series C	0.59	168,756,599	168,756,599	99,481	99,870
Total		182,772,372	182,772,372	\$ 139,576	\$ 139,338

In October 2020, the Company issued 135,180,800 shares of Series C redeemable convertible preferred stock for a purchase price of \$0.5918 per share, payable in cash. Gross proceeds to the Company were \$80,000. The Series C redeemable convertible preferred stock financing triggered the automatic conversion of the Company's outstanding convertible notes into 11,404,246 shares of Series C redeemable convertible preferred stock based on price of \$0.5030 per share (85% of the \$0.5918 original issuance price of the Series C redeemable convertible preferred stock). In addition, the Company issued 22,171,553 shares of Series C redeemable convertible preferred stock to Ares as the initial payment for the Company's license of atacicept from Ares (see Note 11).

In May 2021, immediately prior to the completion of the IPO (see Note 1), all outstanding shares of redeemable convertible preferred stock were automatically converted into 15,774,014 shares of common stock.

## 8. Common stock

As of September 30, 2021, the Company's certificate of incorporation, as amended and restated, 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 September 30, 2021, no cash dividends have been declared or paid.

## 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 220,251 and 2,213,773 shares of Class A common stock for future 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 September 30, 2021, there were 1,510,665 shares available for issuance under the 2021 EIP.

### 2017 EIP and 2021 EIP

Stock option activity under the 2017 EIP and 2021 EIP was as follows:

	Number of options	ave exe pric	hted- erage ercise e per share	Weighted averag remaining contractua life (years	e ) 	Aggregate intrinsic alue (000s)
Balance—December 31, 2020	1,855,507	\$	2.99	9.79	9 \$	8
Granted	1,188,064		8.98			
Exercised	(145,805)		3.77			
Cancelled and forfeited	(3,095)		9.38			
Balance—September 30, 2021	2,894,671		5.43	9.3	5\$	34,521
Options exercisable—September 30, 2021	82,944		3.42	8.9	5 \$	1,155
Vested and expected to vest—September 30, 2021	2,894,671	\$	5.43	9.3	5 \$	34,521

The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2021, was \$206. The weightedaverage grant date fair value of options granted during the nine months ended September 30, 2021, was \$6.66 per share.

#### ESPP

The ESPP enables eligible employees to purchase shares of the Company's 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 September 30, 2021, no shares have been issued pursuant to the ESPP. The ESPP generally provides for six-month consecutive offering periods beginning on September 14, 2021. The ESPP is a compensatory plan as defined by the authoritative guidance for stock compensation. As such, stock-based compensation expense has been recorded for the nine months ended September 30, 2021.

#### Stock-based compensation expense

The following tables summarize the stock-based compensation expense for stock options and restricted stock awards granted to employees and nonemployees that was recorded in the Company's statements of operations and comprehensive loss for the nine months ended September 30, 2021 and 2020.

	Nine months ended September 30,		
	 2021		2020
Research and development	\$ 606	\$	4
General and administrative	1,444		184
Total stock-based compensation expense	\$ 2,050	\$	188

	 Nine months ended September 30,		
	2021		2020
Employees	\$ 1,878	\$	182
Nonemployees	172		6
Total stock-based compensation expense	\$ 2,050	\$	188

As of September 30, 2021, the Company had \$10,348 of unrecognized stock-based compensation expense related to unvested stock options and restricted stock awards, which is expected to be recognized over a weighted-average period of approximately 3.15 years.

The fair value of stock options granted during the nine months ended September 30, 2021 and 2020 was estimated using the Black-Scholes option pricing model based on the following weighted average assumptions.

		Nine months ended September 30,	
	2021	2020	
Expected term (in years)	5.5 – 6.1	5.5 – 6.1	
Expected volatility	75.4% – 76.6%	74.0% - 75.7%	
Risk-free rate	0.6% - 1.1%	0.4% - 1.7%	
Dividend yield	—	—	

#### Restricted stock awards

In October 2020, in conjunction with the Series C redeemable convertible preferred stock issuance, 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 allows the Company to repurchase shares that have not vested. The vesting term of restricted stock is one year. The grant date fair value of the restricted shares was \$6.37.

The following table summarizes the activity for the Company's restricted stock for the nine months ended September 30, 2021.

	Number of shares
Unvested as of December 31, 2020	41,363
Vested	(37,226)
Unvested as of September 30, 2021	4,137

For the nine months ended September 30, 2021, the Company recognized \$236 of stock-based compensation expense related to restricted stock awards that vested during the period.

## 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. There were no employer contributions under this plan for the nine months ended September 30, 2021.

### 11. Licenses and collaborations

#### Yale University

In 2017, PNAi entered into a collaborative research agreement (the "Yale CRA") and license agreement (the "Yale License Agreement") with Yale University, which were assigned to the Company upon the closing of the acquisition of PNAi by the Company in 2017. The purpose of the agreements was to fund the Yale University research program in the field of nanoparticle-sized nucleic acid mimics and peptide nucleic acids as gene editing therapeutics in return for an exclusive license to certain related patent rights owned by Yale University and the option to license any patents discovered or generated under the terms of the collaborative research agreement.

The Yale CRA required funding the labs of collaborators with \$1,500 per year for a minimum of two years. The Yale CRA expired in 2019. No payments were made to Yale University pursuant to the Yale CRA during the year ended December 31, 2019 with no future obligation under this commitment.

As consideration for the Yale License Agreement, PNAi paid an initial fee of \$37 and had the option to issue 5% of the company's common stock on a fully diluted, as converted basis. If the shares were not issued, the agreement could be terminated at Yale University's option. After the completion of the merger with PNAi, the Company exercised the option and issued 264,301 shares of common stock to Yale University with a fair value of \$100. Under the Yale License Agreement, the Company reimbursed Yale University for patent related expenses. The Company reimbursed Yale University \$45 for patent related expenses for the year ended December 31, 2019. The Company and Yale agreed to terminate the Yale License Agreement in 2020 and there are no future payment obligations under the Yale License Agreement.

#### Ares trading S.A.

In October 2020, the Company entered into a license agreement with Ares (the "Ares Agreement"), pursuant to which the Company obtained an exclusive worldwide license to certain patents and related know-how to research, develop, manufacture, use and commercialize therapeutic products containing atacicept, a recombinant fusion protein used to inhibit B cell growth and differentiation, which could potentially treat some autoimmune diseases.

As consideration for the Ares Agreement, the Company issued to Ares a non-refundable license issue fee of 22,171,553 shares of Series C redeemable convertible preferred stock resulting in Ares becoming a related party to the Company. The Series C redeemable convertible preferred stock had a deemed issuance price of \$0.5918 per share, or \$13,121 in the aggregate.

In December 2020, the Company paid Ares \$25,000 in milestone payments 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 \$176,500 upon the achievement of specified BLA filing or regulatory approval milestones and up to \$515,000 upon the achievement of specified commercial milestones.

The non-refundable license issue fee of \$13,121 and milestone payments of \$25,000 were recorded to research and development expense.

Ares is performing manufacturing technology and know-how transfer to the Company over a period not to exceed two years from the effective date of the Ares Agreement. The Company recorded related party expense of \$1,256 due to Ares for these services during the nine months ended September 30, 2021.

Commencing on the first commercial sale of licensed products, the Company is obligated to pay Ares tiered royalties of low double-digit to mid-teen percentages on annual net sales of the licensed products covered by the license. The Company is obligated to pay royalties on a licensed product-by- licensed product and country-by-country basis from the first commercial sale of a product in a country until the latest of (i) 15 years after the first commercial sale of such licensed product in such country; (ii) the expiration of the last valid claim of a licensed patent that covers such licensed product in, or its use, importation or manufacture with respect to, such country; and (iii) expiration of all applicable regulatory exclusivity periods, including data exclusivity, in such country with respect to such product. If the Company were to sublicense its rights under the Ares Agreement, the Company is obligated to pay Ares a percentage ranging from the mid single-digit to the low double-digits of specified sublicensing income received.

### 12. Commitments and contingencies

The aggregate future minimum lease payments for operating leases as of September 30, 2021, are as follows.

	 erating ases(1)	Sublease income	
2021 (remaining 3 months)	\$ 587	\$ (462)	
2022	2,381	(1,901)	
2023	2,458	(1,964)	
2024	2,537	(2,029)	
2025	1,953	(1,569)	
Total payments	\$ 9,916	\$ (7,925)	

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

#### Facilities leases

In April 2015, PNAi entered a lease for approximately 3,800 square feet of office and laboratory space for a term of 39 months in Woburn, Massachusetts. In January 2018, the Company elected to renew this lease for three years, beginning in August 2018. This lease expired in July 2021.

In April 2018, the Company entered into a lease for approximately 24,606 square feet of office and life science research space, which commenced on October 1, 2018, when the Company obtained control of the rented space for a term of 84 months in South San Francisco, California ("the South San Francisco Lease"). In connection with the South San Francisco Lease, the Company maintains a letter of credit issued to the lessor in the amount of \$293, which is secured by restricted cash that is classified as noncurrent based on the term of the underlying lease.

The Company's total future minimum commitment due pursuant to the South San Francisco Lease is \$9,916 as of September 30, 2021. In November 2020, the Company entered into a non-cancellable sublease agreement for the facility, under the terms of which the Company is entitled to receive \$7,925 in sublease payments over the term of the sublease, which ends concurrently with the original lease in September 2025. As tenant, the Company remains responsible for the \$9,916 minimum lease commitment on the facilities.

The Company recorded rent expense totaling \$1,605 for the nine months ended September 30, 2020. No rent expense was recorded for the nine months ended September 30, 2021.

#### Equipment lease

The Company had certain leases on research and laboratory equipment which were assigned to a certain third party as of September 30, 2021. The Company recorded rent expense totaling \$256 for the nine months ended September 30, 2020. No rent expense was recorded for the nine months ended September 30, 2021.

## 13. Restructuring and related activities

During the year ended December 31, 2019, the Company completely vacated its leased facilities in Woburn, Massachusetts. In connection with vacating the leased spaces, the Company recorded a discounted lease-related restructuring liability, which was calculated as the present value of the estimated future facility costs for which the Company would obtain no future economic benefit over the term of the lease, reduced for actual or estimated sublease rentals.

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 \$2,228 and \$768 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 \$321 related to severance and other employee termination costs related to the reduction in the number of employees.

The activity related to the restructuring liabilities for the nine months ended September 30, 2021, is as follows.

		e-related		ployee	
	е	xit costs	term	ination	Total
Balance as of December 31, 2020		2,584		12	2,596
Accretion		116			116
Provision		28			28
Cash payments		(863)		(12)	(875)
Lease assignment to NeuBase		(136)			(136)
Balance as of September 30, 2021	\$	1,729	\$	—	\$1,729

# 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).

		Nine months ended September 30,	
=		2020	
Redeemable convertible preferred stock	_	1,209,599	
Class A common stock options issued and outstanding	2,894,671	164,588	
Unvested restricted stock awards	4,137		
Total	2,898,808	1,374,187	

# 15. Related party transactions

In October 2018, the Company entered into a sublease agreement for a portion of its South San Francisco office space, the term for which commenced on December 7, 2018. The Chief Executive Officer of the sublessor is a member of the Company's board of directors. The initial sublease was established for approximately 400 square feet of space. Prior to the initial expiration of the sublease in April 2019, the space was expanded to approximately 3,700 square feet with the term of the lease extended for an additional two years. The monthly rent charged by the Company to the subtenant is subject to escalating rent payments according to the terms of the Company's lease agreement, and the subtenant is required to reimburse the Company for monthly facility operating expenses based on its proportionate share of total square footage pursuant to the lease. The Company's lease agreement provides that 50% of any profit resulting from the excess of the amount collected from the subtenant less the sum of monthly rent, operating expenses and reimbursement of direct expenditures made by the Company in order to arrange and maintain the sublease is to be shared with the

lessor. To date, no profit has been realized on the sublease arrangement as the monthly collections from the subtenant are equivalent to the Company's cost of rent, operating expense and recovery of professional fees to arrange the sublease. In June 2020, the sublease agreement was terminated. During the nine months ended September 30, 2020, the Company recognized \$160 of sublease income under this agreement, which was recorded as a reduction to the Company's rent expense.

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 (See Note 3 and Note 11).

# 16. Subsequent events

In November 2021, the Company entered into a lease agreement for approximately 5,000 square feet of office space in Brisbane, California. The term of the lease is three years, and rent will be approximately \$288 for the first year with scheduled annual 3% increases. The lease includes renewal options for the Company.

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. ("Pfizer"), under which it acquired MAU868, a monoclonal antibody that was under development by Amplyx for the treatment of BK virus infections. MAU868 is subject to a license agreement between Amplyx and Novartis Pharma AG, as successor in interest to Novartis International Pharmaceutical AG ("Novartis"). Under the Amplyx Agreement, the Company obtained a worldwide, exclusive license from Novartis to develop, manufacture and commercialize MAU868. The Company also assumed certain liabilities of Amplyx. In partial consideration for the Amplyx Agreement, the Company made an upfront initial payment of \$5.0 million to Amplyx. The Company may also be obligated to make certain milestone payments to Amplyx in an aggregate amount up to \$7.0 million based on certain regulatory milestones, and may be required to pay Amplyx low-single digit percentage royalties based on net sales if MAU868 is successfully commercialized. The Company may also be 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, and may be required to pay Novartis mid- to high-single digit royalties based on net sales if MAU868 is successfully commercialized.

In December 2021, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC (the "Lender") as lender and collateral agent. The Loan Agreement provides for a term loan in an aggregate maximum principal amount of \$50.0 million (the "Loan"), of which \$5.0 million was funded in December 2021, and the balance of which is available to be drawn at the Company's option in minimum draws of \$5.0 million during 2022. The Loan matures in December 2026, which may be extended by 12 months subject to certain clinical data milestones. The Company is required to make monthly interest-only payments for 48 months, which may be extended to 60 months if the final maturity date is extended. Initially, the Loan bears interest at 8.254%, with a floating interest rate tied to LIBOR. The Company is permitted to prepay the loan, subject to certain conditions. Upon the maturity date or prepayment of the Loan, the Company is required to make a final payment equal to 5.0% (or 7.0% if the maturity date is extended) of the aggregate principal amount of the Loan. The Loan Agreement does not contain any financial covenants and the Loan is secured by the Company's assets.

# **Report of Independent Registered Public Accounting Firm**

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

# **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Vera Therapeutics, Inc. (the Company) as of December 31, 2019 and 2020, the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2020, 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, 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020, 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. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2018.

San Francisco, California March 19, 2021, except as to note 15B, which is as of May 10, 2021

# Vera Therapeutics, Inc. Balance sheets

(In thousands, except share amounts)

		December		31,	
		2019		2020	
Assets					
Current assets:					
Cash and cash equivalents	\$	3,195	\$	53,654	
Restricted cash, current				50	
Prepaid expenses and other current assets		370		557	
Total current assets		3,565		54,261	
Restricted cash, noncurrent		363		293	
Property and equipment, net		1,394			
Other assets		59			
Total assets	\$	5,381	\$	54,554	
Liabilities, redeemable convertible preferred stock, and stockholders' deficit					
Current liabilities:					
Accounts payable	\$	342	\$	909	
Capital lease payable, current		122		2	
Restructuring liability, current		173		962	
Accrued expenses and other current liabilities		423		533	
Total current liabilities		1,060		2,406	
Capital lease payable, noncurrent		10			
Restructuring liability, noncurrent		—		1,634	
Accrued and other noncurrent liabilities		764		286	
Total liabilities		1,834		4,326	
Commitments and contingencies (Note 11)					
Redeemable convertible preferred stock, \$0.001 par value; 15,907,207 and 182,772,372 shares					
authorized as of December 31, 2019 and 2020, respectively; 14,015,773 and 182,772,372 shares					
issued and outstanding as of December 31, 2019 and 2020, respectively		40,095	1	139,576	
Stockholders' deficit					
Class A common stock, \$0.001 par value; 23,000,000 and 273,986,920 shares authorized as of					
December 31, 2019 and 2020, respectively; 322,007 and 355,296 shares issued and outstanding as					
of December 31, 2019 and 2020, respectively					
Class B non-voting common stock, \$0.001 par value; no shares and 21,593,607 shares authorized as					
of December 31, 2019 and 2020, respectively; no shares issued and outstanding as of December 31,					
2019 and 2020, respectively		_			
Additional paid-in capital		1,486		2,099	
Accumulated deficit		(38,034)		(91,447	
Total stockholders' deficit	(	(36,548)		(89,348	
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	\$	5,381	\$	54,554	

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

# Vera Therapeutics, Inc. Statements of operations and comprehensive loss

(In thousands)

	Year ( Decem	ended ber 31,
	2019	2020
Operating expenses:		
Research and development	\$ 7,290	\$ 45,206
General and administrative	4,410	4,039
Restructuring costs	261	2,996
Total operating expenses	11,961	52,241
Loss from operations	(11,961)	(52,241)
Other income (expense):		
Interest income	159	8
Interest expense	(51)	(166)
Gain on issuance of convertible notes	—	63
Change in fair value of convertible notes		(1,076)
Total other income (expense)	108	(1,171)
Loss before provision for income taxes	\$ (11,853)	\$ (53,412)
Provision for income taxes	(1)	(1)
Net loss and comprehensive loss	\$ (11,854)	\$ (53,413)
Net loss per share attributable to common stockholders, basic and diluted	\$ (40.14)	\$ (166.93)
Weighted-average common shares outstanding, basic and diluted	295,328	319,963

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

# Vera Therapeutics, Inc.

# Statements of redeemable convertible preferred stock and stockholders' deficit

(In thousands, except share amounts)

	Redeem convert preferred	tible	Commo	on stock	Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	capital	deficit	deficit
Balance as of December 31, 2018	14,015,773	\$ 40,095	312,082	\$ —	\$ 1,172	\$ (26,180)	\$ (25,008)
Issuance of Class A common stock upon exercise of options	_	—	9,925	_	51	_	51
Stock-based compensation	—	—	—	—	263	—	263
Net loss		—		_	_	(11,854)	(11,854)
Balance as of December 31, 2019	14,015,773	40,095	322,007	_	1,486	(38,034)	(36,548)
Issuance of Class A common stock upon exercise of options	_	_	33,289	_	282	_	282
Issuance of Series C redeemable convertible preferred stock, net of							
issuance costs of \$389	135,180,800	79,611	_	_	_	_	—
Issuance of Series C redeemable convertible preferred stock upon extinguishment of convertible notes	11,404,246	6,749	_	_	_	_	_
Issuance of Series C redeemable convertible preferred stock for license	22.171.553	13.121	_	_	_	_	_
Stock-based compensation				_	331		331
Net loss	_	—	_	_	_	(53,413)	(53,413)
Balance as of December 31, 2020	182,772,372	\$139,576	355,296	\$ —	\$ 2,099	\$ (91,447)	\$ (89,348)

The accompanying notes are an integral part of these financial statements

# Vera Therapeutics, Inc. Statements of cash flows

(In thousands)

	Year ended December 31	
	2019	2020
Cash flows from operating activities		
Net loss	\$(11,854)	\$(53,413)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	509	251
Impairment loss on property and equipment and intangible assets	10	1,185
Loss on disposal of property and equipment	94	—
Stock-based compensation	263	331
Issuance of Series C redeemable convertible preferred stock for license	_	13,121
Restructuring costs, net of cash paid	173	2,423
Non-cash interest expense on convertible notes	_	134
Issuance costs for convertible notes	—	23
Gain on issuance of convertible notes		(63)
Change in fair value of convertible notes	—	1,076
Changes in operating assets and liabilities:		(
Prepaid expense and other current assets	320	(135)
Other assets	(19)	59
Grants receivable	159	
Accounts payable	(291)	567
Accrued and other current liabilities	60	110
Other liabilities	287	(478)
Net cash used in operating activities	(10,289)	(34,809)
Cash flows from investing activities		
Purchase of property and equipment	(125)	(99)
Proceeds from the sale of property and equipment	<u> </u>	57
Net cash used in investing activities	(125)	(42)
Cash flows from financian activities		
Cash flows from financing activities Proceeds from exercise of stock options	51	230
Proceeds from issuance of Series C redeemable convertible preferred stock	51	80.000
Payment of issuance costs related to issuance of redeemable convertible preferred stock		(389)
Proceeds from issuance of convertible notes		5.602
Payment of issuance costs related to convertible notes		(23)
Payment on capital lease obligations	(188)	(130)
Net cash (used in) provided by financing activities	(137)	85,290
		50.439
Net (decrease) increase in cash and cash equivalents and restricted cash Cash, cash equivalents and restricted cash, beginning of year	(10,551) 14,109	50,439 3,558
		,
Cash, cash equivalents and restricted cash, end of year	\$ 3,558	\$ 53,997
Reconciliation of cash and cash equivalents and restricted cash to the balance sheets		
Cash and cash equivalents	\$ 3,195	\$ 53,654
Restricted cash	363	343
Total cash and cash equivalents and restricted cash	\$ 3,558	\$ 53,997
Supplemental disclosure of cash flow information	_	
Cash paid for interest	\$ 51	\$ 32
Purchases of property and equipment through capital leases	18	—
Issuance of Series C redeemable convertible preferred stock for license	_	13,121
Issuance of Series C redeemable convertible preferred stock upon extinguishment of convertible notes		5,736
Receivables on exercise of stock options		52

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

# Vera Therapeutics, Inc. Notes to financial statements

(Dollar amounts in thousands, except per share data)

## 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 transformative treatments for patients with serious immunological diseases. The Company is headquartered in South San Francisco, California and was incorporated in May 2016 in Delaware. In 2017, the Company acquired all of the outstanding shares of PNA Innovations, Inc. ("PNAi"), which was based in Woburn, Massachusetts.

#### Liquidity

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty.

The Company has incurred recurring net operating losses since its inception and had an accumulated deficit of \$91,447 as of December 31, 2020. The Company had cash and cash equivalents of \$53,654 as of December 31, 2020 and has not generated positive cash flow from operations. To date, the Company has been able to fund its operation primarily through the issuance of redeemable convertible preferred stock and convertible notes.

The Company expects to continue to generate operating losses for the foreseeable future. There can be no assurance that the Company will ever earn revenues or achieve profitability or, if achieved, that they will be sustained on a continuing basis. If the Company is unable to obtain funding, the Company will be forced to delay or reduce some or all of its product development programs, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although the Company continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient future funding on terms acceptable to the Company to fund continuing operations, if at all.

The Company believes that it has sufficient resources to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these financial statements. While the Company believes that its current cash and cash equivalents are adequate to meet its needs for the next 12 months, the Company may need to raise additional equity or borrow funds in order to achieve its longer-term business objectives.

## 2. Basis of presentation and 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"). The U.S. dollar is the Company's functional and reporting currency.

## Reclassification

Certain reclassification of prior period amounts related to restructuring activities has been made to conform to the current year presentation.

#### Emerging growth company status

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

#### Use of estimates

The preparation of the Company's financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Management estimates that affect the reported amounts of assets and liabilities include useful lives of fixed and intangible assets, the accrual of research and development expenses, restructuring liabilities, fair value of common stock and stock-based compensation expense, and the valuation allowance for deferred tax assets. The Company evaluates and adjusts its estimates and assumptions on an ongoing basis using historical experience and other factors. Actual results could differ materially from those estimates.

#### Segment information

The Company operates as a single operating segment. The Company's chief operating decisionmaker, its Chief Executive Officer, manages the Company's entire operations as a whole for the purposes of allocating resources, making operating decisions and evaluating financial performance.

#### 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 and cash equivalents. 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 and cash equivalents to the extent recorded in the balance sheet. The Company has not experienced any losses on its deposits of cash and cash equivalents.

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's product candidates require approvals from the U.S. Food and Drug Administration and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed, or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company.

#### Impact of the COVID-19 coronavirus

The COVID-19 pandemic continues to rapidly evolve. The extent of the impact of the COVID-19 pandemic on the Company's business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on the Company's development activities, planned clinical trial enrollment, future trial sites, contract research organizations, third-party manufacturers, and other third parties with whom the Company does business, as well as its impact on regulatory authorities and the Company's key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, the Company is conducting business as usual, with necessary or advisable modifications to employee travel and with the Company's employees working remotely. The Company will continue to actively monitor the rapidly evolving situation related to the COVID-19 pandemic and may take further actions that alter the Company's operations, including those that may be required by federal, state or local authorities, or that the Company determines are in the best interests of its employees and other third parties with whom the Company does business. At this point, the extent to which the COVID-19 pandemic may affect the Company's business, operations and development timelines and plans, including the resulting impact on expenditures and capital needs, remains uncertain.

#### 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 and as collateral for a credit card, which are classified within current and non-current assets on the balance sheets.

#### **Comprehensive loss**

Comprehensive loss consists of net loss and other gains and losses affecting redeemable convertible preferred stock and stockholders' deficit that, under U.S. GAAP, are excluded from net loss. The Company has no items of other comprehensive loss for the years ended December 31, 2019 and 2020. As such, net loss equals comprehensive loss.

#### Property and equipment, net

Property and equipment are recorded at cost, less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the useful life of the asset category, for which each category the useful life is estimated at five years. Leasehold improvements are capitalized and amortized over the shorter of the lease term or the estimated useful life of the related asset. Expenditures for repairs and maintenance of assets are charged to expense as incurred, whereas major improvements are capitalized as additions to

property and equipment. Amortization of assets under capital leases is included in depreciation expense. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is reflected in the statement of operations and comprehensive loss.

#### Impairment of long-lived assets

The Company reviews its long-lived assets, including property and equipment and intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. During the years ended December 31, 2019 and 2020, the Company recorded asset impairments totaling \$10 and \$1,185, respectively, on certain intangible assets and certain laboratory and office equipment (see Note 3).

#### 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.

#### 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.

#### Redeemable convertible preferred stock

The Company records all shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The carrying value of the Company's redeemable convertible preferred stock is adjusted to reflect dividends if and when declared by the Company's board of directors. No dividends have been declared by the board of directors since inception. The Company classifies its redeemable convertible preferred stock separate from total stockholders' deficit, as the redemption of such stock is not solely under the control of the Company.

#### Stock-Based compensation

The Company recognizes compensation expense based on estimated fair values for all stock-based payment awards made to the Company's employees, nonemployee directors and consultants that are expected to vest. The valuation of stock option awards is determined at the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the Company to make assumptions and judgements about the inputs used in the calculations, such as the fair value of the common stock, expected term, expected volatility of the Company's common stock, risk-free interest rate and expected dividend yield. The valuation of restricted stock awards is measured by the fair value of the Company's 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.

The fair value of the shares of common stock underlying the stock options has historically been 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 determines 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.

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

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

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may

be recognized is the largest amount that is more likely than not of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax allowance, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

#### 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.

The Company's participating securities include the Company's redeemable convertible preferred stock, as the holders are 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, do not have a contractual obligation to share in losses of the Company, and therefore during periods of loss there is no allocation required under the two-class method.

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, adjusted for outstanding shares that are subject to repurchase.

Diluted net loss per share is computed by giving effect to all potentially dilutive securities outstanding for the period using the treasury stock method or the if-converted method based on the nature of such securities. For periods in which the Company reports net losses, diluted net loss per common share attributable to common stockholders is the same as basic net loss per common share attributable to common shares are not assumed to have been issued if their effect is anti-dilutive.

#### Leases

The Company leases office and laboratory space under operating leases and laboratory equipment under capital leases. Leases for which the Company assumes substantially all risks and rewards incidental to ownership of the leased assets are classified as capital leases. The leased assets and the corresponding lease liabilities (net of interest charges) are recognized on the balance sheet as property and equipment, based on the cost of the equipment, and borrowings, respectively, at the inception of the related lease. Each lease payment is apportioned between the reduction of the outstanding lease liability and the related interest expense. The interest expense is recorded on a basis that reflects a constant periodic rate of interest on the outstanding finance lease liability.

Leases for which substantially all risks and rewards incidental to ownership are retained by the lessors are classified as operating leases. Payments made under operating leases (net of any incentive received from the lessors) are recorded on a straight-line basis over the period of the lease.

#### 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.

#### Fair value option

The convertible notes issued in 2020, for which the Company elected the fair value option, are accounted for at fair value on a recurring basis with changes in fair value recognized in the statement of operations and comprehensive loss. Interest accrued on the convertible notes is recorded to interest expense.

#### 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.

The carrying amounts of the Company's cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair value due to their short-term nature.

Money market funds are highly liquid investments that are actively traded. The pricing information for the Company's money market funds are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy. There were no transfers between Levels 1, 2, or 3 for any of the periods presented. As of December 31, 2019, and 2020, the Company held \$2,470 and \$52,301, respectively, in money market funds with no unrealized gains or losses.

The estimated fair value of the convertible notes, which is classified as Level 3 of the fair value hierarchy, is determined by using a scenario-based analysis that estimates the fair value of the convertible notes based on the probability-weighted present value of expected future investment returns, considering possible outcomes available to the noteholder, including conversions in subsequent equity financings, change of control transactions, settlement and dissolution.

#### Recently adopted accounting pronouncements

In November 2016, the FASB issued Accounting Standards Update ("ASU") 2016-18, *Statement of Cash Flows – Restricted Cash (Topic 230)*. This standard requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling

beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted this standard as of January 1, 2019 on a retrospective basis. The adoption of this standard did not have a material impact on its financial statements.

On June 20, 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, to reduce cost and complexity and to improve financial reporting for share-based payments issued to nonemployees (for example, service providers, external legal counsel, suppliers, etc.). This includes allowing for the measurement of awards at the grant date and recognition of awards with performance conditions when those conditions are probable, both of which are earlier than under current guidance for nonemployee awards. The Company adopted this standard as of January 1, 2020 on a retrospective basis. The adoption of this standard did not have a material impact on its financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which amends ASC 820, Fair Value Measurement. This standard modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. The Company adopted this standard as of January 1, 2020 on a retrospective basis. The adoption of this standard did not have a material impact on its financial statements.

#### Recently issued accounting pronouncements

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. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. 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 existing guidance for operating leases today. The Company intends to utilize the modified retrospective approach to adopt this standard effective January 1, 2022. Additionally, the Company intends to utilize the package of available practical expedients, which allows it to (i) not reassess whether any expired or existing contracts are or contain leases; (ii) not reassess the lease classification for expired or existing leases; and (iii) not reassess the treatment of initial direct costs for any existing leases. The Company is currently evaluating the impact this standard will have on its financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify the accounting for income taxes. This standard removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing standards to improve consistent application. The new standard will be effective beginning January 1, 2022. The Company is currently evaluating the impact this standard will have on its financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40). This standard simplifies the accounting for convertible debt instruments and convertible preferred stock by removing the existing guidance in ASC 470-20 that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. ASU 2020-06 is effective for the Company for annual reporting periods, and interim reporting periods within those annual

periods, beginning after December 15, 2023, and early adoption is permitted. The Company is currently evaluating the impact this standard will have on its financial statements.

# 3. Other financial statement information

#### Prepaid expense and other current assets

Prepaid expenses and other current assets consist of the following.

	Decer	mber 31,
	2019	2020
Prepaid expenses	\$ 332	\$ 336
Deposits	34	86
Receivables on exercise of options	_	52
Other	4	83
Total prepaid expenses and other current assets	\$370	\$ 557

#### Property and equipment, net

Property and equipment, net consists of the following as of December 31, 2019.

Equipment under capital lease	\$	929
Laboratory equipment		734
Leasehold improvements		421
Furniture and fixtures		269
Office equipment		61
Total property and equipment	Ĩ	61 2,414
Accumulated depreciation and amortization	(1	1,020)
Total property and equipment, net		1,394

Depreciation and amortization expense for the years ended December 31, 2019 and 2020 was \$432 and \$251, respectively, including amortization expense related to capital leases of \$184 and \$108 for the years ended December 31, 2019 and 2020, respectively.

During the year ended December 31, 2019, the Company disposed of certain laboratory equipment, incurring a loss on disposal of \$94, which is included in research and development expense in the Company's statement of operations and comprehensive loss.

During the year ended December 31, 2020, the Company determined that its property and equipment had no future alternative use and recorded an impairment charge of \$1,185. The Company recorded an impairment charge of \$1,039 for laboratory equipment and furniture and \$146 for office equipment to research and development and general and administrative expense, respectively.

# Accrued and other current liabilities

Accrued and other current liabilities consist of the following.

	Decen	nber 31,
	2019	2020
Accrued expenses	\$318	\$ 128
Accrued payroll	58	405
Other	47	
Total accrued expenses and other current liabilities	\$ 423	\$ 533

# 4. Convertible notes

In March, April, and May 2020, the Company issued convertible notes to certain existing investors of the Company for cash. The principal amount of the convertible notes was \$5,602 in the aggregate with a fixed accrued interest rate of 4% per annum. The convertible notes were either due on or after December 31, 2020 or upon a change of control of the Company, unless earlier converted. No principal or interest was payable prior to maturity as the convertible notes and any accrued interest would automatically convert upon a qualified financing event at a conversion price equal to 85% of the price per share of the qualified financing. Holders also had the option to convert their notes to shares of Series B redeemable convertible stock at a conversion price equal to \$4.2926 per share on the maturity date or upon a change of control of the Company, if no qualified financing occurred prior to such date.

Due to certain embedded features within the convertible notes, the Company elected to account for the convertible notes under the fair value option.

The following table provides the changes in the fair value of the convertible notes for the year ended December 31, 2020.

Issuance of convertible notes	\$ 5,539
Change in fair value of convertible notes	1,210
Conversion into Series C redeemable convertible preferred stock	(6,749)
Balance as of December 31, 2020	\$

In October 2020, the outstanding principal, and accrued interest of \$134, were automatically converted into 11,404,246 shares of the Company's Series C redeemable convertible preferred stock in connection with the closing of the Company's Series C redeemable convertible preferred stock financing (see Note 5) at a conversion price of \$0.5030 per share, which was 85% of the \$0.5918 original issuance price of the Series C redeemable convertible preferred stock.

# 5. Redeemable convertible preferred stock

As of December 31, 2020, the Company's redeemable convertible preferred stock consisted of the following balances (in thousands, except share amounts).

	Issue price	Shares authorized	Shares issued and outstanding	Carrying value	Aggregate liquidation preference
Series Seed	\$1.01	1,010,456	1,010,456	\$ 1,789	\$ 1,020
Series Seed-1	1.92	1,787,640	1,787,640	3,718	3,430
Series A	2.15	6,120,111	6,120,111	12,851	13,136
Series B	4.29	5,097,566	5,097,566	21,737	21,882
Series C	0.59	168,756,599	168,756,599	99,481	99,870
Total		182,772,372	182,772,372	\$ 139,576	\$ 139,338

In October 2020, the Company issued 135,180,800 shares of Series C redeemable convertible preferred stock for a purchase price of \$0.5918 per share, payable in cash. Gross proceeds to the Company were \$80,000. The Series C redeemable convertible preferred stock financing triggered the automatic conversion of the Company's outstanding convertible notes into 11,404,246 shares of Series C redeemable convertible preferred stock based on price of \$0.5030 per share (85% of the \$0.5918 original issuance price of the Series C redeemable convertible preferred stock). In addition, the Company issued 22,171,553 shares of Series C redeemable convertible preferred stock to Ares Trading S.A. ("Ares"), an affiliate of Merck KGaA, Darmstadt, Germany, as the initial payment for the Company's license of atacicept from Ares (see Note 9).

The holders of the Series Seed, Seed-1, A, B, and C redeemable convertible preferred stock (together the "redeemable convertible preferred stock") have various rights, preferences, privileges, and restrictions, with respect to voting, dividends, liquidation, and conversion as follows:

#### Voting

On any matter presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of redeemable convertible preferred stock is entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of redeemable convertible preferred stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Holders of redeemable convertible preferred stock may vote, on an as-converted basis, together with the holders of Class A common stock as a single class.

#### Dividends

Through December 31, 2020, no dividends have been authorized, declared, or paid. The Company may not declare, pay or set aside any dividends on any other class or series of capital stock (other than dividends on shares of common stock payable in shares of common stock) unless the holders of redeemable convertible preferred stock then outstanding first or simultaneously receive a dividend on each outstanding share of redeemable convertible preferred stock in an amount at least equal to (a) in the case of a dividend on common stock or any class or series that is convertible into common stock, that dividend per share to equal the product of (i) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into common stock and (ii) the number of shares of common stock issuable upon conversion of such share of redeemable convertible preferred stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (b) in the case of a dividend on any class

or series that is not convertible into common stock, at a rate per share determined by (i) dividing the amount of the dividend payable on each share of such class or series of capital stock by the Original Issuance Price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (ii) multiplying this fraction by an amount equal to the applicable original issue price; provided that, if the Company declares, pays or sets aside, on the same date, a dividend payable to the holders of redeemable convertible preferred stock is calculated based on the dividend on the class or series of capital stock that would result in the highest preferred stock dividend.

#### Conversion

Each share of redeemable convertible preferred stock is convertible, at the option of the holder, at any time and from time to time, and without the payment of additional consideration by the holder, into such number of fully paid and nonassessable shares of common stock as is determined by dividing the applicable original issue price by the applicable preferred stock conversion price in effect at the time of conversion. The preferred stock conversion price for each share of redeemable convertible preferred stock is initially equal to the original issue price applicable to such share. Each such initial preferred stock conversion price, and the rate at which shares of redeemable convertible preferred stock may be converted into shares of common stock, is subject to adjustment. No fractional shares of common stock will be issued upon conversion of redeemable convertible preferred stock. In lieu of any fractional shares, the Company will pay cash equal to the fraction multiplied by the fair market value of a share of common stock.

#### Liquidation preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Series C redeemable convertible preferred stock then outstanding are entitled to be paid out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to the holders of Series Seed, Series Seed-1, Series A, and Series B redeemable convertible preferred stock, equal to one times the original issue price of the Series C redeemable convertible preferred stock. If upon any such liquidation, dissolution or winding up of the Company the assets of the Company available for distribution to its stockholders are insufficient to pay the holders of shares of Series C redeemable convertible preferred stock the full amount to which they shall be entitled, such holders will share ratably in any distribution of the assets available for distribution in proportion to the respective amounts that would otherwise be payable in respect of the shares of Series C redeemable convertible preferred stock held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

Thereafter, the holders of Series Seed, Series Seed-1, Series A and Series B redeemable convertible preferred stock then outstanding are entitled to be paid out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to the holders of common stock, an amount per share equal to the greater of (i) one times the applicable original issue price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of such series of redeemable convertible preferred stock been converted into common stock immediately prior to such liquidation, dissolution, or winding up. If upon any such liquidation, dissolution or winding up of the Company the assets of the Company available for distribution to its stockholders are insufficient to pay the holders of shares of redeemable convertible preferred stock the full amount to which they shall be entitled, the holders of shares of Series Seed-1, Series A, and Series B redeemable convertible preferred stock will share ratably in any distribution of the assets available for distribution in proportion to the respective amounts that would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

After the payment of all preferential amounts required to be paid to the holders of shares of redeemable convertible preferred stock, the remaining assets of the Company available for distribution to its stockholders will be distributed among the holders of shares of Series C redeemable convertible preferred stock and common stock, pro rata based on the number of shares held by each such holder on an as-converted basis.

#### Redemption

The holders of the Company's redeemable convertible preferred stock have no rights to cause the redemption of their shares outside of a liquidation or winding up of the Company, a change in control, or a sale of substantially all of the Company's assets (a "deemed liquidation event"). A deemed liquidation event would constitute a redemption event that may be outside of the Company's control as a result of the preferred stockholders' control of the Company's board of directors. Accordingly, the redeemable convertible preferred shares are considered contingently redeemable and are classified as temporary equity on the balance sheets. The carrying value of the redeemable convertible preferred stock has not been adjusted to its redemption value as redemption was not probable as of the balance sheet dates presented. The carrying value of the redeemable convertible preferred stock will be adjusted to its redemption value in the future, if redemption becomes probable.

#### Classification

The Company has classified its redeemable convertible preferred stock separate from total stockholders' deficit in the balance sheets as the redeemable convertible preferred shares are contingently redeemable upon a deemed liquidation event and in that event there is no guarantee that all stockholders would be entitled to receive the same form of consideration. No accretion to redemption value was recorded during the years ended December 31, 2019 and 2020 as a deemed liquidation event was not considered probable.

# 6. Common stock

As of December 31, 2020, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 273,986,920 shares of Class A common stock and 21,593,607 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, 2020, no cash dividends had been declared or paid.

# 7. Stock compensation

## 2017 Equity Incentive Plan

In 2017, the Company's Board of Directors adopted the Vera Therapeutics, Inc. 2017 Equity Incentive Plan, which provides for the grant of qualified stock options, nonqualified stock options and other awards, including restricted stock awards, to the Company's employees, directors, and consultants to purchase up to 286,578 shares of the Company's Class A common stock. The grants of stock options and restricted stock awards generally vest either (i) over a four-year period, with 25% vesting on the first anniversary of the grant date and on a ratable monthly basis thereafter for the following three years, or (ii) on a ratable monthly basis over a three-year period and expire ten years from the date of grant. Certain awards provide for accelerated vesting upon a change of control, as defined in the 2017 Equity Incentive Plan.

In 2020, the Company's Board of Directors voted to amend the 2017 Equity Incentive Plan to increase the aggregate authorized number of Class A common stock to be 3,052,169 shares. No other changes were made to the 2017 Equity Incentive Plan. As of December 31, 2020, there were 1,150,088 shares available for future grant under the 2017 Equity Incentive Plan.

#### Stock-based compensation expense

The following tables summarize the stock-based compensation expense for stock options and restricted stock awards granted to employees and nonemployees that was recorded in the Company's statements of operations and comprehensive loss for the years ended December 31, 2019 and 2020.

		ended nber 31,
	2019	2020
Research and development	\$ 40	\$ 4
General and administrative	223	327
Total stock-based compensation expense	\$263	\$ 331
		ended nber 31,
	2019	2020
Employees	\$233	\$ 321
Nonemployees	30	10

\$263

\$ 331

Nonemployees Total stock-based compensation expense

As of December 31, 2020, the Company had \$4,219 of unrecognized stock-based compensation expense related to unvested stock options and restricted stock awards, which is expected to be recognized over a weighted-average period of approximately two years.

The fair value of stock options granted during the years ended December 31, 2019 and 2020, was estimated using the Black-Scholes option pricing model based on the following weighted average assumptions.

	Year ended De	Year ended December 31,		
	2019	2020		
Expected term (in years)	5.5 – 6.0	5.5 – 6.1		
Expected volatility	74.0% - 74.3%	86.1% - 92.5%		
Risk-free rate	2.19% – 2.22%	0.41% - 1.67%		
Dividend yield	—	_		

The following table summarizes the Company's option activity for the year ended December 31, 2020.

	Number of options	av ex pri	ighted- erage ercise ce per hare	Weighted- average remaining contractual life (years)	intr Va	regate insic alue 00s)
Balance—December 31, 2019	158,599	\$	7.88	8.19	\$	10
Granted	1,865,091		2.98			
Exercised	(33,291)		8.45			
Cancelled and forfeited	(134,892)		6.75			
Balance—December 31, 2020	1,855,507	\$	2.99	9.79	\$	8
Options exercisable—December 31, 2020	146,830	\$	3.84	8.17	\$	1
Unvested and expected to vest—December 31, 2020	1,818,708	\$	2.96	9.92	\$	—

The aggregate intrinsic value of stock options exercised during the year ended December 31, 2019 and 2020 was \$6 and \$1, respectively. The weighted average grant date fair value of options granted during the years ended December 31, 2019 and 2020 was \$4.06 per share and \$2.24 per share, respectively.

## Restricted stock awards

In October 2020, in conjunction with the Series C redeemable convertible preferred stock issuance, 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 allows the Company to repurchase shares that have not vested. The vesting term of restricted stock is one year. The grant date fair value of the restricted shares was \$6.37. The following table summarizes the activity for the Company's restricted stock for the year ended December 31, 2020.

	Number of shares
Unvested as of December 31, 2019	10,340
Granted	49,636
Vested	(18,613)
Unvested as of December 31, 2020	41,363

For each of the years ended December 31, 2019 and 2020, the Company recognized \$1 and \$55, respectively, of stock-based compensation expense related to restricted stock awards that vested during the periods.

# 8. 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. There were no employer contributions under this plan for fiscal 2019 and 2020.

## 9. Licenses and collaborations

#### Carnegie Mellon University

In 2012, PNAi entered into a license agreement with Carnegie Mellon University (as amended, the "CMU License Agreement"), which was assigned to the Company upon the closing of the Company's acquisition of PNA in 2017.



The CMU License Agreement provided exclusive, worldwide rights to certain patents and know-how relating to synthetic oligomers. Under the CMU License Agreement, the Company is obligated to pay Carnegie Mellon University up to \$9,000 in aggregate milestone payments upon the achievement of specific sales-based milestones, which have not yet been met. The Company is also responsible for reimbursement for future patent expenses and payment of future royalties based on any sales of a licensed product at a percentage in the low single digits.

If the Company were to sublicense the technology licensed pursuant to the CMU License Agreement, the Company would be obligated to pay CMU a percentage ranging in the low double-digits of specified sublicensing income received, subject to reduction for a specified percentage of sublicensing income payments above a specified threshold that the Company may be obligated to pay other third parties. The Company did not achieve any of the development or sales milestones. Accordingly, no royalty or development milestone payments were made nor required to be made under this agreement.

#### Yale university

In 2017, PNAi entered into a collaborative research agreement (the "Yale CRA") and license agreement (the "Yale License Agreement") with Yale University, which were assigned to the Company upon the closing of the acquisition of PNAi by the Company in 2017. The purpose of the agreements was to fund the Yale University research program in the field of nanoparticle-sized nucleic acid mimics and peptide nucleic acids as gene editing therapeutics in return for an exclusive license to certain related patent rights owned by Yale University and the option to license any patents discovered or generated under the terms of the collaborative research agreement.

The Yale CRA required funding the labs of collaborators with \$1,500 per year for a minimum of two years. The Yale CRA expired in 2019. No payments were made to Yale University pursuant to the Yale CRA during the year ended December 31, 2019, with no future obligation under this commitment.

As consideration for the Yale License Agreement, PNAi paid an initial fee of \$37 and had the option to issue 5% of the company's common stock on a fully diluted, as converted basis. If the shares were not issued, the agreement could be terminated at Yale University's option. After the completion of the merger with PNAi, the Company exercised the option and issued 264,301 shares of common stock to Yale University with a fair value of \$100. Under the Yale License Agreement, the Company reimbursed Yale University for patent related expenses. The Company reimbursed Yale University \$45 for patent related expenses for the year ended December 31, 2019. The Company and Yale agreed to terminate the Yale License Agreement in 2020 and there are no future payment obligations under the Yale License Agreement.

#### Ares trading S.A.

In October 2020, the Company entered into a license agreement with Ares (the "Ares Agreement"), pursuant to which the Company obtained an exclusive worldwide license to certain patents and related know-how to research, develop, manufacture, use and commercialize therapeutic products containing atacicept, a recombinant fusion protein used to inhibit B cell growth and differentiation, which could potentially treat some autoimmune diseases.

As consideration for the Ares Agreement, the Company issued to Ares a non-refundable license issue fee of 22,171,553 shares of Series C redeemable convertible preferred stock resulting in Ares becoming a related party to the Company. The Series C redeemable convertible preferred stock had a deemed issuance price of \$0.5918 per share, or \$13,121 in the aggregate.

As of December 31, 2020, the Company has paid Ares \$25,000 in milestone payments 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 \$176,500 upon the achievement of specified BLA filing or regulatory approval milestones and up to \$515,000 upon the achievement of specified commercial milestones.

The non-refundable license issue fee of \$13,121 and milestone payments of \$25,000 are recorded to research and development expense.

Commencing on the first commercial sale of licensed products, the Company is obligated to pay Ares tiered royalties of low double-digit to mid-teen percentages on annual net sales of the licensed products covered by the license. The Company is obligated to pay royalties on a licensed product-by- licensed product and country-by-country basis from the first commercial sale of a product in a country until the latest of (i) 15 years after the first commercial sale of such licensed product in such country; (ii) the expiration of the last valid claim of a licensed patent that covers such licensed product in, or its use, importation or manufacture with respect to, such country; and (iii) expiration of all applicable regulatory exclusivity periods, including data exclusivity, in such country with respect to such product. If the Company were to sublicense its rights under the Ares Agreement, the Company is obligated to pay Ares a percentage ranging from the mid single-digit to the low double-digits of specified sublicensing income received.

# 10. Income taxes

The provision for income taxes for the years ended December 31, 2019 and 2020 consisted of the following.

2019	
2015	2020
\$ —	\$ —
1	1
1	1
_	
\$ 1	\$ 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.

	Year ended December 31,			
	2019		20	20
Tax at U.S. statutory rate on income before income taxes	\$(2	.,409)	\$(11	,217)
Change in valuation allowance	2	,999	10	,986
Research and development credits		(635)		122
State taxes		1		1
Other		45		109
Total provision for income taxes	\$	1	\$	1

Deferred tax assets and liabilities are determined based on the differences between financial reporting and income tax bases of assets and liabilities, as well as net operating loss carryforwards and are measured using

the enacted tax rates and laws in effect when the differences are expected to reverse. The significant components of the Company's deferred tax assets and liabilities are as follows.

	Dece	ember 31,
	2019	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 7,267	\$ 9,681
Research and other tax credits	2,603	2,652
Property and equipment	—	25
Intangible assets	27	8,019
Stock-based compensation	63	119
Reserves and accruals	108	554
Total deferred tax assets	10,068	21,050
Valuation allowance	(10,002)	(21,050)
Total deferred tax assets, net of valuation allowance	\$ 66	\$ —
Deferred tax liabilities:		
Property and equipment	(66)	—
Total deferred tax liabilities	(66)	_
Net deferred tax assets	\$ —	\$ —

As of December 31, 2020, the Company has federal and state net operating loss carryforwards of \$44,007 and \$3,531, respectively, of which \$10,246 of federal net operating loss carryforwards and \$3,531 of state net operating carryforwards will begin expiring in the year 2032 and 2036, respectively, if not utilized. The Company also has \$33,761 of federal net operating loss carryforwards as of December 31, 2020 that does not expire as a result of recent tax law changes. The Company has \$2,159 and \$1,156 of federal and state research and development tax credit carryforwards, which will begin to expire in the year of 2037 and 2033, respectively.

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 \$10,002 and \$21,050 for the year ended December 31, 2019 and 2020 has been established to offset the deferred tax assets as realization of such assets is uncertain.

The Company accounts for income taxes in accordance with authoritative accounting guidance which states the impact of an uncertain income tax position is recognized at the largest amount that is "more likely than not" to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained. As of December 31, 2019 and 2020, the Company had no material unrecognized tax benefits. No significant interest or penalties were recorded during the years ended December 31, 2019 and 2020. 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.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by the United States and state jurisdictions where applicable. There are currently no pending income tax examinations. The Company's tax years from inception to 2020 are subject to examination by the federal and various state tax authorities due to the carryforward of unutilized net operating losses.

The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted March 27, 2020. The CARES Act provided for various payroll tax incentives, changes to net operating loss carryback and carryforward rules, business interest expense limitation increases, and bonus depreciation on qualified improvement property. Additionally, the Consolidated Appropriations Act of 2021, which was signed on December 27, 2020, provided additional COVID relief provisions for businesses. The Company has evaluated the impact of both statutes and has determined that any impact is not material to its financial statements.

# 11. Commitments and contingencies

The aggregate future minimum lease payments for operating leases as of December 31, 2020, are as follows.

Year ending December 31,	Operating leases(1)	Sublease income
2021	\$ 2,838	\$ (1,746)
2022	2,295	(1,804)
2023	2,351	(1,864)
2024	2,221	(1,926)
2025	2,075	(1,483)
Total payments	\$ 11,780	\$ (8,823)

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

#### Facilities leases

In April 2015, PNAi entered a lease for approximately 3,800 square feet of office and laboratory space for a term of 39 months in Woburn, Massachusetts. In January 2018, the Company elected to renew this lease for three years, beginning in August 2018. In connection with the lease, the Company maintains a letter of credit issued to the lessor in the amount of \$50, which is secured by restricted cash that is classified as noncurrent based on the term of the underlying lease.

In April 2018, the Company entered into a lease for approximately 24,606 square feet of office and life science research space, which commenced on October 1, 2018, when the Company obtained control of the rented space for a term of 84 months in South San Francisco, California (the South San Francisco Lease). In connection with the lease, the Company maintains a letter of credit issued to the lessor in the amount of \$293, which is secured by restricted cash that is classified as noncurrent based on the term of the underlying lease.

The Company's total future minimum commitment due pursuant to the South San Francisco Lease is \$11,128 as of December 31, 2020. In November 2020, the Company entered into a non-cancellable sublease agreement for the facility, under the terms of which the Company is entitled to receive \$8,823 in sublease payments over the term of the sublease, which ends concurrently with the original lease in September 2025. As tenant, the Company remains responsible for the \$11,128 minimum lease commitment on the facilities.

The Company recorded rent expense totaling \$1,726 and \$2,089 for the years ended December 31, 2019 and 2020, respectively.

#### Equipment lease

The Company has certain leases on research and laboratory equipment with total future minimum commitments of \$581 as of December 31, 2020. The Company recorded rent expense totaling \$416 and \$298 for the years ended December 31, 2019 and 2020, respectively.

# 12. Restructuring and related activities

During the year ended December 31, 2019, the Company completely vacated its leased facilities in Woburn, Massachusetts. In connection with vacating the leased spaces, the Company recorded a discounted lease-related restructuring liability, which was calculated as the present value of the estimated future facility costs for which the Company would obtain no future economic benefit over the term of the lease, reduced for actual or estimated sublease rentals.

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 \$2,228 and \$768 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 with no future economic benefit over the term of the leases. In addition, the Company recognized restructuring liability of \$321 related to severance and other employee termination costs related to the reduction in the number of employees. The Company expects this restructuring plan to be completed in 2021.

The activity related to the restructuring liabilities for the years ended December 31, 2019 and 2020 are as follows.

	ease-related exit costs	oloyee ination	Total
Restructuring costs	\$ 261	\$ _	\$ 261
Accretion	14		14
Cash payments	(102)		(102)
Balance as of December 31, 2019	173	_	173
Restructuring costs	2,996	321	3,317
Accretion	24	_	24
Cash payments	(609)	(309)	(918)
Balance as of December 31, 2020	\$ 2,584	\$ 12	\$2,596

# 13. Net loss per common share

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).

	Decem	ber 31,
	2019	2020
Redeemable convertible preferred stock	1,209,599	15,774,014
Class A common stock options issued and outstanding	158,599	1,855,507
Unvested restricted stock awards	10,340	41,363
Total	1,378,538	17,670,884

# 14. Related party transactions

In October 2018, the Company entered into a sublease agreement for a portion of its South San Francisco office space, the term for which commenced on December 7, 2018. The Chief Executive Officer of the sublessor is a member of the Company's board of directors. The initial sublease was established for approximately 400 square feet of space. Prior to the initial expiration of the sublease in April 2019, the space was expanded to approximately 3,700 square feet with the term of the lease extended for an additional two years. The monthly rent charged by the Company to the subtenant is subject to escalating rent payments according to the terms of the Company's lease agreement, and the subtenant is required to reimburse the Company for monthly facility operating expenses based on its proportionate share of total square footage pursuant to the lease. The Company's lease agreement provides that 50% of any profit resulting from the excess of the amount collected from the subtenant less the sum of monthly rent, operating expenses and reimbursement of direct expenditures made by the Company in order to arrange and maintain the sublease is to be shared with the lessor. To date, no profit has been realized on the sublease arrangement as the monthly collections from the subtenant are equivalent to the Company's cost of rent, operating expense and recovery of professional fees to arrange the sublease. In June 2020, the sublease agreement was terminated. During the years ended December 31, 2019 and 2020, the Company recognized \$279 and \$160, respectively, of sublease income under this agreement, which was recorded as a reduction to the Company's rent expense.

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. (See Note 9.)

# 15A. Subsequent events

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 PNAi, including all inventory, machinery, intellectual property, goodwill and licenses, including the CMU License Agreement, and Neubase agreed to assume certain related liabilities.

# **15B. Subsequent events**

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 will convert 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.

# 16. Events (unaudited) subsequent to the date of the report of the independent registered public accounting firm

The sale relating to the Company's investment in PNAi closed on April 26, 2021. The Company received \$796 in cash and 308,635 shares of Neubase common stock, with a fair market value of \$1,759 based on the closing price reported on Nasdaq on the date the sale closed. Of the total Neubase shares issued to the Company, 162,260 were placed in escrow to secure certain obligations under the agreement.

shares



**Class A common stock** 

# **Preliminary prospectus**

J.P. Morgan

Cowen

**Evercore ISI** 

, 2022

# Part II

# Information not required in prospectus

Unless otherwise indicated, all references to "Vera," the "company," "we," "our," "us" or similar terms refer to Vera Therapeutics, Inc.

# Item 13. Other expenses of issuance and distribution.

The following table sets forth all expenses to be paid by us, other than underwriting discounts and commissions, in connection with this offering. All amounts shown are estimates except for the Securities and Exchange Commission (SEC) registration fee, the Financial Industry Regulatory Authority, Inc. (FINRA) filing fee.

SEC registration fee	\$ *
FINRA filing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Custodian transfer agent and registrar fees	*
Miscellaneous expenses	*
Total	\$ *

\* To be provided by amendment.

# Item 14. Indemnification of directors and officers.

Section 145 of the Delaware General Corporation Law (DGCL) authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act of 1933, as amended (Securities Act). Our amended and restated certificate of incorporation permits indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the DGCL, and our amended and restated bylaws provide that we will indemnify our directors and officers and permit us to indemnify our employees and other agents, in each case to the maximum extent permitted by the DGCL.

We have entered into indemnification agreements with our directors and officers, whereby we have agreed to indemnify our directors and officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee, or agent of Vera Therapeutics, Inc., provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, the best interest of Vera Therapeutics, Inc.

At present, there is no pending litigation or proceeding involving a director or officer of Vera Therapeutics, Inc. regarding which indemnification is sought, nor is the registrant aware of any threatened litigation that may result in claims for indemnification.

We maintain insurance policies that indemnify our directors and officers against various liabilities arising under the Securities Act and the Securities Exchange Act of 1934, as amended, that might be incurred by any director or officer in his capacity as such.

# Item 15. Recent sales of Unregistered securities.

Set forth below is information regarding unregistered securities issued by us since January 1, 2019.

#### Equity plan-related issuances

1. Since January 1, 2019, we have granted to certain of our directors, employees and consultants options to purchase 2,401,302 shares of our Class A common stock with per share exercise prices ranging from \$2.32 to \$6.95 under the 2017 Plan.

2. Since January 1, 2019, we have issued to certain of our directors, employees and consultants an aggregate of 263,381 shares of our Class A common stock at per share purchase prices ranging from \$0.02 to \$10.54 pursuant to exercises of options under the PNA Stock Plan and 2017 Plan for an aggregate purchase price of \$1,357,585.11.

#### Other issuances of capital stock and convertible notes

3. Between March 2020 to May 2020, we issued to 12 accredited investors convertible promissory notes for an aggregate principal amount of approximately \$5.6 million. In October 2020, these notes converted into 11,404,246 shares of our Series C preferred stock.

4. In October 2020, we issued an aggregate of (i) 157,352,353 shares of Series C preferred stock to 14 accredited investors at a purchase price of \$0.5918 per share for aggregate cash proceeds of approximately \$93.1 million and (ii) 11,404,246 shares of Series C preferred stock to 12 accredited investors upon the conversion of outstanding convertible promissory notes.

The offers, sales and issuances of the securities described in paragraphs (1) and (2) were deemed to be exempt from registration under Rule 701 promulgated under the Securities Act as transactions under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering. The recipients of such securities were our directors, employees or bona fide consultants and received the securities under our equity incentive plans. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

The offers, sales and issuances of the securities described in paragraphs (3) through (4) were deemed to be exempt under Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D under the Securities Act as a transaction by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business or other relationships, to information about us. No underwriters were involved in these transactions.

# Item 16. Exhibits and financial statement schedules.

# (a) Exhibits.

Exhibit number	Description
1.1#	Form of Underwriting Agreement.
3.1	Fifth Amended and Restated Certificate of Incorporation, as currently in effect (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 18, 2021, and incorporated by reference herein).
3.2	Third Amended and Restated Bylaws, as currently in effect (filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 18, 2021, and incorporated by reference herein).
4.1	Form of Class A Common Stock Certificate (filed as Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021, and incorporated by reference herein).
4.2	Second Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated October 29, 2020 (filed as Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, filed with the SEC on April 23, 2021 and incorporated by reference herein).
5.1#	Form of Opinion of Cooley LLP.
10.1	Vera Therapeutics, Inc. 2017 Equity Incentive Plan (filed as Exhibit 10.1 to the Registrant's Registration Statement or Form S-1, filed with the SEC on April 23, 2021 and incorporated by reference herein).
10.2	Forms of Grant Notice, Stock Option Agreement and Notice of Exercise under the Vera Therapeutics, Inc. 2017 Equ Incentive Plan (filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, filed with the SEC on April 23, 2021 and incorporated by reference herein).
10.3	Vera Therapeutics, Inc. 2021 Equity Incentive Plan (filed as Exhibit 10.3 to the Registrant's Registration Statement o Form S-1, filed with the SEC on May 10, 2021 and incorporated by reference herein).
10.4	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Vera Therapeutics, Inc. 2021 Equity Incentive Plan (filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, filed wi the SEC on May 10, 2021 and incorporated by reference herein).
10.5	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the Vera Therapeutics, Inc. 2021 Equity Incentive Plan (filed as Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021 and incorporated by reference herein).
10.6	Vera Therapeutics, Inc. 2021 Employee Stock Purchase Plan (filed as Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021 and incorporated by reference herein).
10.7	Vera Therapeutics, Inc. 2021 Non-Employee Director Compensation Policy (filed as Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021 and incorporated by reference herein).

E

# Confidential Treatment Requested by Vera Therapeutics, Inc. Pursuant to 17 C.F.R. § 200.83

Exhibit number	Description
10.8	Form of Indemnification Agreement by and between the Registrant and its directors and executive officers (filed as Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021 and incorporated by reference herein).
10.9¥	Amended and Restated Offer Letter by and between the Registrant and Marshall Fordyce, M.D., dated May 7, 202. (filed as Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021 a incorporated by reference herein).
10.10¥	Amended and Restated Offer Letter by and between the Registrant and Joanne Curley, Ph.D., dated May 7, 2021 (filed as Exhibit 10.10 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021 and incorporated by reference herein).
10.11¥	Amended and Restated Offer Letter by and between the Registrant and Celia Lin, M.D., dated May 7, 2021 (filed a Exhibit 10.14 to the Registrant's Registration Statement on Form S-1, filed with the SEC on May 10, 2021 and incorporated by reference herein).
10.12¥	Offer Letter, by and between the Registrant and Sean P. Grant, dated May 30, 2021 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 14, 2021 and incorporated by reference herein
10.13*	License Agreement by and between the Registrant and Ares Trading S.A., dated as of October 29, 2020 (filed as Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, filed with the SEC on April 23, 2021 and incorporated by reference herein).
10.14¥	Loan and Security Agreement between the Registrant and Oxford Finance LLC, dated December 17, 2021.
10.15¥*	Asset Purchase Agreement between the Registrant and Amplyx Pharmaceuticals, Inc. dated December 16, 2021.
10.16*	License Agreement between Novartis International Pharmaceutical AG and Amplyx Pharmaceuticals, Inc. dated August 26, 2019.
10.17*	Amendment No. 1 to License Agreement between Novartis International Pharmaceutical AG and Amplyx Pharmaceuticals, Inc. dated September 24, 2019.
23.1#	Consent of independent registered public accounting firm.
23.2#	Consent of Cooley LLP (included in Exhibit 5.1).
24.1#	Power of Attorney (included on signature page).
101.INS#	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because iXBF tags are embedded within the Inline XBRL document).
101.CAL#	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
.01.SCH#	Inline XBRL Taxonomy Extension Schema 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.
04#	The Cover Page Interactive Data File, formatted in Inline XBRL (included within the Exhibit 101 attachments).

# To be filed by amendment.

- † Previously filed.
- Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit (indicated by asterisks) have been omitted.
- ¥ 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.

#### (b) Financial statement schedules.

All financial statement schedules are omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or the notes thereto.

# Item 17. Undertakings.

- (a) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.
- (b) The undersigned registrant hereby undertakes that:
  - (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
  - (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

# Signatures

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Brisbane, State of California on , 2022.

#### VERA THERAPEUTICS, INC.



Name: Marshall Fordyce, M.D. Title: Chief Executive Officer and President

# **Power of attorney**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Marshall Fordyce, M.D. and Sean Grant, and each one of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in their name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by this registration statement that is to be effective on filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Marshall Fordyce, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	, 2022
Sean Grant	Chief Financial Officer (Principal Financial Officer)	, 2022
Joseph Young	Senior Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer)	, 2022
Kurt von Emster, C.F.A.	Chairperson of the Board	, 2022
Andrew Cheng, M.D., Ph.D.	Director	, 2022

Signature	Title	Date
Beth Seidenberg, M.D.	Director	, 2022
Maha Katabi, Ph.D.	Director	, 2022
Patrick Enright	Director	, 2022
Scott Morrison	Director	, 2022
Kimball Hall	Director	, 2022

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#### LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (as the same may from time to time be amended, modified, supplemented or restated, this "Agreement") dated as of December 17, 2021 (the "Effective Date") among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 115 South Union Street, Suite 300, Alexandria, VA 22314 ("Oxford"), as collateral agent (in such capacity, "Collateral Agent"), the Lenders listed on <u>Schedule 1.1</u> hereof or otherwise a party hereto from time to time including Oxford in its capacity as a Lender (each a "Lender" and collectively, the "Lenders"), and VERA THERAPEUTICS, INC., a Delaware corporation with offices located at 8000 Marina Blvd., Suite 120, Brisbane, CA 94005 ("Borrower"), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

## 1. ACCOUNTING AND OTHER TERMS

**1.1** Accounting terms not defined in this Agreement shall be construed in accordance with GAAP. Calculations and determinations must be made in accordance with GAAP. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to "**Dollars**" or "**\$**" are United States Dollars, unless otherwise noted.

#### 2. LOANS AND TERMS OF PAYMENT

**2.1 Promise to Pay.** Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

#### 2.2 Term Loans.

(a) <u>Availability</u>. (i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on the Effective Date in an aggregate amount of up to Thirty Million Dollars (\$30,000,000.00) according to each Lender's Term A Loan Commitment as set forth on <u>Schedule 1.1</u> hereto (such term loans are hereinafter referred to singly as a "**Term A Loan**", and collectively as the "**Term A Loans**"); provided that (x) the Term A Loan made on the Effective Date (the "**Effective Date Loan**") shall be in the minimum amount of Five Million Dollars (\$5,000,000.00); and (y) if the Effective Date Loan is less than Thirty Million Dollars (\$30,000,000.00), each Term A Loan made after the Effective Date shall be (I) in minimum increments of Five Million Dollars (\$5,000,000.00) or such lesser amount as shall remain available and (II) made during the period from January 3, 2022 through December 31, 2022. After repayment, no Term A Loan may be re-borrowed.

(ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Second Draw Period, to make term loans to Borrower in an aggregate amount up to Twenty Million Dollars (\$20,000,000.00) according to each Lender's Term B Loan Commitment as set forth on <u>Schedule 1.1</u> hereto (such term loans are hereinafter referred to singly as a "**Term B Loan**", and collectively as the "**Term B Loans**"; each Term A Loan or Term B Loan is hereinafter referred to singly as a "**Term Loan**" and the Term A Loans and the Term B Loans are hereinafter referred to collectively as the "**Term Loans**"); provided that, each Term B Loan shall be in minimum increments of Five Million Dollars (\$5,000,000.00) or such lesser amount as shall remain available. After repayment, no Term B Loan may be re-borrowed.

(b) <u>Repayment</u>. Borrower shall make monthly payments of interest only commencing on the first (1<sup>st</sup>) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as

calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to (x) forty-eight (48) months, if the Amortization Date is January 1, 2026 and (y) sixty (60) months, if the Amortization Date is January 1, 2027. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

(c) <u>Mandatory Prepayments</u>. If the Term Loans are accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) the Final Payment, (iii) the Prepayment Fee, plus (iv) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Payment had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to Collateral Agent, for payment to each Lender in accordance with its respective Pro Rata Share, the Final Payment in respect of the Term Loan(s).

## (d) <u>Permitted Prepayment of Term Loans</u>.

(i) Borrower shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least ten (10) days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Payment, (C) the Prepayment Fee, plus (D) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts.

(ii) Notwithstanding anything herein to the contrary, Borrower shall also have the option to prepay part of Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least ten (10) days prior to such prepayment, (ii) prepays such part of the Term Loans in a denomination that is a whole number multiple of Five Million Dollars (\$5,000,000.00), and (iii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) the portion of outstanding principal of such Term Loans plus all accrued and unpaid interest thereon through the prepayment date, (B) the applicable Final Payment with respect to the portion of such Term Loan being prepaid, (C) all other Obligations that are then due and payable, including Lenders' Expenses, interest at the Default Rate with respect to any past due amounts, and the pro rata portion of any fees or expenses otherwise due upon the Maturity Date, and (D) the applicable Prepayment Fee with respect to the portion of such Term Loans being prepaid; provided not more than four (4) voluntary partial prepayments shall be permitted during the term of this Agreement. For the purposes of clarity, any partial prepayment shall be applied pro-rata to all outstanding amounts under each Term Loan, and shall be applied pro-rata within each Term Loan tranche to reduce amortization payments under Section 2.2(b) on a pro-rata basis.

#### 2.3 Payment of Interest on the Credit Extensions.

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the Basic Rate, determined by Collateral Agent on the Funding Date of the applicable Term Loan, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full.

(b) <u>Default Rate</u>. Immediately upon the occurrence and during the continuance of an Event of Default, the Obligations shall accrue interest at a floating per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) <u>360-Day Year</u>. Interest shall be computed on the basis of a three hundred sixty (360) day year, and the actual number of days elapsed.

(d) <u>Debit of Accounts</u>. Collateral Agent and each Lender may debit (or ACH) any deposit accounts (other than Excluded Accounts), maintained by Borrower or any of its Subsidiaries, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes the Lenders under the Loan Documents when due; provided that, except (i) with respect to debits (or ACH) for regularly scheduled principal and interest and (ii) as otherwise previously authorized by Borrower, Collateral Agent shall endeavor to provide prompt notice of such debit (or ACH). Any such debits (or ACH activity) shall not constitute a set-off.

(e) <u>Payments</u>. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Lender's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 2:00 PM Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

2.4 Secured Promissory Notes. The Term Loans shall be evidenced by a Secured Promissory Note or Notes in the form attached as Exhibit D hereto (each a "Secured Promissory Note"), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender's Secured Promissory Note, an appropriate notation on such Lender's Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set forth on such Lender's Secured Promissory Note Record shall be prima facie evidence of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender's Secured Promissory Note Record shall not limit or otherwise affect the obligations of Borrower under any Secured Promissory Note or any other Loan Document to make payments of principal of or interest on any Secured Promissory Note, when due. Upon receipt of an affidavit of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note, Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

2.5 Fees. Borrower shall pay to Collateral Agent:

(a) <u>Good Faith Deposit</u>. Borrower has remitted to Collateral Agent Fifty Thousand Dollars (\$50,000.00) as a good faith deposit, which amount shall be applied towards the facility fee due under Section 2.5(b) hereof on the Effective Date. For the sake of clarity, Borrower shall be responsible for the entire amount of the Lenders' Expenses payable under Section 2(d).

(b) <u>Final Payment</u>. The Final Payment, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(c) <u>Prepayment Fee</u>. The Prepayment Fee, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(d) <u>Lenders' Expenses</u>. All Lenders' Expenses (including reasonable attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due.

**2.6** Withholding. Except as provided in the following sentence, payments received by the Lenders (or the Collateral Agent, if applicable) from Borrower hereunder will be made free and clear of and without deduction for any and all present or future Taxes. If at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other

sum payable hereunder to the Lenders, Borrower shall be permitted to make such withholding or deduction and hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority. Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.6 shall survive the termination of this Agreement. On the date of this Agreement, each Lender shall deliver, and upon a Lender Transfer, the applicable successor or assign shall deliver, to Borrower a complete and properly executed IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax or any similar or successor certificate designated by the IRS (a "Tax Certificate"). Notwithstanding anything to the contrary in this Section 2.6, so long as no Event of Default has occurred, from and after the failure of any Lender to so deliver such a Tax Certificate, the amount due from Borrower with respect to such payment or other sum payable hereunder shall not be required to be increased to the extent necessary to ensure that, after the making of such required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority, until such time as the Tax Certificate has been delivered.

## 3. CONDITIONS OF LOANS

**3.1** Conditions Precedent to Initial Credit Extension. Each Lender's obligation to make a Term A Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

- (a) original Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable;
- (b) duly executed original Control Agreements with respect to any Collateral Accounts, other than Excluded Accounts, maintained by Borrower;
  - (c) duly executed original Secured Promissory Notes in favor of each Lender according to its Term A Loan Commitment Percentage;

(d) the Operating Documents and good standing certificates of Borrower certified by the Secretary of State (or equivalent agency) of Borrower's jurisdiction of organization or formation and each jurisdiction in which Borrower is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the Effective Date;

- (e) a completed Perfection Certificate for Borrower and each of its Subsidiaries;
- (f) the Annual Projections, for the current calendar year;

(g) duly executed original officer's certificate for Borrower and each Subsidiary that is a party to the Loan Documents, in a form acceptable to Collateral Agent and the Lenders;

(h) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;

(i) [reserved];

(j) [reserved];

(k) a duly executed legal opinion of counsel to Borrower dated as of the Effective Date;

(l) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Lenders; and

(m) payment of the fees (if any) and Lenders' Expenses then due as specified in Section 2.5 hereof.

**3.2** Conditions Precedent to all Credit Extensions. The obligation of each Lender to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

(a) receipt by Collateral Agent of an executed Disbursement Letter in the form of Exhibit B attached hereto;

(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the date of the Disbursement Letter and on the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in Section 5 hereof are true, accurate and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date;

(c) in such Lender's sole but reasonable discretion, there has not been any Material Adverse Change or any material adverse deviation by Borrower from the then applicable Annual Projections of Borrower;

(d) to the extent not delivered at the Effective Date, duly executed original Secured Promissory Notes, in number, form and content acceptable to each Lender, and in favor of each Lender according to its Commitment Percentage, with respect to each Credit Extension made by such Lender after the Effective Date; and

(e) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

**3.3 Covenant to Deliver.** Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Credit Extension. Borrower expressly agrees that a Credit Extension made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Credit Extension in the absence of a required item shall be made in each Lender's sole discretion.

**3.4 Procedures for Borrowing.** Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan, Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 1:00 PM Eastern time five (5) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to the Lenders by electronic mail or facsimile a completed Disbursement Letter executed by a Responsible Officer or his or her designee. The Lenders may rely on any telephone notice given by a person whom a Lender reasonably believes is a Responsible Officer or designee. On the Funding Date, each Lender shall credit and/or transfer (as applicable) to the Designated Deposit Account, an amount equal to its Term Loan Commitment.

## 4. CREATION OF SECURITY INTEREST

**4.1 Grant of Security Interest.** Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to Collateral Agent's Lien. If Borrower shall acquire a commercial tort claim (as defined in the Code) with a value in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00), Borrower, shall promptly notify Collateral Agent in a writing signed by Borrower, as the case may be, of the general details thereof (and further details as may be required by Collateral Agent) and grant to Collateral Agent, for the ratable benefit of the Lenders, in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to make Credit Extensions has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower.

**4.2** Authorization to File Financing Statements. Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents, including a notice that any disposition of the Collateral, except to the extent permitted by the terms of this Agreement, by Borrower, or any other Person, shall be deemed to violate the rights of Collateral Agent under the Code.

**4.3 Pledge of Collateral.** Borrower hereby pledges, assigns and grants to Collateral Agent, for the ratable benefit of the Lenders, a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. On the Effective Date, or, to the extent not certificated as of the Effective Date, within ten (10) days of the certification of any Shares, the certificate or certificates for the Shares will be delivered to Collateral Agent, accompanied by an instrument of assignment duly executed in blank by Borrower. To the extent required by the terms and conditions governing the Shares, Borrower shall cause the books of each entity whose Shares are part of the Collateral Agent may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Collateral Agent and cause new (as applicable) certificates representing such securities to be issued in the name of Collateral Agent may reasonably request to perfect or continue the perfection of Collateral Agent's security interest in the Shares. Unless an Event of Default shall have occurred and be continuing. Borrower shall be entitled to exercise any voting rights with respect to the Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violation of any of such terms. All such rights to vote and give consents, waivers and ratifications shall terminate upon the occurrence and continuance of an Event of Default.

#### 5. <u>REPRESENTATIONS AND WARRANTIES</u>

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

**5.1 Due Organization, Authorization: Power and Authority.** Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure

to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate signed by an officer of Borrower or such Subsidiary (each a "Perfection Certificate" and collectively, the "Perfection Certificates"). Borrower represents and warrants that (a) Borrower and each of its Subsidiaries' exact legal name is that which is indicated on its respective Perfection Certificate and on the signature page of each Loan Document to which it is a party; (b) Borrower and each of its Subsidiaries is an organization of the type and is organized in the jurisdiction set forth on its respective Perfection Certificate; (c) each Perfection Certificate accurately sets forth each of Borrower's and its Subsidiaries' organizational identification number or accurately states that Borrower or such Subsidiary has none; (d) each Perfection Certificate accurately sets forth Borrower's and each of its Subsidiaries' place of business, or, if more than one, its chief executive office as well as Borrower's and each of its Subsidiaries' mailing address (if different than its chief executive office); (e) Borrower and each of its Subsidiaries (and each of its respective predecessors) have not, in the past five (5) years, changed its jurisdiction of organization, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries, is accurate and complete in all material respects (it being understood and agreed that Borrower and each of its Subsidiaries may from time to time update certain information in the Perfection Certificates (including the information set forth in clause (d) above) after the Effective Date to the extent permitted by one or more specific provisions in this Agreement); such updated Perfection Certificates subject to the review and approval of Collateral Agent. If Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, Borrower shall notify Collateral Agent of such occurrence and provide Collateral Agent with such Person's organizational identification number within five (5) Business Days of receiving such organizational identification number.

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's or such Subsidiaries' organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect or are being obtained pursuant to Section 6.1(b)), or (v) constitute an event of default under any material agreement by which Borrower or any of such Subsidiaries, or their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

## 5.2 Collateral.

(a) Borrower and each of its Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith (as the same may be updated from time to time in accordance with Section 6.6) with respect of which Borrower or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein. The Accounts are bona fide, existing obligations of the Account Debtors.

(b) On the Effective Date, and except as disclosed on the Perfection Certificate (i) the Collateral is not in the possession of any third party bailee (such as a warehouse), and (ii) no such third party bailee possesses components of the Collateral in excess of One Hundred Thousand Dollars (\$100,000.00). None of the components of the Collateral shall be maintained at locations other than as disclosed in the Perfection Certificates on the Effective Date or as permitted pursuant to Section 6.11.

(c) All Inventory is in all material respects of good and marketable quality, free from material defects, other than drug product prior to release by quality assurance or following the expiration date.

(d) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Perfection Certificates, or otherwise notified to Collateral Agent pursuant to the terms of this Agreement (to the extent Borrower is permitted to take such action resulting in the applicable update by one or more specific provisions of this Agreement), neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other material agreement with respect to which Borrower or such Subsidiaries' interest in such material license or material agreement or any other material property, or (ii) for which a default under or termination of could reasonably be expected to interfere with Collateral Agent's or any Lender's right to sell any Collateral. Borrower shall provide written notice to Collateral Agent and each Lender within fifteen (15) days of Borrower or any of its Subsidiaries entering into or becoming bound by any material license or material agreement with respect to which Borrower or any of its Subsidiaries entering into or becoming bound by any material license or material agreement with respect to which Borrower or any Subsidiary is the licensee (other than (x) over the counter software that is commercially available to the public and (y) licenses which are subject to the immediately preceding sentence).

**5.3 Litigation**. Except as disclosed (i) on the Perfection Certificates, or (ii) in accordance with Section 6.9 hereof, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than Two Hundred Fifty Thousand Dollars (\$250,000.00).

**5.4** No Material Deterioration in Financial Condition; Financial Statements. All consolidated financial statements for Borrower and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP (subject, in the case of unaudited financial statements, to normal year-end non-cash adjustments, consistent with Borrower's past practices), in all material respects, as of the dates and for the time periods presented therein, the consolidated financial condition of Borrower and its Subsidiaries. There has not been any material deterioration in the consolidated financial condition of Borrower and its subsidiaries submitted to any Lender.

5.5 Solvency. Borrower is Solvent and Borrower and its Subsidiaries, on a consolidated basis, are Solvent.

**5.6 Regulatory Compliance.** Neither Borrower nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower's nor any of its Subsidiaries' properties or assets has been used by Borrower or such Subsidiary or, to Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

**5.7 Investments.** Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

5.8 Tax Returns and Payments; Pension Contributions. Borrower and each of its Subsidiaries has timely filed (or timely filed extensions to file) all required Tax returns and reports (or, in the case of Tax returns and reports which are not for federal taxes, all required material Tax returns and reports), and Borrower and each of its Subsidiaries, has timely paid all material foreign, federal, material state, and material local Taxes, assessments, deposits and contributions owed by Borrower and such Subsidiaries, in all jurisdictions in which Borrower or any such Subsidiary is subject to Taxes, including the United States, unless (a) such Taxes are being contested in accordance with the following sentence or (b) in the case of non-federal material Tax returns and reports, material foreign, material state or material local Taxes, if such non-federal material Tax returns and reports, material foreign, material state or material local Taxes, assessments, deposits and contributions do not, individually or in the aggregate, exceed Twenty Five Thousand Dollars (\$25,000.00). Borrower and each of its Subsidiaries, may defer payment of any contested Taxes, provided that Borrower or such Subsidiary, (a) in good faith contests its obligation to pay the Taxes by appropriate proceedings promptly and diligently instituted and conducted, (b) notifies Collateral Agent in writing of the commencement of, and any material development in, the proceedings, and (c) posts bonds or takes any other steps required to prevent the Governmental Authority levying such contested Taxes from obtaining a Lien upon any of the Collateral that is other than a "Permitted Lien." Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed in writing for any of Borrower's or such Subsidiaries', prior Tax years which could result in additional Taxes in excess of Twenty Five Thousand Dollars (\$25,000.00) becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

**5.9** Use of Proceeds. Borrower shall use the proceeds of the Credit Extensions solely as working capital and to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.

**5.10 Shares.** Borrower has full power and authority to create a first lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

**5.11** Full Disclosure. No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not materially misleading in light of the circumstances under which such statements were made, after giving effect to all supplements and updates thereto from time to time (it being recognized that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

**5.12 Definition of "Knowledge.**" For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

## 6. AFFIRMATIVE COVENANTS

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

#### 6.1 Government Compliance.

(a) Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Lenders, in all of the Collateral. Upon the Collateral Agent's request, Borrower shall promptly provide copies to Collateral Agent of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries.

#### 6.2 Financial Statements, Reports, Certificates.

(a) Deliver to the Collateral Agent:

(i) no later than forty-five (45) days after the last day of each fiscal quarter, a company prepared consolidated balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its Subsidiaries for such fiscal quarter certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent;

(ii) no later than one hundred twenty (120) days after the last day of Borrower's fiscal year or within five (5) days of filing with the SEC, audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion on the financial statements (or qualified only as to going concern) from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion; provided that KPMG and any other certified public accounting firm of recognized national standing shall be acceptable to the Collateral Agent;

(iii) no later than thirty (30) days after the last day of each of Borrower's fiscal years, Borrower's annual financial projections for the entire current fiscal year as approved by Borrower's Board of Directors, which such annual financial projections shall be set forth in a month by month format (such annual financial projections as originally delivered to Collateral Agent and the Lenders are referred to herein as the "Annual Projections"; provided that, any revisions of the Annual Projections approved by Borrower's Board of Directors shall be delivered to Collateral Agent and the Lenders no later than seven (7) days after such approval);

(iv) within five (5) Business Days of delivery, copies of all non-ministerial statements, reports and notices made generally available to Borrower's security holders or holders of Subordinated Debt;

Commission;

(v) within five (5) Business Days of filing, all reports on Form 10 K, 10 Q and 8 K filed with the Securities and Exchange

(vi) prompt notice of any amendments of or other changes to the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting such amendments or changes with respect thereto;

(vii) prompt notice of any event that could reasonably be expected to materially and adversely affect the Intellectual Property in a manner that could have a material and adverse effect on Borrower's business as conducted;

(viii) no later than thirty (30) days after the last day of each month, copies of the monthly account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s); and

(ix) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

(b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than forty-five (45) days after the last day of each quarter, deliver to each Lender, a duly completed Compliance Certificate signed by a Responsible Officer.

(c) Keep proper books of record and account in accordance with GAAP in all material respects (subject to normal year-end non-cash adjustments, consistent with Borrower's past practices), in which full, true and correct entries shall be made of all dealings and transactions in relation to its business and activities. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (but not less than five (5) days prior written notice) (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than once every year unless (and more frequently if) an Event of Default has occurred and is continuing.

**6.3 Inventory; Returns.** Keep all Inventory in good and marketable condition, free from material defects, other than drug product prior to release by quality assurance or following the expiration date. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors shall follow customary practices for similarly situated suppliers in the Borrowers business . Borrower must promptly notify Collateral Agent and the Lenders of all returns, recoveries, disputes and claims that involve Inventory with a book value of more than Two Hundred Fifty Thousand Dollars (\$250,000.00) individually or in the aggregate in any calendar year.

**6.4 Taxes; Pensions.** Timely file and require each of its Subsidiaries to timely file, all required Tax returns and reports (or, in the case of Tax returns and reports which are not for U.S. federal taxes, all required material Tax returns and reports) and timely pay, and require each of its Subsidiaries to timely pay, all material foreign, U.S. federal, material state, and material local Taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except for deferred payment of any Taxes contested pursuant to the terms of Section 5.8 hereof, and shall deliver to Lenders, on demand, appropriate certificates attesting to such payments (or contested payments), and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans; provided that, as used herein, "material foreign, U.S. federal, material state, and material local Taxes, assessments, equal to or exceed Twenty Five Thousand Dollars (\$25,000.00).

**6.5 Insurance.** Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent. Subject to the Post Closing Letter, all property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent, as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, subject to the Post Closing Letter, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days prior written notice before any such policy or policies shall be materially altered or canceled. At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the

Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to Five Hundred Thousand Dollars (\$500,000.00) with respect to any loss, but not exceeding Five Hundred Thousand Dollars (\$500,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent may make, at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent deems prudent.

## 6.6 Operating Accounts.

(a) Maintain all of Borrower's and its Subsidiaries' Collateral Accounts, other than Excluded Accounts, in accounts which are subject to a Control Agreement in favor of Collateral Agent.

(b) Borrower shall provide Collateral Agent five (5) days' prior written notice before Borrower or any of its Subsidiaries establishes any Collateral Account at or with any Person other than Silicon Valley Bank or its Affiliates. In addition, for each Collateral Account (other than Excluded Accounts) that Borrower or any Guarantor, at any time maintains, Borrower or such Guarantor shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account in accordance with the terms hereunder prior to the establishment of such Collateral Account, which Control Agreement may not be terminated without prior written consent of Collateral Agent. The provisions of the previous sentence shall not apply to Excluded Accounts.

(c) Neither Borrower nor any of its Subsidiaries shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with Sections 6.6(a) and (b).

**6.7 Protection of Intellectual Property Rights.** Borrower and each of its Subsidiaries shall: (a) use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its owned Intellectual Property that is material to Borrower's business as conducted; (b) promptly upon becoming aware, advise Collateral Agent in writing of material infringement by a third party of its owned Intellectual Property that is material to Borrower's business as conducted; and (c) not allow any owned Intellectual Property material to Borrower's business as conducted to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent.

**6.8** Litigation Cooperation. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, upon reasonable request and during regular business hours (unless an Event of Default has occurred and is continuing), without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower. In such event, Collateral Agent shall work cooperatively with Borrower to minimize disruption, to the extent reasonably possible, of Borrower's ongoing operations.

**6.9** Notices of Litigation and Default. Borrower will give prompt written notice to Collateral Agent and the Lenders of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of Two Hundred Fifty Thousand Dollars (\$250,000.00) or more or which could reasonably be expected to have a Material Adverse Change. Without limiting or contradicting any other more specific provision of this Agreement, promptly (and in any event within three (3) Business Days) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, Borrower shall give written notice to Collateral Agent and the Lenders of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default.

## 6.10 [Intentionally Omitted.]

**6.11 Landlord Waivers; Bailee Waivers.** In the event that Borrower or any of its Subsidiaries, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then Borrower or such Subsidiary will first notify the Collateral Agent and, in the event that the new location is the chief executive office of the Borrower or such Subsidiary or the Collateral at any such new location is valued in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00) in the aggregate, such bailee or landlord, as applicable, must execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be; provided the requirement of this Section 6.11 shall not apply to Collateral locations outside of the United States.

**6.12 Creation/Acquisition of Subsidiaries.** In the event Borrower, or any of its Subsidiaries creates or acquires any Subsidiary, Borrower shall provide prior written notice to Collateral Agent and each Lender of the creation or acquisition of such new Subsidiary and take all such action as may be reasonably required by Collateral Agent or any Lender to cause each such Subsidiary to become a co-Borrower hereunder or to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the assets of such Subsidiary (substantially as described on <u>Exhibit A</u> hereto); and Borrower (or its Subsidiary, as applicable) shall grant and pledge to Collateral Agent, for the ratable benefit of the Lenders, a perfected security interest in the Shares of each such newly created Subsidiary (subject to the limitations in the definition of Shares); provided, however, that solely in the circumstance in which Borrower or any Subsidiary shall not be required to guarantee the Obligations of Borrower under the Loan Documents or grant a continuing pledge and security interest in and to the assets of such Foreign Subsidiary (provided such Foreign Subsidiary shall be subject to the same negative pledge arrangement with Collateral Agent and the Lenders as if party hereto) if the aggregate value of cash and Cash Equivalents held or maintained by such Foreign Subsidiary does not exceed a book value of Two Hundred Fifty Thousand Dollars (\$250,000.00) at any time.

## 6.13 Further Assurances.

(a) Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.

(b) Deliver to Collateral Agent and Lenders, within five (5) days after the same are sent or received, copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or otherwise could reasonably be expected to have a Material Adverse Change.

#### 7. <u>NEGATIVE COVENANTS</u>

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

**7.1 Dispositions.** Convey, sell, lease, transfer, assign, or otherwise dispose of (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn out, surplus or obsolete Inventory or Equipment; (c) in connection with Permitted Liens, Permitted Investments and Permitted Lienses; (d) consisting of the sale or issuance of any Shares that is not, and does not immediately result in, a violation of Section 7.2(c)(ii) hereof; (e) by and between Borrower and any other Borrower or Guarantor; (f) consisting of Borrower's use or transfer of money or Cash Equivalents in connection with transactions not prohibited hereunder, in the ordinary course of

business, and consistent with the then applicable Annual Projections; (g) unwinding of any Permitted Investments, and (h) other assets of Borrower or its Subsidiaries that do not in the aggregate exceed One Hundred Thousand Dollars (\$100,000.00) during any fiscal year.

**7.2 Changes in Business, Management, Ownership, or Business Locations.** (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve; or (c) (i) any Key Person shall cease to be actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent within five (5) days of such change, or (ii) consummate any transaction or series of related transactions in which the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than forty nine percent (49%) of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions (other than by the sale of Borrower's equity securities in a public offering, a private placement of public equity or to venture capital investors so long as Borrower identifies to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations (i) contain less than Two Hundred Fifty Thousand Dollars (\$250,000.00) in assets or property of Borrower or any of its Subsidiaries and (ii) are not Borrower's or its Subsidiaries' chief executive office); (B) change its jurisdiction of organization, (C) change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization.

**7.3 Mergers or Acquisitions.** Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person. A Subsidiary may merge or consolidate into another Subsidiary (provided such surviving Subsidiary is a "co-Borrower" hereunder or has provided a secured Guaranty of Borrower's Obligations hereunder) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom.

7.4 Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

**7.5** Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens that are permitted by the terms of this Agreement to have priority over Collateral Agent's Lien), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property, except (i) as is otherwise permitted in Section 7.1 hereof and the definition of "**Permitted Liens**" herein and (ii) customary restrictions on assignment and transfer in license agreements under which Borrower or a Subsidiary is the licensee.

7.6 Maintenance of Collateral Accounts. Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

**7.7 Distributions; Investments.** (a) Pay any dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock; provided that (i) Borrower may convert any of its convertible securities into other securities pursuant to the terms of such convertible securities or otherwise in exchange thereof and may pay cash in lieu of the issuance of fractional shares provided that the aggregate amount of all such cash payments do not exceed One Hundred Thousand Dollars (\$100,000) per fiscal year, (ii) Borrower may repurchase the stock of current or former employees, officers or consultants pursuant to the terms of employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or similar plans, by the cancellation of indebtedness or otherwise, provided such repurchases do not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) in the aggregate per fiscal year and (iii) Subsidiaries of Borrower may make distributions to Borrower or any Guarantor, or (b) directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so.

**7.8 Transactions with Affiliates.** Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries; (c) transactions of the type described in and permitted pursuant to Section 7.7 hereof, (d) employee agreements or arrangements, compensation arrangements and reimbursements of expenses of current officers, employees or directors in the ordinary course of business approved by Borrower's board of directors, (e) retention, bonus or similar arrangements in the ordinary course of business approved by Borrower's nad (f) transactions between Borrower and any Subsidiaries of Borrower otherwise permitted by the terms of this Agreement.

**7.9 Subordinated Debt.** (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof, except in accordance with the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or Obligations owed to the Lenders.

**7.10 Compliance.** Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to meet the minimum funding requirements of ERISA, or permit a Reportable Event (as described in Section 4043 of ERISA, and for which the 30 day notice requirement has not been waived) or a non-exempt Prohibited Transaction, as defined in Section 406 of ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

**7.11 Compliance with Anti-Terrorism Laws.** Collateral Agent hereby notifies Borrower and each of its Subsidiaries that pursuant to the requirements of Anti-Terrorism Laws, and Collateral Agent's policies and practices, Collateral Agent is required to obtain, verify and record certain information and documentation that identifies Borrower and each of its Subsidiaries and their principals, which information includes the name and address of Borrower and each of its Subsidiaries and their principals and such other information that will allow Collateral Agent to identify such party in accordance with Anti-Terrorism Laws. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate under the control of Borrower or such Subsidiary to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Borrower and each of its Subsidiaries shall immediately notify Collateral Agent if Borrower or such Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries of Borrower and each of its Subsidiaries of Borrower (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. Neither Borrower and of the Subsidiaries shall, nor shall Borrower or any of its Subsidiaries of any contribution of funds, goods or services to or for the benefit of any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property o

## 8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "Event of Default") under this Agreement:

**8.1 Payment Default.** Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof). During the cure period, the failure to cure the payment default is not an Event of Default (but no Credit Extension will be made during the cure period);

#### 8.2 Covenant Default.

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Notice of Litigation and Default), 6.11 (Landlord Waivers; Bailee Waivers), 6.12 (Creation/Acquisition of Subsidiaries) or 6.13 (Further Assurances) or Borrower violates any covenant in Section 7; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within ten (10) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Grace periods provided under this Section shall not apply, among other things, to financial covenants or any other covenants set forth in subsection (a) above;

8.3 Material Adverse Change. A Material Adverse Change occurs;

#### 8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any Lender or any Lender's Affiliate or any bank or other institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, in excess of Fifty Thousand Dollars (\$50,000.00), or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets, in excess of Fifty Thousand Dollars (\$50,000.00), by any government agency, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; and

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

**8.5 Insolvency.** (a) Borrower or any of its Subsidiaries is or becomes Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Credit Extensions shall be made while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

**8.6** Other Agreements. There is a default in any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of Five Hundred Thousand Dollars (\$500,000.00) or that could reasonably be expected to have a Material Adverse Change; provided, however, that the Event of Default under this Section 8.6 caused by the occurrence of a breach or default under such other agreement shall be cured or waived for purposes of this Agreement upon Collateral Agent receiving written notice from the party asserting such breach or default of such cure or waiver of the breach or default under such other agreement, if at the

time of such cure or waiver under such other agreement (x) Collateral Agent has not declared an Event of Default under this Agreement and/or exercised any rights with respect thereto; (y) any such cure or waiver does not result in an Event of Default under any other provision of this Agreement or any Loan Document; and (z) in connection with any such cure or waiver under such other agreement, the terms of any agreement with such third party are not modified or amended in any manner which could in the good faith business judgment of Collateral Agent be materially less advantageous to Borrower or any Guarantor;

**8.7** Judgments. One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Five Hundred Thousand Dollars (\$500,000.00) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof (provided that no Credit Extensions will be made prior to the satisfaction, vacation, or stay of such judgment, order or decree);

**8.8 Misrepresentations.** Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made;

**8.9** Subordinated Debt. A default or breach occurs under any agreement between Borrower or any of its Subsidiaries and any creditor of Borrower or any of its Subsidiaries that signed a subordination, intercreditor, or other similar agreement with Collateral Agent or the Lenders, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;

**8.10** Guaranty. (a) Any Guaranty terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any Guaranty; (c) any circumstance described in Sections 8.3, 8.4, 8.5, 8.7, or 8.8 occurs with respect to any Guarantor, or (d) the: liquidation, winding up, or termination of existence of any Guarantor;

**8.11 Governmental Approvals.** Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term *and* such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or

**8.12** Lien Priority. Any Lien created hereunder or by any other Loan Document shall at any time fail 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 which are permitted to have priority in accordance with the terms of this Agreement; provided that such circumstance is not solely due to Collateral Agent's failure to file an appropriate continuation financing statement, amendment financing statement or initial financing statement.

## 9. <u>RIGHTS AND REMEDIES</u>

## 9.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, and at the written direction of Required Lenders shall, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (ii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower money or extend credit for Borrower's benefit or under any other agreement between Borrower and Collateral Agent and/or the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right at the written direction of the Required Lenders, without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;

(ii) apply to the Obligations any (a) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, or (b) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower; and/or

(iii) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Collateral Agent requests and make it available in a location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. Collateral Agent is hereby granted a limited non exclusive, non-sub-licensable, royalty free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, solely to the extent necessary in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any account maintained with Collateral Agent or the Lenders and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of Borrower's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written

consent of Required Lenders following the occurrence of an Exigent Circumstance. As used in the immediately preceding sentence, "**Exigent Circumstance**" means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

**9.2 Power of Attorney.** Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney-in-fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make Credit Extensions hereunder. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide Credit Extensions terminates.

**9.3 Protective Payments.** If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

9.4 Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other indebtedness or obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to Pro Rata Share unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's portion of any Term Loan and the ratable

distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its ratable share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its ratable share, then the portion of such payment or distribution in excess of such Lender's ratable share shall be received by such Lender in trust for and shall be promptly paid over to the other Lender for application to the payments of amounts due on the other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for Collateral Agent and other Lenders for purposes of perfecting Collateral Agent's security interest therein.

**9.5** Liability for Collateral. So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

**9.6** No Waiver; Remedies Cumulative. Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

**9.7 Demand Waiver.** Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

## 10. <u>NOTICES</u>

All notices, consents, requests, approvals, demands, or other communication (collectively, "**Communication**") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile or electronic mail transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address, facsimile number, or email address by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower:

VERA THERAPEUTICS, INC. 8000 Marina Blvd., Suite 120 Brisbane, CA 94005 Attn: [\*\*\*] Fax: [\*\*\*] Email: [\*\*\*]

with a copy (which shall not constitute notice) to:	Cooley LLP 55 Hudson Yards New York, NY 10001-2157 Attn: [***] Email: [***]
If to Collateral Agent:	OXFORD FINANCE LLC 115 South Union Street, Suite 300 Alexandria, VA 22314 Attention: [***] Fax: [***] Email: [***]
with a copy (which shall not constitute notice) to:	Barnes & Thornburg LLP 655 W. Broadway, Suite 1300 San Diego, California 92101 Attn: [***] Email: [***]

## 11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER, AND JUDICIAL REFERENCE

California law governs the Loan Documents without regard to principles of conflicts of law. Borrower, Collateral Agent and each Lender each submit to the exclusive jurisdiction of the State and Federal courts in Santa Clara County, California; provided, however, that nothing in this Agreement shall be deemed to operate to preclude Collateral Agent or any Lender from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of Collateral Agent or any Lender. Borrower expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

## TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER, COLLATERAL AGENT AND EACH LENDER EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR EACH PARTY TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES' AGREEMENT TO WAIVE THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY, if the above waiver of the right to a trial by jury is not enforceable, the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties (or, if they cannot agree, by the Presiding Judge of the Santa Clara County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a jury, in Santa Clara County, California; and the parties hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure §§ 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and permanent injunctions and appointing receivers. All such proceedings shall be closed

to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the Santa Clara County, California Superior Court for such relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings. The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The parties gudge shall oversee discovery and may enforce all discovery rules and orders applicable to judicial proceedings in the same manner as a trial court judge. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to California Code of Civil Procedure § 644(a). Nothing in this paragraph shall limit the right of any party at any time to exercise self-help remedies, foreclose against collateral, or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this paragraph.

## 12. GENERAL PROVISIONS

12.1 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's and each Lender's prior written consent (which may be granted or withheld in Collateral Agent's and each Lender's discretion, subject to Section 12.6). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "Lender Transfer") all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents; provided, however, that any such Lender Transfer (other than a transfer, pledge, sale or assignment to an Eligible Assignee) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of the Required Lenders (such approved assignee, an "Approved Lender"). Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender as Collateral Agent reasonably shall require. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) shall be permitted, without Borrower's consent, to any Person which is an Affiliate or Subsidiary of Borrower, a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent.

12.2 Indemnification. Borrower agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an "Indemnified Person") harmless against; (a) all obligations, demands, claims, and liabilities (collectively, "Claims") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable attorneys' fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct.

12.3 Time of Essence. Time is of the essence for the performance of all Obligations in this Agreement.

**12.4** Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

**12.5 Correction of Loan Documents.** Collateral Agent and the Lenders may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties; so long as Collateral Agent and the Lenders provide Borrower with written notice of such correction.

**12.6 Amendments in Writing; Integration.** (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature;

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term "Required Lenders" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.6 or the definitions of the terms used in this Section 12.6 insofar as the definitions affect the substance of this Section 12.6; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Section 12.10. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the preceding sentence;

(iv) the provisions of the foregoing clauses (i), (ii) and (iii) are subject to the provisions of any interlender or agency agreement among the Lenders and Collateral Agent pursuant to which any Lender may agree to give its consent in connection with any amendment, waiver or modification of the Loan Documents only in the event of the unanimous agreement of all Lenders.

(b) Other than as expressly provided for in Section 12.6(a)(i)-(iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

**12.7 Counterparts.** This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

**12.8 Survival.** All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.9 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

12.9 Confidentiality. In handling any confidential information of Borrower, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, or in connection with a Lender's own financing or securitization transactions and upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Credit Extensions (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement with the Lenders and Collateral Agent with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.9 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.9.

**12.10 Public Announcement.** Notwithstanding anything else herein to the contrary, Borrower hereby agrees that Collateral Agent and each Lender may make a public announcement of the transactions contemplated by this Agreement, and may publicize the same on its company website, in marketing materials, newspapers and other publications, and otherwise, and in connection therewith may use Borrower's name, tradenames, logos, and any information related to the transactions to the extent such information is not confidential.

12.11 Right of Set Off. Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

**12.12 Cooperation of Borrower**. If necessary, Borrower agrees to (i) execute any documents (including new Secured Promissory Notes) reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment or Term Loan to an assignee in accordance with Section 12.1, (ii) make Borrower's management available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments or Credit Extensions (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent or the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment or Term Loan reasonably may request, provided that, unless an Event of Default has occurred or is continuing, such prospective participant or assignee is not a direct competitor of Borrower as reasonably determined by Collateral Agent. Subject to the provisions of Section 12.9, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower prior to entering into this Agreement; provided that, unless an Event of Default has occurred or is continuing, such prospective participant or assignee is not a direct competitor of Borrower as reasonably determined by Collateral Agent. Lender's credit evaluation of Borrower prior to entering into this Agreement; provided that, unless an Event of Default has occurred or is continuing, such prospective participant or assignee is not a direct competitor of Borrower as reasonably determined by Collateral Agent.

## 13. **DEFINITIONS**

**13.1 Definitions.** As used in this Agreement, the following terms have the following meanings:

"Account" is any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

"Account Debtor" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

"Affiliate" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.

"Agreement" is defined in the preamble hereof.

"Amortization Date" is, January 1, 2026; provided that, if Borrower achieves the Atacicept Milestone, then, upon Borrower's written request to Collateral Agent therefor within thirty (30) days of the later of (i) achievement of the Atacicept Milestone and (ii) March 31, 2023, "Amortization Date" shall be January 1, 2027.

"Annual Projections" is defined in Section 6.2(a).

"**Anti-Terrorism Laws**" are any laws relating to terrorism or money laundering, including Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

"Approved Fund" is any (i) investment company, fund, trust, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business or (ii) any Person (other than a natural person) which temporarily warehouses loans for any Lender or any entity described in the preceding clause (i) and that, with respect to each of the preceding clauses (i) and (ii), is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender.

## "Approved Lender" is defined in Section 12.1.

"Atacicept Milestone" means Borrower has achieved, on or before December 31, 2025, either (i) positive Phase 2b data of atacicept in IgA Nephropathy or (ii) positive pivotal trial data of atacicept in Lupus Nephritis; written evidence of which, in form and content reasonably acceptable to Collateral Agent, has been reviewed and approved by Collateral Agent.

"**Basic Rate**" is the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to the greater of (i) eight and one quarter percent (8.25%) and (ii) the sum of (a) the greater of (x) the thirty (30) day U.S. LIBOR rate reported in the <u>Wall Street Journal</u> on the last Business Day of the month that immediately precedes the month in which the interest will accrue, and (y) nine-hundredths of one percent (0.09%), plus (b) eight and sixteen one-hundredths percent (8.16%). Notwithstanding the foregoing, the Basic Rate for the Term Loan for the period from the Effective Date through and including December 31, 2021, shall be eight and eight and two hundred fifty-four thousandths of one percent (8.254%). Notwithstanding anything to the contrary herein or in any other Loan Document, upon the occurrence of a LIBOR Transition Event, Collateral Agent may amend this Agreement to replace the Basic Rate with a LIBOR Replacement Rate. Any such amendment with respect to a LIBOR Transition Event will become effective at 5:00 p.m. (Eastern Standard Time) on the third Business Day after Collateral Agent has notified Borrower of such amendment. Any determination, decision or election that may be made by Collateral Agent pursuant hereto will be conclusive and binding absent manifest error and may be made in Collateral Agent's sole discretion and without consent from any other party.

"**Blocked Person**" is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) a Person that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"Borrower" is defined in the preamble hereof.

"**Borrower's Books**" are Borrower's or any of its Subsidiaries' books and records including ledgers, federal, and state Tax returns, records regarding Borrower's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"Business Day" is any day that is not a Saturday, Sunday or a day on which Collateral Agent is closed.

"**Cash Equivalents**" are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., and (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent. For the avoidance of doubt, the direct purchase by Borrower or any of its Subsidiaries of any Auction Rate Securities, or purchasing participations in, or entering into any type of swap or other derivative transaction, or otherwise holding or engaging in any ownership interest in any type of Auction Rate Security by Borrower or any of its Subsidiaries, are prohibited from purchasing, purchasing participations in, entering into any type of swap or other equivalent derivative transaction, or otherwise holding or engaging in any ownership interest in any type of debt instrument, including, without limitation, any corporate or municipal bonds with a long-term nominal maturity for which the interest rate is reset through a dutch auction and more commonly referred to as an auction rate security (each, an "**Auction Rate Security**").

"Claims" are defined in Section 12.2.

"**Code**" is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of California; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of California, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"Collateral" is any and all properties, rights and assets of Borrower described on Exhibit A.

"Collateral Account" is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Subsidiary at any time, other than Excluded Accounts.

"Collateral Agent" is, Oxford, not in its individual capacity, but solely in its capacity as agent on behalf of and for the benefit of the Lenders.

"Commitment Percentage" is set forth in <u>Schedule 1.1</u>, as amended from time to time.

"Commodity Account" is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"Communication" is defined in Section 10.

"Compliance Certificate" is that certain certificate in the form attached hereto as Exhibit C.

"**Contingent Obligation**" is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

"**Control Agreement**" is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a Securities Account or a Commodity Account, Borrower and such Subsidiary, and Collateral Agent pursuant to which Collateral Agent obtains control (within the meaning of the Code) for the benefit of the Lenders over such Deposit Account, Securities Account, or Commodity Account.

"**Copyrights**" are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

"Credit Extension" is any Term Loan or any other extension of credit by Collateral Agent or Lenders for Borrower's benefit.

"Default Rate" is defined in Section 2.3(b).

"Deposit Account" is any "deposit account" as defined in the Code with such additions to such term as may hereafter be made.

"Designated Deposit Account" is Borrower's deposit account, account number 3301503616, maintained with Silicon Valley Bank.

"Disbursement Letter" is that certain form attached hereto as Exhibit B.

"Dollars," "dollars" and "\$" each mean lawful money of the United States.

"Effective Date" is defined in the preamble of this Agreement.

"Effective Date Loan" is defined in Section 2.2(a)(i).

"Eligible Assignee" is (i) a Lender, (ii) an Affiliate of a Lender, (iii) an Approved Fund and (iv) any commercial bank, savings and loan association or savings bank or any other entity which is an "accredited investor" (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans as one of its businesses, including insurance companies, mutual funds, lease financing companies and commercial finance companies, in each case, which either (A) has a rating of BBB or higher from Standard & Poor's Rating Group and a rating of Baa2 or higher from Moody's Investors Service, Inc. at the date that it becomes a Lender or (B) has total assets in excess of Five Billion Dollars (\$5,000,000,000,00), and in each case of clauses (i) through (iv), which, through its applicable lending office, is capable of lending to Borrower without the imposition of any withholding or similar taxes; provided that notwithstanding the foregoing, "Eligible Assignee" shall not include, unless an Event of Default has occurred and is continuing, (i) Borrower or any of Borrower's Affiliates or Subsidiaries or (ii) a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent. Notwithstanding the foregoing, (x) in connection with assignments by a Lender due to a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party and (y) in connection with a Lender's own financing or securitization transactions, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Collateral Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee as Collateral Agent reasonably shall require.

"**Equipment**" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"ERISA" is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

"Event of Default" is defined in Section 8.

"**Excluded Accounts**" are deposit accounts (a) exclusively used for payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any of its Subsidiaries', employees and identified to Collateral Agent by Borrower as such in the Perfection Certificates or (b) subject to a Lien permitted pursuant to clause (b), (h) or (i) of the definition of Permitted Liens.

"Federal Reserve Bank of New York's Website" means the website of the Federal Reserve Bank of New York at http://www.newyorkfed.org, or any successor source.

"**Final Payment**" is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Maturity Date, or (b) the acceleration of any

Term Loan, or (c) the prepayment of a Term Loan pursuant to Section 2.2(c) or (d), equal to the original principal amount of such Term Loan multiplied by the Final Payment Percentage, payable to Lenders in accordance with their respective Pro Rata Shares.

"Final Payment Percentage" is five percent (5.00%); provided that, if the Amortization Date is extended to January 1, 2027, then "Final Payment Percentage" shall mean seven percent (7.00%).

"Foreign Subsidiary" is a Subsidiary that is not an entity organized under the laws of the United States or any territory thereof.

"Funding Date" is any date on which a Credit Extension is made to or on account of Borrower which shall be a Business Day.

"GAAP" is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

"General Intangibles" are all "general intangibles" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

"Governmental Approval" is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"Governmental Authority" is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

"Guarantor" is any Person providing a Guaranty in favor of Collateral Agent.

"Guaranty" is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

"Indemnified Person" is defined in Section 12.2.

"**Insolvency Proceeding**" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

"**Insolvent**" means not Solvent.

"Intellectual Property" means all of Borrower's or any Subsidiary's right, title and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;

(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;

- (c) any and all source code;
- (d) any and all design rights which may be available to Borrower;

(e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

"**Inventory**" is all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"**Investment**" is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance, or capital contribution to any Person.

"IRC" means the U.S. Internal Revenue Code of 1986, as amended.

"**Key Person**" is each of Borrower's (i) Chief Executive Officer, who is Marshall Fordyce, MD as of the Effective Date, (ii) Chief Financial Officer, who is Sean Grant as of the Effective Date and (iii) Chief Medical Officer, who is Celia Lin, MD as of the Effective Date.

"Lender" is any one of the Lenders.

"Lenders" are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

"Lenders' Expenses" are all reasonable, documented out-of-pocket audit fees and expenses, costs, and expenses (including reasonable and documented attorneys' fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

**"LIBOR Replacement Rate"** means the sum of: (a) the alternate benchmark rate (which may include SOFR) that has been selected by Collateral Agent giving due consideration to (i) any selection or recommendation of a replacement rate or the mechanism for determining such a rate by the Relevant Governmental Body or (ii) any evolving or then-prevailing market convention for determining a rate of interest as a replacement to the LIBOR rate for U.S. dollar-denominated syndicated credit facilities and (b) the LIBOR Replacement Spread; provided that, if the LIBOR Replacement Rate as so determined would be less than zero, the LIBOR Replacement Rate will be deemed to be zero for the purposes of this Agreement.

**"LIBOR Replacement Spread"** means, with respect to any replacement of the Basic Rate, the spread adjustment, or method for calculating or determining such spread adjustment, (which may be a positive or negative

value or zero) that has been selected by Collateral Agent giving due consideration to (i) any selection or recommendation of a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of the LIBOR rate by the Relevant Governmental Body or (ii) any evolving or then-prevailing market convention for determining a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of the LIBOR rate by the Relevant Governmental Body or (ii) any evolving or then-prevailing market convention for determining a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of the LIBOR rate for U.S. dollar-denominated syndicated credit facilities at such time.

"LIBOR Transition Event" means the occurrence of one or more of the following events with respect to the LIBOR rate:

(1) a public statement or publication of information by or on behalf of the administrator of the LIBOR rate announcing that such administrator has ceased or will cease to provide the LIBOR rate, permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide the LIBOR rate;

(2) a public statement or publication of information by the regulatory supervisor for the administrator of the LIBOR rate, the U.S. Federal Reserve System, an insolvency official with jurisdiction over the administrator for the LIBOR rate, a resolution authority with jurisdiction over the administrator for the LIBOR rate or a court or an entity with similar insolvency or resolution authority over the administrator for the LIBOR rate, which states that the administrator of the LIBOR rate has ceased or will cease to provide the LIBOR rate permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide the LIBOR rate; or

(3) a public statement or publication of information by the regulatory supervisor for the administrator of the LIBOR rate announcing that the LIBOR rate is no longer representative.

"Lien" is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"Loan Documents" are, collectively, this Agreement, the Perfection Certificates, each Compliance Certificate, each Disbursement Letter, the Post Closing Letter, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified.

"**Material Adverse Change**" is (a) a material impairment in the perfection or priority of Collateral Agent's Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower or any Subsidiary; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

"**Maturity Date**" is (x) December 1, 2026, if the Amortization Date is January 1, 2026; or (y) December 1, 2027, if the Amortization Date is January 1, 2027.

"**Obligations**" are all of Borrower's obligations to pay when due any debts, principal, interest, Lenders' Expenses, the Prepayment Fee, the Final Payment, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents, or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower's duties under the Loan Documents.

"OFAC" is the U.S. Department of Treasury Office of Foreign Assets Control.

"**OFAC Lists**" are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"**Operating Documents**" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"**Patents**" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

"Payment Date" is the first (1<sup>st</sup>) calendar day of each calendar month, commencing on February 1, 2022.

"Perfection Certificate" and "Perfection Certificates" is defined in Section 5.1.

"Permitted Indebtedness" is:

- (a) Borrower's Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;
- (b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s);
- (c) Subordinated Debt;
- (d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed One Hundred Thousand Dollars (\$100,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made); furthermore, notwithstanding anything to the contrary herein and strictly for the purposes of this clause (e) of the definition of Permitted Indebtedness and for no other purpose, any obligations of a Person that are or would have been treated as operating leases or capital leases for purposes of GAAP prior to the issuance by the Financial Accounting Standards Board on February 25, 2016 of an Accounting Standards Update (the "ASU") shall continue to be accounted for as operating leases or capital leases (whether or not such operating lease obligations or capital lease obligations, as applicable, were in effect on such date) notwithstanding the fact that such obligations are required in accordance with the ASU (on a prospective or retroactive basis or otherwise) to be treated as capitalized lease obligations in accordance with GAAP;

- (f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower's business;
- (g) to the extent constituting Indebtedness, Permitted Investments;

(h) reimbursement obligations in connection with letters of credit that are secured by cash or cash equivalents and issued on behalf of the Borrower or a Subsidiary thereof for purposes of securing real estate leases in an aggregate principal amount not to exceed One Million Dollars (\$1,000,000.00) at any time;

(i) Indebtedness in an aggregate amount not to exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) at any time outstanding in respect of credit cards;

(j) other Indebtedness in an amount not to exceed Two Hundred Fifty Thousand Dollars (\$250,000.00);

(k) to the extent constituting Indebtedness, royalty, milestone and other contingent obligations arising under license and other arrangements enter into in the ordinary course of business; and

(l) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (k) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be.

### "Permitted Investments" are:

(a) Investments disclosed on the Perfection Certificate(s) and existing on the Effective Date;

(b) (i) Investments consisting of cash and Cash Equivalents and (ii) any other Investments permitted by Borrower's investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;

(d) Investments consisting of deposit accounts (x) in which Collateral Agent has a perfected security interest (y) with respect to which no Control Agreement is required hereunder;

(e) Investments in connection with Transfers permitted by Section 7.1;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors; not to exceed Fifty Thousand Dollars (\$50,000.00) in the aggregate for (i) and (ii) in any fiscal year;

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (h) shall not apply to Investments of Borrower in any Subsidiary;

(i) Investments in joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the licensing of technology, which licensing is non-exclusive or, if exclusive constitutes a Permitted License, the development of technology or the providing of technical support; provided, that the aggregate cash portion of all such Investments shall not exceed One Hundred Thousand Dollars (\$100,000.00) in any fiscal year;

(j) Investments consisting of equity interests received as consideration by Borrower in transactions in the ordinary course of Borrower's business; provided that such equity interests shall become Collateral hereunder and shall be pledged to the Collateral Agent;

(k) Investments (i) by Borrower in a Subsidiary that is a co-Borrower and (ii) by Subsidiaries in Borrower or in a Subsidiary that is a co-Borrower;

(l) the formation of new Subsidiaries after the Effective Date, subject to compliance with all applicable provisions of this Agreement, including, without limitation, Section 6.1; and

(m) additional Investments in an amount not to exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) in any fiscal year.

"**Permitted Licenses**" are (A) licenses of over-the-counter software that is commercially available to the public, and (B) non-exclusive and exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, <u>provided</u>, that, with respect to each such license described in clause (B), (i) no Event of Default has occurred or is continuing at the time of such license; (ii) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; (iii) in the case of any exclusive license, (x) Borrower delivers ten (10) days' prior written notice and a brief summary of the terms of the proposed license to Collateral Agent and the Lenders and delivers to Collateral Agent and the Lenders copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof, and (y) any such license could not result in a legal transfer of title of the licensed property but may be exclusive in respects other than territory and may be exclusive as to territory only as to discrete geographical areas outside of the United States; and (iv) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower or any of its Subsidiaries are paid to a Deposit Account that is governed by a Control Agreement.

## "Permitted Liens" are:

(a) Liens existing on the Effective Date and disclosed on the Perfection Certificates or arising under this Agreement and the other Loan Documents;

(b) Liens for Taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the IRC, and the Treasury Regulations adopted thereunder;

(c) liens securing Indebtedness permitted under clause (e) of the definition of "**Permitted Indebtedness**," provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Two Hundred Fifty Thousand Dollars (\$250,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), <u>but</u> any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(h) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(b) hereof;

- (i) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7;
- (j) Liens consisting of Permitted Licenses;

(k) Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of custom duties that are promptly paid on or before the date they become due; and

(l) Liens on cash or cash equivalents securing obligations permitted under clause (h) or (i) of the definition of Permitted Indebtedness.

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"Post Closing Letter" is that certain Post Closing Letter dated as of the Effective Date by and between Collateral Agent and Borrower.

"**Prepayment Fee**" is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

(i) for a prepayment made on or after the Funding Date of such Term Loan through and including the first anniversary of the Funding Date of such Term Loan, three percent (3.00%) of the principal amount of such Term Loan prepaid;

(ii) for a prepayment made after the date which is after the first anniversary of the Funding Date of such Term Loan through and including the second anniversary of the Funding Date of such Term Loan, two percent (2.00%) of the principal amount of the Term Loans prepaid; and

(iii) for a prepayment made after the second anniversary of the Funding Date of such Term Loan and prior to the Maturity Date, no Prepayment Fee shall be applicable.

"**Pro Rata Share**" is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

"Registered Organization" is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

**"Relevant Governmental Body"** means the Federal Reserve Board and/or the Federal Reserve Bank of New York, or a committee officially endorsed or convened by the Federal Reserve Board and/or the Federal Reserve Bank of New York or any successor thereto.

"**Required Lenders**" means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an "**Original Lender**") have not assigned or transferred any of their interests in their Term Loan, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least sixty six percent (66%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender's interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

"**Requirement of Law**" is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

"Responsible Officer" is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower acting alone.

"Second Draw Period" is the period commencing on January 3, 2022 and ending on the earlier of (i) December 31, 2022 and (ii) the occurrence of an Event of Default (which has not been waived by Collateral Agent and the Lenders in their sole discretion or otherwise cured by Borrower as expressly permitted in accordance with this Agreement); provided, however, that the Second Draw Period shall not commence if an Event of Default has occurred and is continuing.

"Secured Promissory Note" is defined in Section 2.4.

"Secured Promissory Note Record" is a record maintained by each Lender with respect to the outstanding Obligations owed by Borrower to Lender and credits made thereto.

"Securities Account" is any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

"**Shares**" is one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or Borrower's Subsidiary, in any Subsidiary; provided that, in the event Borrower, demonstrates to Collateral Agent's reasonable satisfaction, that any Foreign Subsidiary does not satisfy the holding period requirement pursuant to Section 245A and Section 246(c)(5) of the IRC, "Shares" shall mean sixty-five percent (65%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or its Subsidiary in such Foreign Subsidiary.

"SOFR" with respect to any day means the secured overnight financing rate published for such day by the Federal Reserve Bank of New York, as the administrator of the benchmark, (or a successor administrator) on the Federal Reserve Bank of New York's Website.

"**Solvent**" is, with respect to any Person: the fair salable value of such Person's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person's liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature.

"Subordinated Debt" is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Lenders.

"Subsidiary" is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

"**Tax**" or "**Taxes**" means Taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to Tax or penalties applicable thereto).

"Term A Loan" is defined in Section 2.2(a)(i) hereof.

"Term B Loan" is defined in Section 2.2(a)(ii) hereof.

"Term Loan" is defined in Section 2.2(a)(ii) hereof.

"**Term Loan Commitment**" is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on <u>Schedule 1.1</u>. "**Term Loan Commitments**" means the aggregate amount of such commitments of all Lenders.

"**Trademarks**" means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

"Transfer" is defined in Section 7.1.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

# **BORROWER:**

VERA THERAPEUTICS, INC.

By /s/ Marshall Fordyce

Name: Marshall Fordyce Title: Chief Executive officer

# COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By /s/ Colette H. Featherly

Name: Colette H. Featherly

Title: Senior Vice President

[Signature Page to Loan and Security Agreement]

# **SCHEDULE 1.1**

# **Lenders and Commitments**

	Term A Loans	
Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$ 30,000,000.00	100.00%
TOTAL	\$ 30,000,000.00	100.00%
Lender	Term B Loans	
	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$ 20,000,000.00	100.00%
TOTAL	\$ 20,000,000.00	100.00%
	Aggregate (all Term Loans)	
Lender	Torm Loon Commitment	Commitment Descentage

Lender	Term Loan Commitment		Commitment Percentage
OXFORD FINANCE LLC	\$	50,000,000.00	100.00%
TOTAL	\$	50,000,000.00	100.00%

#### Exhibit 10.15

Certain identified information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[\*\*\*]".

Execution Copy

#### ASSET PURCHASE AGREEMENT

This Asset Purchase Agreement (the "**Agreement**") is made and entered into as of December 16, 2021 between Amplyx Pharmaceuticals, Inc., a Delaware corporation (the "**Seller**"), and Vera Therapeutics, Inc., a Delaware corporation (the "**Buyer**").

WHEREAS, on April 27, 2021 (the "**Merger Date**") Seller became a wholly-owned subsidiary of Pfizer Inc. ("**Pfizer**") pursuant to an Agreement and Plan of Merger, dated April 12, 2001, among Pfizer, Appaloosa Merger Sub Inc. and the Seller (the "**Pfizer-Amplyx Agreement**");

WHEREAS, Seller is developing an anti-BKV monoclonal antibody referred to as "MAU868" for the treatment of BKV disease pursuant to a License Agreement, dated August 26, 2019 (the "**Novartis License**"), between Novartis International Pharmaceutical AG ("**Novartis**") and the Seller; and

WHEREAS, Seller desires to sell to Buyer, and Buyer desires to acquire from Seller, all of Seller's right, title and interest in and to certain assets, including intellectual property rights, pertaining to MAU868 on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the representations, warranties, covenants and agreements contained herein, the parties hereto hereby agree as follows:

### ARTICLE I

#### DEFINITIONS AND TERMS

Section 1.1 <u>Definitions</u>. As used in this Agreement, the following terms shall have the meanings set forth or as referenced below:

"Affiliate" shall mean, with respect to any Person, any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person at any time during the period for which the determination of affiliation is being made. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") shall mean the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such Person, whether by the ownership of fifty percent (50%) or more of the voting stock or units of such Person, or by contract or otherwise.

"Agreement" shall have the meaning set forth in the preamble.

"Allocation" shall have the meaning set forth in Section 2.7.

"Antibody" means (a) the fully human monoclonal antibody referred to as "MAU868" described more fully on Exhibit A to the Novartis License, (b) the monoclonal antibodies claimed in the patent rights set forth on Exhibit C to the Novartis License, and (c) any [\*\*\*].

"Assignment and Assumption Agreement" shall have the meaning set forth in Exhibit A.

"Assumed Liabilities" shall have the meaning set forth in Section 2.4.

"**Business Day**" shall mean any day other than a Saturday, a Sunday or a day on which banks in New York, New York and San Francisco, California, United States of America are authorized or obligated by Law or executive order to close.

"Buyer" shall have the meaning set forth in the preamble to this Agreement.

"Buyer Material Adverse Effect" shall have the meaning set forth in Section 4.4.

"Closing" shall have the meaning set forth in Section 2.8(a).

"Closing Date" shall have the meaning set forth in Section 2.8(a).

"Collateral Source" shall have the meaning set forth in Section 6.6.

"Confidentiality Agreement" shall mean the Confidentiality Agreement dated as of August 5, 2021, between Pfizer and Buyer.

"European Regulatory Approval" means Regulatory Approval from the European Medicines Agency or any successor entity thereto or the applicable Governmental Authority in any one of the five major European markets (France, Germany, Italy, Spain or the United Kingdom).

"Excluded Assets" shall have the meaning set forth in Section 2.3.

"FDA" shall mean the United States Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.

"First Commercial Sale" means the first sale of a Product to a Third Party for distribution, use or consumption in such country after the Regulatory Approvals have been obtained for the Product in such country. For clarity, First Commercial Sale shall not include any sale or transfer of any Product prior to receipt of Regulatory Approval, such as "treatment IND sales," "named patient sales" and "compassionate use sales."

"Governmental Authority" shall mean any supranational, national, federal, state or local judicial, legislative, executive or regulatory authority.

"Governmental Authorizations" shall mean all licenses, permits, certificates and other authorizations and approvals issued by the relevant Governmental Authority that are required to carry on the research activities conducted by Seller and its Affiliates using the Purchased Assets as of the date of this Agreement under the applicable Laws.

"Governmental Order" shall mean any order, writ, judgment, injunction, decree, stipulation, determination or award entered by or with any Governmental Authority.

"Income Taxes" mean the United States federal income Tax and any state, local or non-U.S. net income Tax or any franchise or business Tax incurred in lieu of a Tax on net income.

"Indemnified Party" shall have the meaning set forth in Section 6.3.

"Indemnifying Party" shall have the meaning set forth in Section 6.3.

"Indication" shall have the meaning set forth in Novartis License.

"**Intellectual Property Rights**" shall mean and include all rights of the following types, which may exist or be created under the laws of any jurisdiction in the world: (i) rights associated with works of authorship, including exclusive exploitation rights, copyrights, moral rights, and mask works; (ii) trademark and trade name rights and similar rights; (iii) trade secret rights; (iv) Patents and industrial property rights; (v) other proprietary rights in intellectual property of every kind and nature; and (vi) all registrations, renewals, extensions, continuations, divisions, or reissues of, and applications for, any of the rights referred to in clauses (i) through (vi) above.

"Law" shall mean any federal, state, foreign or local law, common law, statute, ordinance, rule, regulation, code or Governmental Order.

"Liabilities" shall mean any debts, liabilities or obligations, whether accrued or fixed, known or unknown, absolute or contingent, matured or unmatured or determined or determinable.

"Lien" shall mean any lien, security interest, mortgage, charge or similar encumbrance.

"Loss" or "Losses" shall have the meaning set forth in Section 6.1(a).

"Merger Date" shall have the meaning set forth in the recitals.

"Net Sales" shall have the meaning set forth in the Novartis License.

"Novartis" shall have the meaning set forth in the recitals.

"Novartis License" shall have the meaning set forth in the recitals.

"Patent Assignment Agreement" shall have the meaning set forth in Exhibit A.

"**Patents**" shall mean (a) all national, regional and international patents and patent applications, including provisional patent applications and any and all rights to claim priority thereto; (b) all patent applications filed either from such patents, patent applications, or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations, and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications or other patents resulting from post-grant proceedings ((a), (b), and (c)); and (e) any similar patent rights, including so-called pipeline protection or any importation, revalidation, confirmation, or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

"Permitted Encumbrances" shall mean (a) all Liens [\*\*\*]; or (b) such Liens and other imperfections of title [\*\*\*].

"**Person**" shall mean any individual, firm, corporation, partnership, limited liability company, trust, joint venture, Governmental Authority or other legal entity or organization.

"Pfizer" shall have the meaning set forth in the recitals.

"Pfizer-Amplyx Agreement" shall have the meaning set forth in the recitals.

"**Product**" means any product in any dosage strength or formulation containing, incorporating or comprising an Antibody, either alone or in combination with other agents.

"**Purchased Assets**" shall have the meaning set forth in Section 2.1, it being understood that the Purchased Assets do not include the Excluded Assets.

"Regulatory Approval" shall have the meaning set forth in Novartis License.

"Required Third Party Consent" shall have the meaning set forth in Section 2.2(a).

"Retained Liabilities" shall have the meaning set forth in Section 2.5.

"Royalty Term" shall have the meaning set forth in the Novartis License.

"Seller" shall have the meaning set forth in the preamble to this Agreement.

"Seller Material Adverse Effect" shall mean any change, effect, event, circumstance, occurrence or state of facts that, individually or in the aggregate, would be reasonably likely to (a) be materially adverse to the ability of the Seller to perform its obligations hereunder, (b) materially impair the value or the use of the Antibody and Purchased Assets, or (c) prevent, materially impede or delay the consummation of the transactions contemplated hereby other than any change, effect, event, circumstance, occurrence or state of facts relating to (i) the economy or financial markets in general, (ii) the consummation of the transactions as contemplated by this Agreement, (iii) [\*\*\*], (iv) [\*\*\*], and (vi) [\*\*\*].

"Tax" or "Taxes" means any federal, state, local and non-U.S. taxes, including without limitation, income, gross receipts, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, ad valorem/personal property, stamp, excise, occupation, sales, use, transfer, value added, alternative minimum, estimated, license, severance, registration, natural resources, environmental, customs duties, escheat, fringe benefits, goods and services, intangible, inventory, land, recording, rent, windfall profits, capital gains, capital stock, franchise, payroll, employment, property, add-on minimum, and other taxes imposed by a Governmental Authority, including any interest, penalty or addition thereto, whether disputed or not, and shall include any liability for such amounts as a result of being a member of a combined, consolidated, unitary or affiliated group (including pursuant to Treasury Regulation Section 1.1502-6 or comparable provisions of state, local or non-U.S. tax law) and including any liability for taxes as a transferee or successor, by contract or otherwise.

"Tax Action" shall have the meaning set forth in Section 5.4(b).

"Third Party" shall mean any Person other than Seller, Buyer or an Affiliate of either Seller or Buyer.

"Third Party Claim" shall have the meaning set forth in Section 6.4(a).

"VAT" shall have the meaning set forth in Section 5.4(a).

Section 1.2 Other Definitional Provisions.

(a) The words "**hereof**", "**herein**", "**hereto**" and "**hereunder**" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement.

- (b) The definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms.
- (c) The terms "dollars" and "\$" shall mean United States dollars.

(d) The term **"including**" shall mean **"including, without limitation**" and the words **"included**" and **"include**" shall have corresponding meanings.

(e) When a reference is made in this Agreement to an Article, a Section, Exhibit or Schedule, such reference shall be to an Article of, a Section of, or an Exhibit or Schedule to, this Agreement unless otherwise indicated.

(f) When a reference is made in this Agreement to the terms of the Novartis License, such reference shall be to the Novartis License as is in effect on the date hereof and not as it may be subsequently amended or changed.

### ARTICLE II

### PURCHASE AND SALE

Section 2.1 <u>Purchase and Sale of the Purchased Assets</u>. Upon the terms and subject to the conditions set forth herein, effective at the Closing, Seller shall sell, convey, assign and transfer, and hereby sells, conveys, assigns and transfers to Buyer, and Buyer shall purchase, acquire and accept, and hereby purchases, acquires and accepts from the Seller, free and clear of all Liens, other than Permitted Encumbrances, all of the Seller's right, title and interest in and to the following assets (collectively, the "**Purchased Assets**"):

(a) the investigational new drug application filed with the FDA for authorization for the investigation of the Antibody listed on Schedule 2.1(a) ("Seller IND");

(b) the development and regulatory files, documentation, data, results and other electronic records identified on Schedule 2.1(b) ("Seller Development and Regulatory Documentation");

(c) the contracts to which Seller is a party that are [\*\*\*], including, in any event, the contracts identified on Schedule 2.1(c) ("Seller Contracts");

- (d) the Patents listed on Schedule 2.1(d) ("Seller Patents"); and
- (e) the chemical and biological materials listed on Schedule 2.1(e) ("Seller Product Inventory").

# Section 2.2 Consents.

(a) Buyer acknowledges and agrees that certain Purchased Assets may not be assignable or transferable without the consent of a Third Party (each, a "**Required Third Party Consent**"), and, at or prior to the Closing Date, such consents have not been obtained. After the Closing Date, Seller will [\*\*\*] to obtain those Required Third Party Consents [\*\*\*]; <u>provided</u>, <u>however</u>, that [\*\*\*]. Upon obtaining the Required Third Party Consent such Purchased Asset shall be transferred and assigned to, and assumed by, Buyer hereunder.

(b) With respect to any Purchased Asset that is subject to a Required Third Party Consent that has not been obtained pursuant to Section 2.2(a), after the Closing and [\*\*\*] (i) [\*\*\*] and (ii) [\*\*\*], the parties hereto shall [\*\*\*].



(c) Buyer agrees that [\*\*\*]. Buyer further agrees that [\*\*\*].

Section 2.3 <u>Excluded Assets</u>. Notwithstanding any provision in this Agreement, Buyer is not purchasing any asset that is not expressly identified on Schedule 2.1 (the "**Excluded Assets**") including:

- (a) [\*\*\*];
- (b) [\*\*\*]; and
- (C) [\*\*\*].

Section 2.4 <u>Assumption of Certain Liabilities</u>. Upon the terms and subject to the conditions of this Agreement, Buyer agrees, effective at the Closing, to assume all Liabilities of the Seller and its Affiliates, of any kind, character or description, whether accrued, absolute, contingent or otherwise, [\*\*\*] (other than Retained Liabilities), to the extent (but only to the extent) arising out of or relating to the Purchased Assets (collectively, the "Assumed Liabilities").

Section 2.5 <u>Retained Liabilities</u>. Notwithstanding any provision in this Agreement, Seller and its Affiliates shall retain and be responsible for the following (collectively, the "**Retained Liabilities**"):

(a) the Liabilities of Seller set forth on Schedule 2.5(a);

(b) all Liabilities of Seller, or any member of any consolidated, affiliated, combined or unitary group of which Seller is or has been a member, for Income Taxes attributable to taxable periods, or portions thereof, ending on or before the Closing Date;

- (c) all Liabilities for which Seller or its Affiliates expressly has responsibility pursuant to the terms of this Agreement; and
- (d) all Liabilities to the extent arising out of or relating to Excluded Assets.

## Section 2.6 Consideration.

(a) <u>Upfront Payment</u>. In partial consideration of the sale and transfer of the Purchased Assets, Buyer shall pay Seller five million dollars (\$5,000,000) in cash at the Closing (the "**Upfront Payment**").

(b) <u>Milestone Payments</u>. In partial consideration of the sale and transfer of the Purchased Assets, Buyer shall make the following one-time cash payments to Seller upon achievement of the corresponding milestone event set forth below (the "**Milestone Payments**"):

- (i) [\*\*\*] upon [\*\*\*];
- (ii) [\*\*\*] upon [\*\*\*].



The aggregate Milestone Payments under this Section 2.6(b) shall not exceed seven million dollars (\$7,000,000), regardless of the number of times any milestone event has been achieved or the number of Products achieving such milestone event. Buyer shall notify Seller in writing within [\*\*\*] after the achievement of the applicable milestone event. Seller shall invoice Buyer for the corresponding Milestone Payment, and Buyer shall make such Milestone Payment to Seller within [\*\*\*] after receiving such invoice from Seller.

(c) <u>Earn-out</u>. In partial consideration of the sale and transfer of the Purchased Assets, on a Product-by-Product and country-by-country basis, commencing upon the First Commercial Sale of a particular Product in a particular country, until the expiration of the Royalty Term for such Product in such country, Buyer shall pay to Seller an earnout equal to [\*\*\*] of the aggregate Net Sales of such Product in such country.

(d) <u>Earn-out Report and Payment</u>. Within [\*\*\*] after the end of each calendar quarter, commencing with the first calendar quarter in which there are any Net Sales of a Product anywhere in the world, Buyer shall provide Seller with a report setting forth the amount of Net Sales of the Products on a country-by-country basis and the earnout payable on such Net Sales pursuant to Section 2.6(c). [\*\*\*], Buyer shall pay the applicable royalty payments due to Seller for such calendar quarter. All payments under this Agreement will be payable in US Dollars. When conversion of payments from any foreign currency is required to be undertaken by Buyer, the US Dollar equivalent will be calculated using Buyer's then-current standard exchange rate methodology as applied in its external reporting. If there is no standard exchange rate methodology applied by Buyer in its external reporting in accordance with its Accounting Standards, then any amount in a currency other than US Dollars shall be converted to US Dollars using the exchange rate most recently quoted in the *Wall Street Journal* in New York as of [\*\*\*]. Without limiting any other rights or remedies available to the Seller hereunder, if Buyer [\*\*\*].

(e) <u>Records and Audits</u>. Buyer will keep, and will cause its Affiliates to keep, complete, true and accurate books and records in accordance with its Accounting Standards in relation to Net Sales and the earnouts payable to Seller under section 2.6(c), above. Buyer will [\*\*\*] and in the event such audit reveals an underpayment or overpayment by the Buyer, the underpaid or overpaid amount will be settled promptly.

Section 2.7 <u>Allocation of the Consideration</u>. All considerations paid by Buyer to Seller pursuant to Section 2.6 shall be allocated for Tax purposes among the Purchased Assets as mutually agreed to by the parties (the "**Allocation**"). Seller and Buyer agree not to take a position on any Income Tax return, before any Governmental Authority or in any judicial proceeding that is inconsistent with the Allocation.

# Section 2.8 Closing.

(a) On the terms and subject to the conditions of this Agreement, the closing of the transactions contemplated by this Agreement ("**Closing**") shall take place at the offices of Pfizer Inc., 235 East 42nd Street, New York, New York 10017-5755 (or, if agreed by the parties, electronically through the exchange of documents), at 12:00 p.m. (EST) on the date hereof, or at such other time and place as the parties hereto shall agree (the "**Closing Date**"). At Closing, there shall be an exchange of funds and documents. For purposes of this Agreement, unless otherwise agreed in writing by the parties, Closing shall be treated as if it occurred as of 12:01 a.m. on the Closing Date.

(b) At the Closing, Seller shall deliver, or cause to be delivered, to Buyer the instruments and documents set forth in <u>Exhibit A</u>, in each case in a form reasonably acceptable to Buyer.

(c) At the Closing, Buyer shall deliver, or cause to be delivered, to Seller the following: (i) the Upfront Payment, by wire transfer in immediately available funds, and (ii) the instruments and documents set forth in <u>Exhibit B</u>, in each case in a form reasonably acceptable to Seller. Seller shall provide wire transfer instructions to the Buyer at least [\*\*\*] prior to the Closing.

#### ARTICLE III

#### **REPRESENTATIONS AND WARRANTIES OF SELLER**

Except as set forth in Seller's Disclosure Schedules, Seller represents and warrants to Buyer as follows:

Section 3.1 Organization. Seller is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware.

#### Section 3.2 Authority; Binding Effect.

(a) Seller has all requisite corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution and delivery by Seller of this Agreement and the performance by Seller of its obligations hereunder have been, or will have been at the Closing, duly authorized by all requisite corporate action.

(b) This Agreement has been duly executed and delivered by Seller and, assuming the due authorization, execution and delivery by Buyer of this Agreement, constitutes a valid and binding obligation of Seller, enforceable against it in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by general principles of equity (regardless of whether enforcement is sought in a proceeding in equity or law).

Section 3.3 <u>Non-Contravention</u>. The execution, delivery and performance by Seller of this Agreement, and the consummation of the transactions contemplated hereby do not and will not (i) violate any provision of the certificate of incorporation or bylaws of Seller; (ii) assuming receipt of all Required Third Party Consents, conflict with, or result in the breach of or constitute a default under, any contract, agreement, lease or license to which Seller is a party and which relates exclusively to the Purchased Assets or (iii) assuming compliance with the matters set forth in Section 3.4 and Section 4.5, violate or result in a breach of or constitute a default under any Law or other restriction of any Governmental Authority to which the Seller is subject; except, with respect to clauses (ii) and (iii), for any violations, breaches, conflicts or defaults, that have not had, and would not reasonably be expected to have, individually or in the aggregate, a Seller Material Adverse Effect.

Section 3.4 <u>Governmental Authorization</u>. The execution and delivery by Seller of this Agreement and the consummation of the transactions contemplated hereby do not require any consent or approval of any Governmental Authority, except for consents or approvals, the failure of which to obtain has not had, and would not reasonably be expected to have, individually or in the aggregate, a Seller Material Adverse Effect.

Section 3.5 <u>Title to Purchased Assets</u>. The Seller owns, leases or has the legal right to use the Purchased Assets and has good title to the Purchased Assets, free and clear of all Liens other than Permitted Encumbrances.

Section 3.6 <u>Seller Contracts</u>. Since [\*\*\*], no default or event of default or event, occurrence, condition or act has occurred, with respect to Seller, or to Seller's knowledge, with respect to the other contracting Third Party, which, with the giving of notice or the lapse of the time, would become a default or event of default under any Seller Contract. Since [\*\*\*], Seller has not received written notice of, the cancellation, modification or termination of any Seller Contract. True, correct and complete copies of all Seller Contracts have been delivered to Buyer.

Section 3.7 <u>Litigation</u>. [\*\*\*], there are no (i) outstanding judgments, orders, injunctions or decrees of any Governmental Authority or arbitration tribunal against it or related to any of the Purchased Assets; (ii) lawsuits, actions or proceedings pending against it with respect to any of the Purchased Assets; or (iii) investigations by any Governmental Authority, which are pending against it with respect to any of the Purchased Assets.

Section 3.8 <u>No Debarment</u>. None of the Seller nor its current directors, officers, agents, representatives or consultants are under investigation by the FDA or other regulatory authorities for debarment action or presently debarred pursuant to the Generic Drug Enforcement Act of 1992, as amended, or any analogous laws.

Section 3.9 <u>Brokers</u>. No broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of Seller.

Section 3.10 <u>No Other Representations or Warranties</u>. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS ARTICLE 3, THE PURCHASED ASSETS ARE PROVIDED BY SELLER TO BUYER HEREUNDER "AS-IS" AND SELLER MAKES NO OTHER REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE, OR OTHERWISE, AND SELLER SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED OR STATUTORY WARRANTIES WITH RESPECT TO THE PURCHASED ASSETS. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, THE SELLER MAKES NO REPRESENTATION AND EXTENDS NO WARRANTY WITH RESPECT TO (A) THE ACCURACY OF ANY INFORMATION CONTAINED IN THE SELLER IND OR THE SELLER DEVELOPMENT AND REGULATORY DOCUMENTATION, (B) THE PROSPECTS OF THE ANTIBODY,

ANY PRODUCT OR THE PURCHASED ASSETS, OR (C) THE VALIDITY OR ENFORCEABILITY OF, AND NON-INFRINGEMENT WITH RESPECT TO, THE SELLER PATENTS OR THE SELLER INTELLECTUAL PROPERTY RIGHTS.

## ARTICLE IV

# **REPRESENTATIONS AND WARRANTIES OF BUYER**

Buyer represents and warrants to Seller as follows:

Section 4.1 <u>Organization and Qualification</u>. Buyer is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware.

Section 4.2 <u>Corporate Authorization</u>. Buyer has all requisite corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution and delivery by Buyer of this Agreement and the performance by Buyer of its obligations hereunder have been, or will have been at the Closing, duly authorized by all requisite corporate action.

Section 4.3 <u>Binding Effect</u>. This Agreement has been duly executed and delivered by Buyer and, assuming the due authorization, execution and delivery by Seller of this Agreement, constitutes a valid and binding obligation of Buyer, enforceable against it in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by general principles of equity (regardless of whether enforcement is sought in a proceeding in equity or law).

Section 4.4 <u>Non-Contravention</u>. The execution, delivery and performance by Buyer of this Agreement and the consummation of the transactions contemplated hereby do not and will not (i) violate any provision of the certificate of incorporation or bylaws of Buyer; (ii) conflict with, or result in the breach of, or constitute a default under, any contract, agreement, lease or license to which Buyer is a party, or (iii) assuming compliance with the matters set forth in Section 3.4 and Section 4.5, violate or result in a breach of or constitute a default under any Law or other restriction of any Governmental Authority to which Buyer is subject; except, with respect to clauses (ii) and (iii), for any violations, breaches, conflicts or defaults, that have not had, and would not reasonably be expected to have, individually or in the aggregate, a material adverse effect on the ability of Buyer to perform its obligations under this Agreement (a "**Buyer Material Adverse Effect**").

Section 4.5 <u>Governmental Authorization</u>. The execution and delivery by Buyer of this Agreement and the consummation of the transactions contemplated hereby do not require any consent or approval of any Governmental Authority, except for consents or approvals, the failure of which to obtain has not had, and would not reasonably be expected to have, individually or in the aggregate, a Buyer Material Adverse Effect.

Section 4.6 <u>Hart-Scott-Rodino Compliance</u>. The Buyer has determined that the transaction contemplated under this Agreement does not require clearance under the Hart-Scott-Rodino Antitrust Improvement Act of 1976, 15 U.S.C. §18a and the regulations promulgated thereunder, 16 C.F.R. §§ 801.1 et seq.

Section 4.7 <u>Financial Capability</u>. Buyer has sufficient funds to purchase the Purchased Assets and to consummate the transactions and perform its obligations under this Agreement on the terms and subject to the conditions contemplated herein and therein.

Section 4.8 <u>Brokers</u>. No broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of Buyer.

Section 4.9 No Inducement or Reliance; Independent Assessment. Buyer and its Affiliates [\*\*\*].

Section 4.10 No Other Representations or Warranties. EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES OF BUYER EXPRESSLY SET FORTH IN THIS ARTICLE 4, BUYER DOES NOT MAKE ANY REPRESENTATIONS OR WARRANTIES, AND BUYER HEREBY DISCLAIMS ANY OTHER REPRESENTATIONS OR WARRANTIES, WHETHER MADE BY BUYER, OR ANY OF ITS AFFILIATES OR REPRESENTATIVES, WITH RESPECT TO THE EXECUTION AND DELIVERY OF THIS AGREEMENT TO WHICH IT IS OR WILL BE A PARTY, OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY, NOTWITHSTANDING THE DELIVERY OR DISCLOSURE TO THE SELLER OR ANY OF ITS REPRESENTATIVES OF ANY DOCUMENTATION OR OTHER INFORMATION WITH RESPECT TO ANY ONE OR MORE OF THE FOREGOING.

#### ARTICLE V

#### **COVENANTS**

Section 5.1 Information and Documents.

(a) Except for the Purchased Assets, all information received by Buyer and given by or on behalf of the Seller in connection with this Agreement and the transactions contemplated hereby will be held by Buyer and its Affiliates, agents and representatives as "Confidential Information" of Pfizer, as defined in, and pursuant to the terms of, the Confidentiality Agreement. From and after the Closing, notwithstanding anything to the contrary in the Confidentiality Agreement, (i) all Purchased Assets shall be deemed, and treated by Seller, its Affiliates, agents and representatives as the "Confidential Information" (as defined in the Confidentiality Agreement) of Buyer only and (ii) [\*\*\*] shall be deemed to include information related to the Purchased Assets.

(b) From and after the Closing, Seller shall not publish, present, or otherwise disclose, and shall cause its Affiliates, agents and representatives, and Third Party licensees or contractors, and its and their respective employees and agents and representatives not to disclose any information related to the Antibody, Product or the Purchased Assets, without the prior written consent of Buyer. For clarity, from and after the Closing, Buyer shall be free to publish, present, or otherwise disclose information related to the Antibody, Product or the Purchased Assets, subject to the Confidentiality Agreement, if applicable.

(c) From and after the Closing, upon reasonable advance notice, the Seller, on the one hand, and Buyer, on the other hand, shall cause to be furnished or to be provided access to the other party and its representatives such financial, Tax and operating data and other available information with respect to the Purchased Assets, in each case in its then existing form, as such party and its representatives shall from time to time reasonably request in order to complete their legal and regulatory requirements and to complete their Tax returns and for any other reasonable business purpose, including in respect of litigation (other than litigation between the parties this Agreement or their Affiliates) and insurance matters. Buyer and its Affiliates shall, for a period of [\*\*\*], keep such materials reasonably accessible and not destroy or dispose of such materials without the written consent of Seller. Each party shall promptly reimburse the other for such other party's reasonable out-of-pocket expenses associated with requests made by the requesting party under this Section 5.1, but no other charges shall be payable by the requesting party to the other party in connection with such requests. In the event either party reasonably determines that any such provision of any such information could be commercially detrimental, violate any Law or contract, or result in the waiver any privilege, the parties shall take all commercially reasonable measures to permit the compliance with such obligations in a manner that avoids any such harm or consequence.

Section 5.2 <u>Compliance</u>. Each of the parties hereto agrees to use its commercially reasonable efforts to consummate and make effective the transactions contemplated by this Agreement, including (i) to comply promptly with all legal requirements that may be imposed on it with respect to this Agreement and the transactions contemplated hereby (which actions shall include furnishing all information required by applicable Law in connection with approvals of or filings with any Governmental Authority); and (ii) subject to Section 2.2, to obtain any consent, authorization, order or approval of, or any exemption by, any Governmental Authority or other public or private Third Party required to be obtained or made by Buyer or Seller in connection with the acquisition of the Purchased Assets or the taking of any other action contemplated by this Agreement.

Section 5.3 Transfer of Purchased Assets. Following the Closing, Seller shall [\*\*\*], and shall [\*\*\*].

# Section 5.4 <u>Taxes</u>.

(a) <u>General</u>. It is understood and agreed between the parties that any payments made under this Agreement are exclusive of any value added or similar Tax ("**VAT**"), which shall be added thereon as applicable. In the event any payments made by Buyer to Seller pursuant to this Agreement become subject to withholding Taxes under the Laws of any jurisdiction, Buyer shall deduct and withhold the amount of such Taxes for the account of Seller to the extent required by applicable Law and such amounts payable to Seller shall be reduced by the amount of Taxes deducted and withheld, which shall be treated as paid to Seller in accordance with this Agreement. To the extent that Buyer is required to deduct and withhold Taxes on any payments under this Agreement, Buyer shall

pay the amounts of such Taxes to the proper Governmental Authority in a timely manner and promptly transmit to the payee an official tax certificate or other evidence of such withholding sufficient to enable Seller to claim such payments of Taxes. Buyer shall provide any Tax forms to Seller that may be reasonably necessary in order for Buyer not to withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income Tax treaty. Each party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable Law, of withholding Taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the party bearing such withholding Tax or VAT.

(b) <u>Tax Actions</u>. Notwithstanding anything in this Agreement to the contrary, if an action, including but not limited to any assignment of its rights or obligations under this Agreement, or any failure to comply with applicable Laws or filing or record retention requirements (a "**Tax Action**") by a party leads to the imposition of withholding Tax liability or VAT on the other party that would not have been imposed in the absence of a Tax Action or in an increase in such liability above the liability that would have been imposed in the absence of such Tax Action, then (i) the sum payable by the party that caused the Tax Action (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that the other party receives a sum equal to the sum which it would have received had no Tax Action occurred and (ii) the sum payable by the party that caused a Tax Action (in respect of which such deduction or withholding is required to be made) shall be made to the other party after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with applicable Law. For the avoidance of doubt, a party shall only be liable for increased payments pursuant to this Section 5.4(b) to the extent such party engaged in a Tax Action that created or increased a withholding Tax or VAT on the other party.

Section 5.5 <u>Cooperation</u>. The parties agree to cooperate and produce on a timely basis any Tax forms or reports, including an IRS Form W-8BEN, reasonably requested by the other party in connection with any payment made by Buyer to Seller under this Agreement.

Section 5.6 <u>Pfizer Assurance</u>. [\*\*\*] For a period of [\*\*\*] after the Closing Date, [\*\*\*].

#### ARTICLE VI

#### **INDEMNIFICATION**

#### Section 6.1 Indemnification by Seller.

(a) Subject to the provisions of this ARTICLE VI, Seller agrees to defend, indemnify and hold harmless Buyer and its Affiliates, and their respective directors, officers, agents, employees, successors and assigns, from and against any and all claims, actions, causes of action, judgments, awards, Liabilities, losses, costs (including reasonable attorney's fees) or damages (collectively, a "Loss" or, the "Losses") claimed or arising from (i) any Retained Liability, (ii) any breach by Seller of any of its covenants or agreements contained in this Agreement or (iii) any breach of any representation or

warranty of Seller contained in this Agreement, except to the extent resulting from (A) any Assumed Liability, (B) any breach by Buyer of any of its covenants or agreements in this Agreement, or (C) any breach of any representation or warranty of Buyer contained in this Agreement.

(b) Buyer acknowledges and agrees that Seller shall not have any Liability under any provision of this Agreement for any Loss to the extent that such Loss relates to action taken by Buyer or any other Person relating to the Purchased Assets (other than action taken by Seller in breach of this Agreement) on or after the Closing Date. Buyer shall take, and shall cause its Affiliates to take, all reasonable steps to mitigate any Loss upon becoming aware of any event that would reasonably be expected to, or does, give rise thereto, including incurring costs only to the minimum extent necessary to remedy the breach that gives rise to the Loss.

# Section 6.2 Indemnification by Buyer.

(a) Subject to the provisions of this ARTICLE VI, Buyer agrees to defend, indemnify and hold harmless Seller and its Affiliates, and their respective directors, officers, agents, employees, successors and assigns, from and against any and all Loss claimed or arising from (i) any Assumed Liability, (ii) any breach by Buyer of any of its covenants or agreements in this Agreement, or (iii) any breach of any representation or warranty of Buyer contained in this Agreement, except to the extent resulting from (A) any Retained Liability, (B) any breach by Seller of any of its covenants or agreements in this Agreement, or (C) any breach of any representation or warranty of Seller contained in this Agreement.

(b) Seller shall take, and cause its Affiliates to take, all reasonable steps to mitigate any Loss upon becoming aware of any event that would reasonably be expected to, or does, give rise thereto, including incurring costs only to the minimum extent necessary to remedy the breach that gives rise to the Loss.

Section 6.3 <u>Notice of Claims</u>. If any of the Persons to be indemnified under this ARTICLE VI (the "**Indemnified Party**") has suffered or incurred any Loss, the Indemnified Party shall so notify the party from whom indemnification is sought (the "**Indemnifying Party**") promptly in writing describing such Loss, the amount or estimated amount thereof, if known or reasonably capable of estimation, and the method of computation of such Loss, all with reasonable particularity and containing a reference to the provisions of this Agreement or any other agreement or instrument delivered pursuant hereto in respect of which such Loss shall have occurred. If any action at Law or suit in equity is instituted by or against a Third Party with respect to which the Indemnified Party intends to claim any Liability as a Loss under this ARTICLE VI, the Indemnified Party shall promptly notify the Indemnifying Party of such action or suit and tender to the Indemnifying Party the defense of such action or suit. A failure by the Indemnified Party to give notice and to tender the defense of the action or suit in a timely manner pursuant to this Section 6.3 shall not limit the obligation of the Indemnifying Party under this ARTICLE VI, except (i) to the extent such Indemnifying Party is actually prejudiced thereby, (ii) expenses that are incurred during the period in which notice was not provided shall not be deemed a Loss and (iii) as provided by Section 6.5.

## Section 6.4 Third Party Claims.

(a) The Indemnifying Party under this ARTICLE VI shall have the right, but not the obligation, to conduct and control, through counsel of its choosing, the defense of any third party claim, action, suit or proceeding (a "**Third Party Claim**"). Except with the prior written consent of the Indemnified Party, the Indemnifying Party may compromise or settle a Third Party Claim that provides for injunctive or other non-monetary relief affecting the Indemnified Party or that does not completely release the Indemnified Party. Should the Indemnifying Party so elect to conduct and control the defense of any Third Party Claim, the Indemnifying Party shall not be liable to the Indemnified Party for legal expenses subsequently incurred by the Indemnified Party in connection with the defense thereof. No Indemnified Party may compromise or settle any Third Party Claim for which the Indemnified Party to participate in, but not control, the defense of any such action or suit through counsel chosen by the Indemnified Party, provided that the fees and expenses of such counsel shall be borne by the Indemnified Party. If the Indemnifying Party elects not to control or conduct the defense or prosecution of a Third Party Claim, the Indemnified Party shall have the full right to defend against such Third Party Claim and shall be entitled to settle or agree to pay in full such Third Party Claim and to recover any amounts paid plus all expenses incurred by the Indemnified Party (including attorneys' fees) from the Indemnifying Party. The Indemnifying Party nevertheless shall have the right to participate in the defense or prosecution of such Third Party Claim and, at its own expense, to employ counsel of its own choosing for such purpose.

(b) The parties hereto shall cooperate in the defense or prosecution of any Third Party Claim, with such cooperation to include (i) the retention of and the provision to the Indemnifying Party of records and information that are reasonably relevant to such Third Party Claim and (ii) the making available of employees on a mutually convenient basis for providing additional information and explanation of any material provided hereunder.

Section 6.5 <u>Expiration</u>. Notwithstanding anything in this Agreement to the contrary except for the next sentence, if the Closing shall have occurred, all covenants, agreements, representations and warranties made herein shall survive the Closing. Notwithstanding the foregoing, except for a party's [\*\*\*], all representations and warranties made herein, and all indemnification obligations under Section 6.1(a)(iii) and Section 6.2(a)(iii) with respect to any such representation or warranty, shall terminate and expire on, and no action or proceeding seeking damages or other relief for breach of any thereof or for any misrepresentation or inaccuracy with respect thereto shall be commenced after, [\*\*\*], unless prior to such [\*\*\*] a claim for indemnification with respect thereto shall have been made, with reasonable specificity, by written notice given under Section 6.3.

Section 6.6 <u>Losses Net of Insurance, Etc.</u> The amount of any Loss for which indemnification is provided under Section 6.1 or Section 6.2 shall be net of (i) any amounts recovered by the Indemnified Party pursuant to any indemnification by or indemnification agreement with any Third Party, or (ii) any insurance proceeds (net of any increase in premiums directly relating to such Loss as reasonably demonstrated by the

Indemnified Party) or other funds received directly by the Indemnified Party as an offset against such Loss (each Person named in clauses (i) and (ii), a "**Collateral Source**"). If the amount to be netted hereunder from any payment required under Section 6.1 or Section 6.2 is determined after payment by the Indemnifying Party of any amount otherwise required to be paid to an Indemnified Party pursuant to this ARTICLE VI, the Indemnified Party shall repay to the Indemnifying Party, promptly after such determination, any amount that the Indemnifying Party would not have had to pay pursuant to this ARTICLE VI had such determination been made at the time of such payment.

Section 6.7 <u>Sole Remedy</u>. The parties hereto acknowledge and agree that [\*\*\*].

Section 6.8 <u>No Consequential Damages</u>. EXCEPT FOR A PARTY'S FRAUDULENT OR WILLFUL MISCONDUCT, NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED HEREIN, NEITHER PARTY TO THIS AGREEMENT SHALL BE LIABLE TO OR OTHERWISE RESPONSIBLE TO THE OTHER PARTY HERETO OR ANY AFFILIATE OF ANY OTHER PARTY HERETO FOR CONSEQUENTIAL, INCIDENTAL OR PUNITIVE DAMAGES THAT ARISE OUT OF OR RELATE TO THIS AGREEMENT OR THE PERFORMANCE OR BREACH HEREOF OR ANY LIABILITY RETAINED OR ASSUMED HEREUNDER. THIS SECTION SHALL NOT LIMIT THE DAMAGES RECOVERABLE BY EITHER PARTY IN CONNECTION WITH ANY BREACH OF THE CONFIDENTIALITY AGREEMENT.

## ARTICLE VII

#### **MISCELLANEOUS**

Section 7.1 <u>Notices</u>. All notices or other communications hereunder shall be deemed to have been duly given and made if in writing and if served by personal delivery upon the party for whom it is intended, if delivered by registered or certified mail, return receipt requested, or by a national courier service, or if sent by facsimile, <u>provided</u> that the facsimile is promptly confirmed by telephone confirmation thereof, to the Person at the address set forth below, or such other address as may be designated in writing hereafter, in the same manner, by such Person:

To Seller:

Amplyx Pharmaceuticals, Inc. c/o Pfizer Inc. 235 East 42<sup>nd</sup> Street New York, NY 10017 Attention: [\*\*\*]

With a copy to:

c/o Pfizer Inc. 235 East 42nd Street New York, NY 10017 Attention: [\*\*\*\*]

To Buyer:

Vera Therapeutics, Inc. 170 Harbor Way, 3rd Floor South San Francisco, CA 94080 Attention: [\*\*\*]

Section 7.2 <u>Amendment; Waiver</u>. Any provision of this Agreement may be amended or waived if, and only if, such amendment or waiver is in writing and signed, in the case of an amendment, by Buyer and Seller, or in the case of a waiver, by the party against whom the waiver is to be effective. No failure or delay by any party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege.

Section 7.3 <u>Assignment</u>. No party to this Agreement may assign this Agreement, or any of its rights or obligations under this Agreement, without the prior written consent of the other party hereto, except that either party may, without such consent, assign this Agreement in its entirety to an Affiliates or to a successor in interest in connection with a merger or sale of all or substantially all of the business or assets to which this Agreement pertains; <u>provided</u>, <u>however</u>, that no such assignment by a Party shall relieve such Party of any of its obligations hereunder, and that any such assignment by such Party does not adversely affect the other Party or any of its Affiliates.

Section 7.4 <u>Entire Agreement</u>. This Agreement (including all Schedules and Exhibits), the Assignment and Assumption Agreement and the Patent Assignment Agreement contain the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral or written, with respect to such matters, except for the Confidentiality Agreement which will remain in full force and effect for the term provided for therein and other than any written agreement of the parties that expressly provides that it is not superseded by this Agreement.

Section 7.5 <u>Fulfillment of Obligations</u>. Any obligation of any party to any other party under this Agreement, which obligation is performed, satisfied or fulfilled by an Affiliate of such party, shall be deemed to have been performed, satisfied or fulfilled by such party.

Section 7.6 <u>Parties in Interest</u>. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and permitted assigns. Nothing in this Agreement, express or implied, is intended to confer upon any Person other than Buyer, Seller or their respective successors or permitted assigns, any rights or remedies under or by reason of this Agreement.

Section 7.7 <u>Public Disclosure</u>. Notwithstanding anything herein to the contrary, each of the parties to this Agreement hereby agrees with the other parties hereto that, except as may be required to comply with the requirements of any applicable Laws, and the rules and regulations of the SEC or each stock exchange upon which the securities of either of the parties is listed, no press release or similar public announcement or communication shall, if prior to the Closing, be made or caused to be made concerning the execution or performance of this Agreement unless the parties shall have consulted in advance with respect thereto.

Section 7.8 <u>Expenses</u>. Except as otherwise expressly provided in this Agreement, whether or not the transactions contemplated by this Agreement are consummated, all costs and expenses incurred in connection with this Agreement and the transactions contemplated hereby shall be borne by the party incurring such expenses. For the avoidance of doubt, Buyer, at their sole cost and expense, shall make all appropriate filings, notices and applications with the applicable Governmental Authority to reflect the sale, transfer and assignment of any Purchased Asset. Notwithstanding the foregoing, all Taxes (including any value added taxes but excluding any Income Taxes) and fees relating to the transfer of the Purchased Assets shall be paid by Buyer.

Section 7.9 <u>Governing Law; Jurisdiction</u>. This Agreement shall be governed in all respects, including validity, interpretation and effect, by the internal laws of the State of New York. The parties hereto agree that the [\*\*\*] shall have exclusive jurisdiction over any dispute or controversy arising out of or relating to this Agreement and any judgment, determination, arbitration award, finding or conclusion reached or rendered in any other jurisdiction shall be null and void between the parties hereto. Each party waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety, or other security that might be required of any other party with respect thereto.

Section 7.10 <u>Counterparts</u>. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which shall constitute one and the same agreement.

Section 7.11 <u>Headings</u>. The heading references herein and the table of contents hereto are for convenience purposes only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

Section 7.12 <u>Severability</u>. The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof. If any provision of this Agreement, or the application thereof to any Person or any circumstance, is invalid or unenforceable, (a) a suitable and equitable provision shall be substituted therefor in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid or unenforceable provision and (b) the remainder of this Agreement and the application of such provision to other Persons or circumstances shall not be affected by such invalidity or unenforceability, nor shall such invalidity or unenforceability affect the validity or enforceability of such provision, or the application thereof, in any other jurisdiction.

[Remainder of page intentionally blank]

IN WITNESS WHEREOF, the parties have executed or caused this Agreement to be executed as of the date first written above.

# AMPLYX PHARMACEUTICALS, INC.

By: /s/ Deborah Baron

Name: Deborah Baron Title: President

VERA THERAPEUTICS, INC.

By: /s/ Marshall Fordyce

Name: Marshall Fordyce Title: Chief Executive Officer

Acknowledged and agreed by Pfizer solely with respect to Section 5.6:

PFIZER INC.

By: <u>/s/ Deborah Baron</u>

Name:Deborah BaronTitle:SVP Worldwide Business Development

[Signature Page to Asset Purchase Agreement.]

# <u>Exhibit A</u>

List of instruments and documents to be provided by Seller: [\*\*\*]

# <u>Exhibit B</u>

List of instruments and documents to be provided by Buyer: [\*\*\*]

#### Exhibit 10.16

# Certain identified information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[\*\*\*]".

#### EXECUTION VERSION

# LICENSE AGREEMENT

This License Agreement ("<u>Agreement</u>"), made as of August 26, 2019 ("<u>Effective Date</u>"), is by and between Novartis International Pharmaceutical AG, a corporation organized under the laws of Switzerland, with its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland ("<u>Novartis</u>") and Amplyx Pharmaceuticals, Inc., a corporation organized and existing under the laws of Delaware, with a principal place of business at 12730 High Bluff Drive, Suite 160, San Diego, California 92130 ("<u>Company</u>"). Novartis and Company are each referred to individually as a "<u>Party</u>" and together as the "<u>Parties</u>."

#### Background

Novartis Controls (as defined below) the Novartis Patents and the Novartis Know-How (each as defined below) relating to the Antibodies (as defined below). Company is a pharmaceutical company focused on developing medicines to treat infectious diseases. Company wishes to obtain, and Novartis wishes to grant, rights under the Novartis Technology (as defined below) to develop, make, use and sell Antibodies and Products (as defined below).

For good and valuable consideration, the Parties agree as follows:

# 1. DEFINITIONS AND INTERPRETATION

**1.1 Definitions.** Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized will have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

"<u>Accounting Standards</u>" means, with respect to Company, United States Generally Accepted Accounting Principles (US GAAP) and means, with respect to Novartis, International Financial Reporting Standards (IFRS), in each case, as generally and consistently applied throughout the Party's organization. Each Party will promptly notify the other Party in the event that it changes the Accounting Standards pursuant to which its records relating to this Agreement are maintained; *provided, however*, that each Party may only use internationally recognized accounting principles (*e.g.*, IFRS or US GAAP).

"<u>Affiliate</u>" means, with respect to a particular Person, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control" or "controlled" means direct or indirect ownership of [\*\*\*] or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or [\*\*\*] or more of the equity interest in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby the entity or Person controls or has the

right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity. In the case of entities organized under the laws of certain countries, the maximum percentage ownership permitted by law for a foreign investor may be less than [\*\*\*], and in such case such lower percentage will be substituted in the preceding sentence, *provided* that such foreign investor has the power to direct the management and policies of such entity.

"Agreement" has the meaning set forth in the Preamble (i.e., in the first paragraph of this Agreement).

"Agreement Term" has the meaning set forth in Section 11.1.

"Alliance Manager" will have the meaning set forth in Section 3.1.

"<u>Antibody</u>" means (a) the fully human monoclonal antibody referred to as "MAU868" described more fully on *Exhibit A*, (b) the monoclonal antibodies claimed in the Patent Rights set forth on *Exhibit C*, and (c) any [\*\*\*]

"Antibody Material" has the meaning set forth in Section 6.1.

"<u>Applicable Law</u>" means any national, supranational, regional, federal, state, local or foreign law (including common law), statute or ordinance, or any rule, regulation, judgment, order, writ or decree of or from any court, or other Regulatory Authority or other governmental authority having jurisdiction over or related to the subject item or subject Person that may be in effect from time to time, including, as applicable, GCP, GLP, and GMP.

"Auditor" has the meaning set forth in Section 8.9(b).

"<u>BLA</u>" means a Biologics License Application in the United States for authorization to market a Product, as defined in the FDC Act and the regulations promulgated thereunder, submitted to the FDA.

"<u>Biosimilar Product</u>" means, with respect to a Product and on a country-by-country basis, a product that **(a)** is marketed for sale in such country by a Third Party (not licensed, supplied or otherwise provided by Company or its Affiliates or sublicensees); **(b)** contains the corresponding Product as an active pharmaceutical ingredient or is highly similar to and has no clinically meaningful differences from the corresponding Product; and **(c)** such product is approved as a "Biosimilar Biologic Product" under Title VII, Subtitle A Biologics Price Competition and Innovation Act of 2009, Section 42 U.S.C. 262, Section 351 of the PHSA, or, outside the United States, in accordance with European Directive 2001/83/EC on the Community Code for medicinal products (Article 10(4) and Section 4, Part II of Annex I) and European Regulation EEC/2309/93 establishing the Community procedures for the authorization and evaluation of medicinal products, each as amended, and together with all associated guidance, and any counterparts thereof or equivalent process inside or outside of the United States or EU to the foregoing.

"Business Day" means a day (other than a Saturday, Sunday or a public holiday) on which the banks are open for business in Basel, Switzerland, San Diego, California, and Cambridge, Massachusetts.

"<u>Calendar Quarter</u>" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30, and December 31.

"Calendar Year" means a period of twelve consecutive calendar months ending on December 31.

"Claims" means all Third Party demands, claims, actions and proceedings and liability (whether criminal or civil, in contract, tort or otherwise).

"<u>CMO</u>" means a contract manufacturing organization.

"<u>Commercialize</u>" means to market, promote, distribute, import, export, offer to sell or sell a Product, including to conduct all associated postlaunch regulatory activities, including medical affairs oversight, and "<u>Commercialization</u>" means activities to Commercialize a Product. "Commercialize" and "Commercialization" exclude Manufacture and Manufacturing.

"Commercially Reasonable Efforts" means, (a) with respect to the efforts to be expended by a Party to accomplish any objective (other than any objective relating to Development or Commercialization of an Antibody or Product by a Party, which is covered by clause (b) below), such reasonable, diligent, and good faith efforts as such Party would normally use to accomplish a similar objective under similar circumstances, and (b) with respect to any objective relating to Development or Commercialization of an Antibody or Product by a Party, the application by such Party (on its own or acting through any of its Affiliates or sublicensees or subcontractors), consistent with the exercise of prudent scientific and business judgment, of efforts and resources typically used by similarly-sized and similarly-situated biotechnology or pharmaceutical companies, as compared to such Party, to perform the obligation at issue, which efforts will be substantially equivalent to those efforts commonly made by such Party in an active and ongoing program to Develop and Commercialize a product owned by it or to which it has exclusive rights, which product is of a similar stage of development or in a similar stage of product life as an Antibody or Product, with similar developmental risk profiles and of similar market and commercial potential as an Antibody or Product, taking into consideration the intellectual property and competitive landscape relevant to such product, the safety and efficacy profile of a product, anticipated or approved labeling, the regulatory approval (including any reimbursement approval) risks associated with such product, and all other actual or anticipated scientific, technical, commercial and other relevant factors. "Commercially Reasonable Efforts" shall be determined on a country-by-country and Indication-by-Indication basis for an Antibody or Product, as applicable, and it is anticipated that the level of effort and resources that constitute "Commercially Reasonable Efforts" may change over time, reflecting changes in the status of an Antibody or Product, as applicable, and the country(ies) involved.

"Company" has the meaning set forth in the Preamble.

"Company Indemnitees" has the meaning set forth in Section 14.1.

"<u>Confidential Information</u>" means all Know-How and other information and data provided or made available by or on behalf of a Party to the other Party or any of its Affiliates, during the Agreement Term or previously pursuant to the confidentiality agreement between the Parties, dated January 24, 2019, whether made available orally, in writing or in electronic form. The terms of this Agreement shall constitute the Confidential Information of both Parties.

"<u>Control</u>" or "<u>Controlled</u>" means, with respect to any Regulatory Filings, Regulatory Approvals, Know-How, Patent Rights, other intellectual property rights, or any proprietary or trade secret information, the legal authority or right (whether by ownership, license or otherwise, other than by a license granted under this Agreement) of a Party or its Affiliates, to assign or grant a license or a sublicense of or under or other rights to access and use such Regulatory Filings, Regulatory Approvals, Know-How, Patent Rights, or intellectual property rights to another Person, or to otherwise disclose or transfer such proprietary or trade secret information to another Person, in each case as provided herein, without breaching the terms of any agreement with a Third Party or misappropriating the proprietary or trade secret information of a Third Party.

"Develop" or "Development" means all drug or biopharmaceutical development activities, including test method development, assay development and audit development, toxicology, formulation, quality assurance/quality control development, statistical analysis, clinical studies, packaging development, regulatory affairs, and the preparation, filing, and prosecution of Regulatory Filings as necessary to obtain Regulatory Approval, to market or sell a Product. "Develop" and "Development" exclude Manufacture and Manufacturing.

"Development Plan" has the meaning set forth in Section 3.2(a).

"Development and Commercialization Report" has the meaning set forth in Section 3.2(b).

"Effective Date" has the meaning in the preamble.

"EMA" means the European Medicines Agency or any successor entity thereto.

"<u>European Commission</u>" means the authority within the European Union that has the legal authority to grant Regulatory Approvals in the European Union based on input received from the EMA or other competent Regulatory Authorities.

"<u>European Regulatory Approval</u>" means Regulatory Approval from the EMA or the applicable Regulatory Authority in any of the [\*\*\*] major European markets [\*\*\*].

"FDA" means the United States Food and Drug Administration or any successor entity thereto.

"Field" means the diagnosis, prevention, mitigation or treatment of any disease, disorder or condition in humans.

"FDC Act" has the meaning set forth in Section 13.1(f).

"<u>First Commercial Sale</u>" means, with respect to a Product in a particular country, the first arm's length sale to a Third Party for value for use or consumption of any such Product following receipt of Regulatory Approval of such Product in such country.

"<u>First Patient First Dose</u>" means, with respect to a Product, the administration of the first dose of such Product to the first patient in the applicable clinical trial.

"Force Majeure" has the meaning set forth in Section 15.6.

"<u>GCP</u>" means the then-current ethical, scientific, and quality standards required by FDA or European Commission for designing, conducting, recording, and reporting trials that involve the participation of human subjects, as set forth in FDA regulations in 21 C.F.R. Parts 11, 50, 54, 56, and 312 and related FDA guidance documents, and by the International Conference on Harmonization E6: Good Clinical Practices Consolidated Guideline, or as otherwise required by Applicable Laws.

"<u>GLP</u>" means the then-current good laboratory practice as required by the FDA under 21 C.F.R. part 58 and all applicable FDA rules, regulations, orders and guidances, and the requirements with respect to current good laboratory practices prescribed by the European Community, the OECD (Organization for Economic Cooperation and Development Council) and the ICH Guidelines, or as otherwise required by Applicable Laws.

"<u>GMP</u>" means the then-current good manufacturing practices and regulations as required by the FDA under provisions of 21 C.F.R. parts 210 and 211 and all applicable FDA rules, regulations, orders and guidances, and the requirements with respect to current good manufacturing practices prescribed by the European Community under provisions of "The Rules Governing Medicinal Products in the European Community, Volume 4, Good Manufacturing Practices, Annex 13, Manufacture of Investigational Medicinal Products, July 2003," or as otherwise required by Applicable Laws.

"ICC" has the meaning set forth in Section 15.5(b).

"<u>IND</u>" means any investigational new drug application, clinical trial application or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirement of such Regulatory Authority, and any amendments thereto.

"Indemnification Claim Notice" has the meaning set forth in Section 14.3(b).

"Indemnified Party" has the meaning set forth in Section 14.3(b).

"Indemnifying Party" has the meaning set forth in Section 14.3(b).

"<u>Indication</u>" means a separate defined, well-categorized class of human disease syndrome or medical condition. For clarity, different stages of the same disease or condition will not be different Indications, different lines of treatment of the same disease or condition will not be different Indications, and the treatment or prevention of the same disease or condition in different demographic groups (*e.g.*, adult and pediatric) will not be different Indications, but

treatment of a disease or condition in different patient populations (*e.g.*, renal transplant patients, hematopoietic stem cell transplant patients, and progressive multifocal leukoencephalopathy patients) will be a different Indication.

"Infringement Claim" has the meaning set forth in Section 9.7.

"Insolvency Event" means:

- (a) Company ceases to function as a going concern by suspending or discontinuing its business;
- (b) Company is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against Company (except for involuntary bankruptcy proceedings that are dismissed within [\*\*\*] days);
- (c) an administrative receiver, receiver and manager, interim receiver, custodian, sequestrator, or similar officer is appointed for Company;
- (d) a resolution to wind up Company is passed at a meeting of the directors or shareholders of Company;
- (e) a resolution is passed by Company or Company's directors to make an application for an administration order or to appoint an administrator for all of Company's assets; or
- (f) Company makes any general assignment for the benefit of all of its creditors.

"Invalidity Claim" has the meaning set forth in Section 9.4.

"Invoice" means an invoice in a form reasonably acceptable to Company and to Novartis.

"<u>Know-How</u>" means all proprietary or confidential information, know-how and data, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology applicable to any Antibody or Product or to its manufacture, use, research, or development, including, for clarity, all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formulae, expertise and information, regulatory filings and copies thereof.

"Loss of Market Exclusivity" means, with respect to any Product in any country, that a Biosimilar Product has been launched (*i.e.*, is being sold) in the relevant country by a Third Party.

"Losses" means all losses, liabilities, damages, costs, fees, and expenses (including reasonable attorneys' fees and litigation expenses).

"<u>MAA</u>" means an application for the authorization to market the Product in any country or group of countries outside the United States, as defined in the Applicable Laws and filed with the Regulatory Authority of such given country or group of countries.

"<u>Manufacture</u>" means, with respect to an Antibody or Product, to manufacture, process, formulate, package, label, hold, store, quality control and release such Antibody or Product, and "<u>Manufacturing</u>" means activities to Manufacture a Product.

"<u>Manufacturing Know-How</u>" means all Know-How Controlled by Novartis or any of its Affiliates as of the Effective Date and reasonably necessary or useful to Manufacture Antibodies or Products in the Field. For clarity, Manufacturing Know-How shall exclude rights under any Manufacturing Patents.

"<u>Manufacturing Patents</u>" means the Patent Rights Controlled by Novartis or any of its Affiliates as of the Effective Date that are reasonably necessary or useful to Manufacture Antibodies or Products in the Field.

"Manufacturing Technology" means the Manufacturing Patents and the Manufacturing Know-How.

"Manufacturing Technology Improvements" has the meaning set forth in Section 2.4.

"<u>Meeting Hour</u>" means an hour spent by personnel of Novartis or its Affiliates in direct interaction with personnel of Company or its Affiliates in face-to-face meetings or teleconferences to answer questions or otherwise provide information related to transferred data and information as contemplated by this Agreement, independent of the number of participants from Novartis or its Affiliates attending the meeting or phone conference, and for time spent in activities responding to Company's requests during such meetings, but do not include hours spent by personnel of Novartis or its Affiliates to prepare for the meetings.

"Milestone" means a milestone relating to a Product, as set forth in Sections 8.3 and 8.4.

"Milestone Catch-Up Payment" has the meaning set forth in Section 8.3(d).

"<u>Milestone Payment</u>" means the payment to be made by Company to Novartis upon the achievement of the corresponding Milestone, as set forth in <u>Sections 8.3</u> and <u>8.4</u>.

"Net Sales" means [\*\*\*]

"<u>Non-Compete</u>" has the meaning set forth in Section 2.3(a).

"Novartis" has the meaning set forth in the Preamble.

"<u>Novartis Indemnitees</u>" has the meaning set forth in <u>Section 14.2</u>.

"<u>Novartis Know-How</u>" means the Know-How Controlled by Novartis or any of its Affiliates summarized on *Exhibit B*. Notwithstanding any other provision of this Agreement, "Novartis Know-How" excludes Manufacturing Know-How.

"Novartis Patents" means the Patent Rights set forth on Exhibit C, other than any Manufacturing Patents.

"Novartis Technology" means the Novartis Know-How and Novartis Patents.

"Party" or "Parties" has the meaning set forth in the Preamble.

"Patent Rights" means:

- (a) all patent applications, including any provisional patent applications, in any country;
- (b) any patent application claiming priority from such patent application or provisional application, including all divisionals, continuations, substitutions, continuations-in-part, provisionals, converted provisionals and continued prosecution applications;
- (c) any patent that has issued or in the future issues from any of the foregoing patent applications ((a) and (b)), including any utility model, petty patent, design patent, and certificate of invention;
- (d) any re-examinations, reissues, additions, renewals, extensions, registrations, supplemental protection certificates of any of the foregoing patents or patent applications ((a), (b), and (c)); and
- (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent application or patent.

"<u>Person</u>" means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization or other entity.

"Pharmacovigilance Agreement(s)" has the meaning set forth in Section 5.2.

"<u>Phase II Clinical Trial</u>" means a clinical study of an investigational product in humans with the primary objective of characterizing its activity in a specific disease state as well as generating more detailed safety, tolerability, and pharmacokinetics information, as described in U.S. 21 C.F.R. Part 312.21(b), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States, including a human clinical trial that is also designed to satisfy the requirements of 21 C.F.R. 312.12(a) or corresponding foreign regulations and is subsequently optimized or expanded to satisfy the requirements of 21 C.F.R. 312.12(b) or corresponding foreign regulations, or otherwise to enable a Phase III Clinical Trial (e.g., a phase I/II clinical trial).

"<u>Phase III Clinical Trial</u>" means a controlled clinical study of an investigational product in patients that incorporates accepted endpoints for confirmation of statistical significance of efficacy and safety with the aim to obtain Regulatory Approval, as described in 21 C.F.R. 312.21(c), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States.

"PRC" means the People's Republic of China, including the Hong Kong Special Administrative Region, the Macau Special Administrative Region, and Taiwan.

"<u>Pricing Reimbursement Approval</u>" means the authorization or approval of pricing or reimbursement for a pharmaceutical product in a country or jurisdiction by the relevant Regulatory Authority, government agency, or other body responsible for such activities in such jurisdiction(s) under Applicable Law.

"<u>Product</u>" means any product in any dosage strength or formulation containing, incorporating or comprising an Antibody, either alone or in combination with other agents.

"Product Marks" has the meaning set forth in Section 9.7.

"<u>Regulatory Approval</u>" means, with respect to a Product in any country or jurisdiction, any approval, registration, license or authorization from a Regulatory Authority in such country or other jurisdiction that is necessary to market and sell a Product in such country or jurisdiction, and includes Pricing Reimbursement Approval only if legally required for sale to a Third Party for use or consumption of such Product in such country. For clarity, approval by the applicable Regulatory Authority of a BLA for a Product in the United States or an MAA for a Product in any other country or jurisdiction shall constitute Regulatory Approval of such Product in such country or jurisdiction.

"<u>Regulatory Authority</u>" means any governmental authority or agency responsible for authorizing or approving the marketing or sale of pharmaceutical products in a jurisdiction (*e.g.*, the FDA, European Commission or EMA, the Japanese Ministry of Health, Labour and Welfare, and corresponding national or regional regulatory agencies or organizations).

"<u>Regulatory Exclusivity</u>" means the ability to exclude Third Parties from marketing and selling a Product in a country, whether through data exclusivity rights, orphan drug designation, or such other rights conferred by a Regulatory Authority in such country, other than through Patent Rights.

"<u>Regulatory Filings</u>" means, with respect to an Antibody or Product, any submission to a Regulatory Authority of any appropriate regulatory application, including any IND, BLA, MAA, or the corresponding application in any other country or group of countries, and any supplement or amendment thereto.

"<u>Royalty Term</u>" means, on a Product-by-Product and country-by-country basis, the period commencing on the First Commercial Sale of such Product in such country until the latest of:

[\*\*\*]

"Sales & Royalty Report" means a written report or reports showing each of:

(a) the Net Sales of each Product, on a country-by-country basis, during the reporting period by Company and its Affiliates and sublicensees (for the purpose of this definition, "sublicensees" will not include any distributors or wholesalers), the amount of any adjustments to royalties payable in accordance with <u>Section 8.6</u>; and

(b) the resulting total royalties payable, in USD, which will have accrued hereunder with respect to such Net Sales.

"SEC" means the United States Securities and Exchange Commission, or any successor agency thereto.

"Senior Officers" means, [\*\*\*]

"<u>Stock Issuance Agreement</u>" means the Series C-1 Preferred Stock Issuance Agreement, dated as of the Effective Date, by and between Company and Novartis Institutes for BioMedical Research, Inc.

"<u>Specified Primary Endpoint</u>" means the primary endpoint, as defined in the clinical trial protocol for a multiple-dose Phase II Clinical Trial of a Product for a specified Indication.

"Sublicense Consideration" has the meaning set forth in Section 8.7(a).

"Sublicense Percentage" means (a) with respect to a sublicense first granted prior to the First Patient First Dose of any Product in a Phase III Clinical Trial, [\*\*\*], and (b) with respect to a sublicense first granted after the First Patient First Dose of any Product in a Phase III Clinical Trial, [\*\*\*].

"Tax" or "Taxes" means any form of tax or taxation, levy, duty, charge, social security charge, contribution, or withholding in the nature of a tax (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a governmental authority.

"<u>Terminated Product</u>" means the Product or Antibody that is affected by the termination of the Agreement, in its entirety or on a Product-by-Product or country-by-country basis. In the case of termination of this Agreement in its entirety, all Products shall be deemed Terminated Products.

"<u>Terminated Territory</u>" means, with respect to a Terminated Product, those countries for which this Agreement has been terminated and, in the case of termination of this Agreement in its entirety, all countries of the world.

"Termination Date" has the meaning set forth in Section 12.1(a).

"Territory" means worldwide.

"Third Party" means any Person other than a Party or an Affiliate of a Party.

"<u>Third Party Acquisition</u>" means an acquisition by Novartis or its Affiliate of a Third Party or a portion of the business of a Third Party (whether by merger or acquisition of all or substantially all of the stock or all or substantially all of the assets of such Third Party or of any operating or business division of such Third Party or similar transaction).

"Third Party Infringement" has the meaning set forth in Section 9.3(a).

"<u>United States</u>" or "<u>US</u>" means the United States of America, its territories and possessions.

"<u>USD</u>" means US Dollars.

"Valid Claim" means

- (a) claim of an issued and unexpired patent included within the Novartis Patents that:
  - (i) has not been irrevocably or unappealably disclaimed or abandoned, or been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction; and
  - (ii) has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer, or otherwise; or
- (b) a claim included in a patent application included within the Novartis Patents that has not been cancelled, withdrawn or abandoned, nor been pending for more than seven years from the earliest filing date to which such patent application or claim is entitled.
- **1.2** Interpretation. In this agreement unless otherwise specified:
  - (a) "includes" and "including" will mean, respectively, includes and including without limitation;
  - (b) a Party includes its permitted successors and assignees;
  - (c) a statute or statutory instrument or any of their provisions is to be construed as a reference to that statute or statutory instrument or such provision as the same may have been or may from time to time hereafter be amended or re-enacted;
  - (d) words denoting the singular will include the plural and vice versa and words denoting any gender will include all genders;
  - (e) the Exhibits and other attachments form part of the operative provision of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the Exhibits and attachments;
  - (f) the headings in this Agreement are for information only and will not be considered in the interpretation of this Agreement;
  - (g) general words will not be given a restrictive interpretation by reason of their being preceded or followed by words indicating a particular class of acts, matters or things;
  - (h) references to "days" will mean calendar days unless otherwise indicated;
  - (i) the word "or" shall mean "and/or" unless the context otherwise requires; and

(j) the terms and conditions of this Agreement are the result of negotiations between the Parties and that this Agreement will not be construed in favor of or against any Party by reason of the extent to which any Party participated in the preparation of this Agreement.

# 2. LICENSES

# 2.1 License Grant.

- (a) Subject to the terms and conditions of this Agreement, Novartis hereby grants to Company a sublicensable (in accordance with Section 2.2) license under the Novartis Technology to research, Develop, make, have made, use, import, sell, offer for sale and otherwise Commercialize the Antibodies and Products in the Field in the Territory. Subject to the retained rights set forth in Section 2.3, the license set forth in this Section 2.1 shall be exclusive (even as to Novartis and its Affiliates).
- (b) Subject to the terms and conditions of this Agreement, including <u>Sections 2.2</u> and <u>6.4(b)</u>, Novartis hereby grants to Company a non-exclusive, sublicensable (in accordance with Section 2.2) license under the Manufacturing Technology to use and practice the Manufacturing Technology in the Territory solely to have Manufactured by CMOs (pursuant to the conditions of such Manufacturing contained in this Agreement, including <u>Section 6.4</u>) the Antibodies and Products for the research, Development, use, import, sale, offer for sale, and other Commercialization of the Antibodies and the Products in the Field in the Territory.
- 2.2 Sublicense Rights. Subject to <u>Section 8.7</u>, Company may sublicense (through multiple tiers) the license set forth in <u>Section 2.1</u>, subject to the applicable terms of this Agreement; *provided*, that in no event shall Company or any sublicensee sublicense the Manufacturing Technology to any Person, including any academic institution, other than a CMO as contemplated by <u>Section 6.4(b)</u>. Company shall provide Novartis with a copy of any such sublicense agreement within [\*\*\*] after the execution thereof, *provided* that such copy may be subject to redaction as reasonably appropriate to protect sensitive financial provisions, but only to the extent such provisions are not necessary to confirm compliance with this Agreement. Each sublicense of the Novartis Technology and Manufacturing Technology shall be consistent with the terms and conditions of this Agreement, and Company will remain liable for the performance or failure to perform of its sublicensees and Affiliates under their respective sublicensed rights to the same extent as if such activity were performed (or was failed to be performed) by Company. Each sublicense shall obligate the sublicensee thereunder to comply with all applicable terms of this Agreement, including this <u>Section 2.2</u> and <u>Sections 8.7</u>, <u>8.9</u> and <u>10</u>.

# 2.3 Retained Rights.

(a) Notwithstanding anything to the contrary in this Agreement, Novartis, its Affiliates, and its and their agents will retain the right to use the Novartis Technology (i) in order to perform its obligations under this Agreement, and (ii) for purposes of research and development by or on behalf of Novartis or its Affiliates; *provided* that, for a period of [\*\*\*] after the Effective Date, Novartis shall not, whether by itself or through an

Affiliate or Third Party, and shall not enable or facilitate any Affiliate or Third Party to, research, develop, make, have made, use, import, sell, offer for sale or otherwise promote any product containing, incorporating or comprising any monoclonal antibody intended to target BK virus protein VP1 and therapeutically treat BK virus disease, other than (A) any such product acquired by Novartis or its Affiliate as a result of a Third Party Acquisition or (B) any such product technically developed or manufactured at arms' length for a Third Party in accordance with a fee-for-services contract manufacturing services agreement between such Third Party and Novartis or its Affiliate(the "<u>Non-Compete</u>"). As used herein, "monoclonal antibody" means an intact antibody and antigen-binding antibody fragments thereof, including single chain fragments, monovalent fragments and single domain fragments, and including bivalent, multispecific, human, humanized, non-human, and chimeric versions of any of the foregoing.

- (b) Notwithstanding anything to the contrary in this Agreement, Novartis and its Affiliates retain the right to use for any purpose any learning, skills, ideas, concepts, techniques, know-how and information, including general methodologies and general SAR (structure-activity relationship) concepts, retained in intangible form in the unaided memory of Novartis's (or its Affiliate's) directors, employees, contractors, advisors, agents and other personnel of Novartis (or its Affiliates) who had access to the Novartis Technology or Manufacturing Technology; provided that Novartis complies with the Non-Compete and <u>Article 10</u>.
- (c) Without prejudice to any other rights that Novartis may have, and without limiting the license set forth in <u>Section 2.1, the Non-Compete</u>, and Company's rights under <u>Sections 2.2</u>, <u>4.1(b)</u>, <u>4.1(d)</u>, and <u>4.2(b)</u>, Company acknowledges and agrees that, as between the Parties, Novartis retains full and unencumbered rights under the Manufacturing Technology. Company further acknowledges and agrees that, as between the Parties, Novartis or its Affiliates are the sole owner(s) of all right, title and interest in and to the Manufacturing Technology, and Company has not acquired, and shall not acquire, any right, title or interest in or to the Manufacturing Technology, other than the non-exclusive license expressly set forth in this Agreement.
- 2.4 Grant Back. If Company or any Affiliate or sublicensee thereof, either itself or through or in collaboration with any Third Party, to the extent permitted under the conditions of this Agreement, further develops or evolves improvements to the Manufacturing Technology, (a) Company automatically and without further action hereunder hereby grants to Novartis a non-exclusive, royalty free, sublicensable, worldwide license to any such improvements to Manufacturing Technology Controlled by Company, *provided* that, any such improvements (collectively, "<u>Manufacturing Technology Improvements</u>") shall not include any cell line or Manufacturing Technology, and in the event any such Third Party is a CMO, Company shall use Commercially Reasonable Efforts to obtain an assignment or license of any such improvements to Manufacturing Technology developed or generated by on or behalf of such CMO, and (b) Company shall not at any time during the Agreement Term seek any Patent Rights with respect to such Manufacturing Technology Improvements.

2.5 Know-How Unrelated to Antibodies or Products. Company acknowledges that some of the Novartis Know-How disclosed to Company under this Agreement may include documents or materials that include information, data or other Know-How which is unrelated to the Antibodies or Products, and Novartis will use Commercially Reasonable Efforts to redact or delete such information, data or other Know-How prior to disclosure to Company or to otherwise exclude portions of such documents or materials from disclosure to the extent such portions are unrelated to the Antibodies and Products. Notwithstanding such efforts, to the extent that such information, data or other Know-How is disclosed to Company or its Affiliates, no license is granted to Company to use such information, data or Know-How for any purpose or to disclose such information, data or Know-How to any Person, and such information, data and Know-How shall be deemed to be Novartis' Confidential Information and not subject to disclosure or use by Company or its Affiliates, pursuant to <u>Section 10.3(c)</u> or otherwise.

# 3. GOVERNANCE; INFORMATION UPDATES

**3.1** Alliance Managers. Within [\*\*\*] after the Effective Date, each Party will appoint (and notify the other Party of the identity of) a senior representative having a general understanding of pharmaceutical development and commercialization issues to act as its alliance manager under this Agreement ("<u>Alliance Manager</u>"). The Alliance Managers will (a) serve as the contact point between the Parties for the purpose of providing Novartis with information on the progress of the Development, Manufacture, and Commercialization of Antibodies and Products by or on behalf of Company; (b) be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination, and collaboration between the Parties, including in particular in connection with the disclosure of Know-How from Novartis to Company as described in <u>Section 4</u>; (c) provide a single point of communication for seeking consensus both internally within the respective Party's organization and facilitating review of external corporate communications; and (d) raise cross-Party or cross-functional disputes in a timely manner. Each Party may replace its Alliance Manager on written notice to the other Party.

# 3.2 Development Plans; Reports.

- (a) Within [\*\*\*] after the Effective Date, Company will provide Novartis with a summary development plan setting forth the anticipated Development activities to be conducted by or on behalf of Company related to the Antibodies and Products during the following [\*\*\*] period (the "Development Plan"). No later than [\*\*\*] Company will update the Development Plan and provide a summary, in reasonable detail, of the anticipated Development activities to be conducted by or on behalf of Company during the following [\*\*\*] period.
- (b) Within [\*\*\*] Company will provide to Novartis a written summary of all Development and, if applicable, Commercialization activities that Company, its Affiliates, or their respective agents or sublicensees have conducted in [\*\*\*] (each, a "Development and Commercialization Report"). The Development and Commercialization Report will include sufficient information to reasonably determine if Company is in compliance with its obligations under Section 5.1(c) and Section 7.2 of this Agreement. If

Manufacturing of any Antibody or Product is based on Manufacturing Technology licensed hereunder, the Development and Commercialization Report shall also include the activities related to Manufacturing of Antibodies or Products and potential or actual Manufacturing Technology Improvements.

**3.3 Meetings**. Upon Novartis's request [\*\*\*] the Alliance Managers will meet (either in person or by teleconference) to review the Development Plan and Development and Commercialization Report and to discuss Company's Development and Commercialization activities and activities related to Manufacturing Technology.

# 4. DISCLOSURE OF LICENSOR KNOW-HOW & COOPERATION

### 4.1 Know-How Delivery.

- (a) Except with respect to documentation related to Manufacturing Technology, Novartis shall provide to Company an electronic copy of the documentation listed in *Exhibit B-1* (including the safety information identified therein) within [\*\*\*] If any such documentation is not available in electronic format, Novartis shall use its Commercially Reasonable Efforts to provide a hard copy of such documentation within [\*\*\*]. The Parties acknowledge that the disclosure by Novartis of such Know-How will consist of the disclosure of data residing in Novartis' databases, and will not include any database architecture or require any experimental work performed by Novartis for the purpose of technology transfer.
- (b) Company acknowledges that Novartis will disclose to Company information related to Manufacturing Technology in a staggered manner and solely on an as-needed basis. To facilitate the obtaining or maintaining of any Regulatory Approvals for Products by Company, Novartis will, as required in connection with a Regulatory Filing, and to the extent not contained within any Regulatory Filing transferred to Company pursuant to <u>Section 4.1(a)</u>, timely (i) provide qualitative composition of cell culture media directly to Company, provided that Company acknowledges and agrees that it may use such information solely for purposes of the applicable Regulatory Filing, and (ii) elect in its sole discretion to either (A) provide quantitative composition of cell culture media directly to the applicable Regulatory Authority, or (B) provide Company with a right of reference to an appropriate Regulatory Filing covering the Manufacturing Technology, including the cell culture media. Company acknowledges that this is a material provision of this Agreement.
- (c) Except with respect to data or information related to Manufacturing Technology, during [\*\*\*], if Company or Novartis identifies other information or data in Novartis' Control as of Effective Date and that is reasonably necessary for the continued Development of the Antibodies or Products, Novartis will use Commercially Reasonable Efforts to provide such information or data to the extent it remains within Novartis's possession or Control at the time of such identification, and such other information shall be deemed to be Novartis Know-How and licensed for Company's use under this Agreement, subject to <u>Section 2.4</u>.

(d) Copies of Regulatory Filings, the most recent draft of documents prepared for Regulatory Filing, Regulatory Approvals (if any) and Pricing Reimbursement Approvals (if any), and all written correspondence with Regulatory Authorities, in each case, solely to the extent related to any Antibody or Product, that Novartis or its Affiliates Control as of the Effective Date, are identified in *Exhibit F* and will be transferred to Company as set forth in Sections 4.1(a)-(c); *provided*, that Novartis, as of the Effective Date, hereby assigns all of its rights, title and interests in and to any and all INDs filed with the FDA covering any Antibody or Product, and, within [\*\*\*], Novartis will notify the FDA of the transfer of all such INDs to Company pursuant to a form of notice reasonably acceptable to Company, *provided*, *further*, that if Novartis is restricted under Applicable Law from transferring any of the foregoing items to Company, Novartis shall grant, and hereby does grant, to Company a right of reference or use to such item. At the request of Company, Novartis shall promptly take all permitted actions reasonably necessary to effect such transfer or grant of right of reference or use to Company.

#### 4.2 Know-How Transfer Assistance.

- (a) Except with respect to Manufacturing Technology, [\*\*\*] and upon Company's reasonable request, Novartis shall use Commercially Reasonable Efforts to answer questions regarding the Know-How provided to Company pursuant to <u>Section 4.1</u>, at no additional cost to Company. Such assistance shall be limited to interpretation for explanation of the Novartis Know-How that is provided to Company under <u>Section 4.1</u>, and in no event shall Novartis be required to provide further strategic guidance, analysis, or other consulting services relating to Company's efforts to research, Develop or Commercialize the Antibodies or Products. Novartis shall provide such assistance solely to Company or its Affiliates, and not to any Third Party (*e.g.*, service providers or contract manufacturers of Company). The Parties' Alliance Managers will agree on the format, timing, and scope of the relevant Know-How assistance; *provided* that [\*\*\*].
- (b) For CMC-related transfer activities, as set forth in *Exhibit B-2*, the total amount of transfer assistance provided by Novartis shall not [\*\*\*] Notwithstanding the foregoing, disclosure of the quantitative composition of the cell culture media as contemplated by <u>Section 4.1(b)</u> shall not be subject to the foregoing limitations, and shall take place when reasonably requested by Company in connection with regulatory submissions.
- (c) If Company requests additional assistance of the type provided for in <u>Section 4.2(a)</u> [\*\*\*], Novartis will in good faith consider providing such assistance but will be under no obligation to do so. Any such additional assistance will be limited to [\*\*\*] and shall be provided pursuant to a written task order describing the scope of the agreed upon assistance, and Novartis will charge Company at the rate of [\*\*\*] per FTE for such services.

- (d) To the extent that the services described in <u>Section 4.2(a)</u> and <u>4.2(b)</u> require Novartis to engage a Third Party service provider, the costs of such Third Party will be paid exclusively by Company.
- (e) For clarity, except as expressly set forth herein and as otherwise agreed to by the Parties, all assistance pursuant to this <u>Section 4.2</u> will be provided remotely (*e.g.*, e-mail, telephone or video conferences) and shall not require travel by Novartis personnel.
- **4.3** Acknowledgment Regarding Personnel. Company acknowledges that many of the scientists and other key personnel who have been involved in the research and Development of Antibodies and Products are no longer employed or engaged by Novartis or its Affiliates as of the Effective Date. Nothing contained herein, express or implied, shall require Novartis to seek information or assistance from any such scientists or other key personnel in order to perform its obligations under this Agreement and, with respect to scientists and other key personnel who are employed or engaged by Novartis or its Affiliates as of the Effective Date, nothing shall preclude the right of Novartis or its Affiliates to terminate the employment or engagement of any employee or independent contractor at any time and for any reason.
- **4.4 Disclaimer of Warranties.** Company acknowledges that all of the Know-How provided to Company pursuant to <u>Section 4.1</u> and any assistance provided pursuant to <u>Section 4.2</u> is provided "as is" and "where is," without representation or warranty of any kind, except as expressly set forth in <u>Section 13</u>. *Novartis hereby expressly disclaims any and all other warranties with respect to such Know-How and assistance, including implied warranties of merchantability or fitness for a particular purpose*. Novartis will have no obligation to update, revise, amend, or modify any of the Know-How or assistance provided to Company pursuant to this <u>Section 4</u> or otherwise in this Agreement, including with respect to documents that are in "draft" or "incomplete" form as of the Effective Date. For clarity, in no event will Novartis be required to conduct additional experiments or research in connection with its activities described in this <u>Section 4</u>.
- **4.5 Third Party Vendors and Service Providers.** The Parties acknowledge that Novartis and its Affiliates will not transfer or assign any agreements that it or they may have with vendors or service providers (*e.g.*, contract research organizations, contract clinical trial sites, consultants, *etc.*) in connection with the transactions contemplated by this Agreement. To the extent that Company proposes to engage one or more of such vendors and service providers in connection with the Development or Commercialization of an Antibody or Product after the Effective Date, at Company's written request, Novartis will provide reasonable assistance to Company in such efforts by issuing a letter of authorization to enable Company to request access to or copies of any information or documents identified in *Exhibit B* from any such vendor or service provider, solely to the extent related to the applicable Antibody or Product held by such vendors or service providers, at Company's sole cost and expense and pursuant to a separate agreement to be entered into between Company and any such vendors or service providers.

# 5. DEVELOPMENT; REGULATORY

# 5.1 Development and Regulatory Obligations.

- (a) Following the Effective Date, Company will be solely responsible for all research and Development of Antibodies and Products, including all regulatory matters arising in connection therewith, at its own cost and expense.
- (b) Company shall notify Novartis in writing of each material Regulatory Filing submitted to a Regulatory Authority by Company, its Affiliates or sublicensees that is based upon, incorporates, or references Manufacturing Technology within [\*\*\*] If the applicable Regulatory Authority raises any issue or question related to Manufacturing Technology, whether or not as applicable for an Antibody or Product, Company shall notify Novartis [\*\*\*] including providing a copy of any related correspondence and other documentation, shall consult with Novartis with respect to its response, and shall incorporate Novartis's reasonable comments related to the Manufacturing Technology prior to responding to such Regulatory Authority. Novartis shall provide timely, reasonable assistance to Company in responding to such issues or questions from Regulatory Authorities relating to the Manufacturing Technology. For clarity, if Novartis elected to provide the quantitative composition of the cell culture media directly to the Regulatory Authority under Section 4.1(b) and the Regulatory Authority has questions or issues concerning the quantitative composition of the cell culture media, Novartis may elect to respond directly to the Regulatory Authority, and is not required to provide a copy of such response to Company.
- (c) Company will itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Develop and obtain [\*\*\*]
- **5.2 Pharmacovigilance**. Company and Novartis shall cooperate with regard to the reporting and handling of safety information involving or relating to the Antibodies or the Products to the extent required by Applicable Laws. In time to ensure that all regulatory requirements are met, and to the extent required by Applicable Laws or any Regulatory Authority, Company will enter into written agreement(s) with Novartis and its Affiliates containing customary terms that will govern the exchange of adverse event and other safety information reporting obligations relating to the Antibodies or the Products (the "<u>Pharmacovigilance Agreement(s)</u>"), to ensure that adverse events and other safety information is exchanged and reported to the relevant Regulatory Authorities in compliance with the Applicable Laws and requirements of Regulatory Authorities.

# 6. MATERIAL TRANSFER; MANUFACTURING.

**6.1 Transfer of Antibody Material.** As soon as reasonably practicable after the Effective Date, and in any event [\*\*\*] Novartis will use its Commercially Reasonable Efforts to make available for pick-up (either free carrier or ex works, Incoterms 2010, at Novartis' discretion) the material identified on *Exhibit D* (the "<u>Antibody Material</u>"), in the form as such material currently exists, from Novartis', its Affiliates', or any Third Party's facilities where such Antibody Material is currently stored, at no additional cost to Company. [\*\*\*]

- **6.2 Disclaimer; Restrictions on Use.** Except as expressly set forth in <u>Section 13.5</u>, any Antibody Material transferred to Company pursuant to this Agreement is provided "as is" and "where is", and without representation or warranty of any kind, and Novartis hereby expressly disclaims any and all other warranties with respect to such Antibody Material, including any implied warranties of merchantability and fitness for a particular purpose.
- **6.3 Documentation and Transfer Process.** In connection with the transfer of the Antibody Material as described in <u>Section 6.1</u>, the following shall apply:
  - (a) Novartis will share with Company any MSDSs and customs value information to the extent (i) readily available to Novartis (and not otherwise available to Company), and (ii) reasonably necessary to permit Company to pick up the Antibody Material in accordance with Applicable Law and this Agreement;
  - (b) Company will be solely responsible for any re-testing associated with the Antibody Material prior to use;
  - (c) with respect to any released Antibody Material, Novartis will provide the certificate of analysis associated with its release;
  - (d) Company will be responsible for all documentation, licenses, customs clearance, costs, *etc.* that are needed for and related to the pick-up, transport, and subsequent delivery of the Antibody Material to the first destination as designated by Company and thereafter;
  - (e) unless Novartis otherwise agrees in writing, the Antibody Material will not be picked up from any one location in more than one installment; and
  - (f) the Antibody Material made available by Novartis will only be used according to its specifications, including release specifications, and in accordance with Applicable Laws, and Novartis will have no further obligation with respect to the Antibody Material.

#### 6.4 Manufacturing Technology.

- (a) Limited Rights. Company acknowledges that the process for Manufacturing Antibodies is based upon the Manufacturing Technology, all of which is proprietary to Novartis. Company further acknowledges that it does not and will not receive any rights in or to the Manufacturing Technology other than the non-exclusive license solely for the purpose to Develop and Commercialize Antibody as set forth in Section 2.1(b). Company acknowledges that this is a material provision of this Agreement.
- (b) CMOs. Notwithstanding the provisions of Section 2.2 of this Agreement, Company shall establish processes related to the cell bank and drug substance processes as part of the Manufacturing Technology solely at a CMO. Company is recommended, but not required, to use [\*\*\*] In the event that Company elects to use a CMO other than the aforementioned, Company shall be prohibited from establishing or transferring the Manufacturing Technology to any such CMO or geographical site except with the

specific prior written approval of Novartis, in its sole discretion. Any contract with a CMO shall highlight the confidential nature of the Manufacturing Technology and the Antibody. If Company wishes to develop or generate its own cell line that does not use any Manufacturing Technology, Company may do so and may then use a CMO for its own cell line without requiring the prior consent of Novartis.

- (c) Technical Development. Company acknowledges that Novartis is providing the Manufacturing Technology to Company "as is" and that Novartis will not perform additional development, testing or Manufacturing. Company is solely responsible for the buildup of its own supply chain. Upon notice by Company of its selection of a CMO, and specific prior approval of Novartis of such CMO if required under Section 6.4(b), Novartis will support Company in its efforts to establish CMOs for technical development and manufacturing in a paper-based manner and within a time frame of [\*\*\*] For the sake of clarity, Novartis will not provide consulting to Company in respect of further Development, Commercialization or Regulatory Approvals, except as set forth in Section 4.2.
- (d) Cell Bank. Novartis will provide a portion of the project-specific cell bank to Company's CMO selected in accordance with <u>Section 6.4(b)</u> as provided in *Exhibit E*; provided, that Company shall not transfer any portion of the project-specific cell bank provided to Company by Novartis to any Third Party other than a CMO permitted as provided under <u>Section 6.4(b)</u> and shall not, directly or indirectly, itself or through any Affiliate or sublicensee reverse engineer any portion of the project-specific cell bank provided to Company by Novartis. Generation of additional cell banks as well as release for use in Manufacturing is the sole responsibility of Company. Novartis will not provide or transfer the parental cell line to Company at any time. In the event that it is necessary for Company to access the parental cell line, Novartis will support Company by execution of these activities at the costs of Company and upon execution of a purchase order, either internally at Novartis or contracted to a Third Party, in Novartis's sole discretion and at Company's sole cost. Novartis will assist Company to source the Novartis cell media, which is part of the Manufacturing Technology, from the Novartis supplier via a Letter of Authorization.

# 7. COMMERCIALIZATION

- **7.1 Commercialization**. Company will be solely responsible for all aspects of Commercialization of the Products, including planning and implementation, distribution, booking of sales, pricing, and reimbursement, at its sole cost and expense.
- **7.2** Efforts. Company will itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Commercialize at least one Product, after obtaining Regulatory Approval.

# 8. FINANCIAL PROVISIONS

- **8.1 Initial Payment.** In consideration of the licenses and rights granted to Company hereunder, Company will make a one-time, non-refundable payment to Novartis in the amount of USD \$5,000,000, *via* wire transfer, within fifteen days after the Effective Date.
- **8.2** Equity Consideration. In further consideration of the licenses and rights granted to Company hereunder, Company shall issue certain securities to Novartis, as set forth in the Stock Purchase Agreement.

# 8.3 Development and Regulatory Milestones.

(a) In further consideration of the licenses and rights granted to Company hereunder, upon achievement of each of the following Milestones set forth below for any Product by Company, its Affiliates, or its sublicensees (as applicable), the corresponding Milestone Payments will be payable to Novartis:

Development or Regulatory Milestone	Milestone Payment (in US Dollars)
[***] [***]	[***]
[***] [***]	[***]
[***] [***]	[***]
[***] [***]	[***]
[***] [***]	[***]
[***] [***]	[***]

- (b) The Specified Primary Endpoint will be considered "Achieved" when the Specified Primary Endpoint has been met.
- (c) Each Milestone Payment will be deemed earned as of the first achievement of the corresponding Milestone and will be paid by Company to Novartis within [\*\*\*] after it has been invoiced for the relevant Milestone Payment. Company will provide Novartis with written notice of the achievement of each Milestone within [\*\*\*] after such Milestone is achieved.
- (d) In the event that a Milestone is achieved, but a Milestone Payment with respect to any previous Milestone has not been paid by Company, then Company shall pay all such unpaid Milestone Payments with respect to such previous Milestone(s) at the same time that the Milestone Payment for the later Milestone is paid (a "<u>Milestone Catch-Up Payment</u>"); provided, however, that no Milestone Catch-Up Payment shall be made (i) in respect of Milestone 3 based upon the achievement of Milestone 4; (ii) in respect of Milestone 5, or (iii) in respect of Milestone 3, 4, or 5 based upon the achievement of Milestone 6, except in the case where [\*\*\*]

(e) Each Milestone in the table above will be paid only once. The total potential Milestone Payments that may be paid under this <u>Section 8.3</u> is [\*\*\*].

#### 8.4 Sales Milestones.

(a) Company will make each of the following one time payments the first time that worldwide Net Sales of all Products in a given Calendar Year by it, its Affiliates, or their sublicensees meet the corresponding thresholds:

Net Sales of Products in any Calendar Year during the Royalty Term (in US Dollars)	Milestone Payment (in US Dollars)
[***]	[***]
[***]	[***]
[***]	[***]

- (b) For example, if Net Sales of Products in the first Calendar Year of Net Sales equals [\*\*\*]
- (c) Each Milestone Payment in the table above will be paid only once. The total potential Milestone Payments that may be paid under this <u>Section 8.4</u> is [\*\*\*].
- (d) Each Milestone Payment will be deemed earned as of the first achievement of the corresponding sales Milestone. Company will provide Novartis with written notice of the achievement of each Milestone within [\*\*\*] after such sales milestone is achieved, and each Milestone Payment will be paid to Novartis within [\*\*\*] after Company's receipt of the Invoice for the achievement of the relevant sales milestone.

# 8.5 Royalty Payments.

(a) In consideration of the licenses and rights granted to Company hereunder, during the applicable Royalty Term, Company will make royalty payments to Novartis on Net Sales of Products by Company, its Affiliates and sublicensees, at the rates set forth below:

Aggregate Net Sales of Products in any Calendar Year (in US Dollars)	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]

- (b) For example, if Net Sales of Products in a Calendar Year are [\*\*\*], the royalty on such Net Sales will be equal to [\*\*\*]
- (c) Following the expiration of the applicable Royalty Term for a Product in a country, the license granted to Company under <u>Section 2.1</u> of this Agreement with respect to such Product in such country will continue in effect, but will become non-exclusive, fully paid-up, royalty-free, perpetual and irrevocable.
- (d) Within [\*\*\*] Company will provide to Novartis a Sales & Royalty Report. Novartis will submit an Invoice to Company with respect to the royalty amount shown therein. Company will pay such royalty amount within [\*\*\*] after receipt of the Invoice.

#### 8.6 Know-How Royalty; Loss of Market Exclusivity; Third Party Obligations.

- (a) If the Royalty Term for a Product in a country continues solely due to (i) clause (b) (or clauses (b) and (c)) of the definition of Royalty Term then the royalties payable by Company to Novartis for Net Sales of such Product in such country will thereafter be reduced by [\*\*\*], or (ii) clause (c) of the definition of Royalty Term then the royalties payable for Net Sales of such Product in such country will thereafter be reduced by [\*\*\*].
- (b) If a Loss of Market Exclusivity exists with respect to such Product in such country, and (i) the Net Sales of such Product in that country in a Calendar Quarter are at least [\*\*\*] unless Novartis can demonstrate that such reduction is not attributable in material part to the Loss of Market Exclusivity, then the royalties payable by Company to Novartis with respect to Net Sales of such Product in such country will thereafter be reduced by [\*\*\*], (ii) the Net Sales of such Product in that country in a Calendar Quarter are at least [\*\*\*] less than the average Net Sales of such Product in that country during the last complete Calendar Quarter immediately preceding the launch of such Biosimilar Product, unless Novartis can demonstrate that such reduction is not attributable in material part to the Loss of Market Exclusivity, then the royalties payable by Company to Novartis with respect to such Net Sales of such Product in such country will thereafter be reduced by [\*\*\*], or (iii) the Net Sales of such Product in that country in a Calendar Quarter are at least [\*\*\*] less than the average Net Sales of such Product in that country during the last complete Calendar Quarter are at least [\*\*\*] less than the average Net Sales of such Product in that country during the last complete Calendar Quarter are at least [\*\*\*] less than the average Net Sales of such Product in that country during the last complete Calendar Quarter are at least [\*\*\*] less than the average Net Sales of such Product in that country during the last complete Calendar Quarter immediately preceding the launch of such Biosimilar Product, unless Novartis can demonstrate that such reduction is not attributable in material part to the Loss of Market Exclusivity, then the royalties payable by Company to Novartis with respect to such Net Sales of such Product in such country will thereafter be reduced by [\*\*\*]. For clarity, only one of each of the foregoing clauses (i) through (iii) of this <u>Section 8.6(b)</u> shall be applicable at any time.
- (c) If Company reasonably determines that, in order to avoid infringement of any Patent Right not licensed hereunder that covers any Antibody or Product in a country, and Company or any of its Affiliates or sublicensees acquires or licenses such rights from

a Third Party and is required to pay a royalty to such Third Party, Company will have the right to deduct [\*\*\*] of such royalty payments actually paid by Company or its Affiliate or sublicensee to such Third Party under such license from the royalty due with respect to any Product incorporating such Antibody to Novartis under <u>Section 8.5</u>.

- (d) The reductions and deductions set forth in this <u>Section 8.6</u> are cumulative and shall apply, in each case, to the maximum extent applicable; *provided*, that in no event will any royalty payment due to Novartis from Company under <u>Section 8.5(a)</u> in a given country in a given Calendar Quarter be reduced by more than (x) [\*\*\*] through operation of <u>Sections 8.6(a)</u>, <u>8.6(b)(i)</u> and <u>8.6(c)</u> or (y) [\*\*\*] through operation of Sections 8.6(a), 8.6(b)(iii) and 8.6(c).
- (e) Any reduction pursuant to <u>Section 8.6(a)</u> or 8.6(b) of the royalties payable by Company to Novartis with respect to Net Sales of a particular Product in a particular country under <u>Section 8.5(a)</u> will be calculated as follows:
  - (i) First, the effective, or "blended," royalty rate applicable to worldwide aggregate annual Net Sales of such Product (excluding Net Sales of any Product in any country that occur after the date of the expiration of the Royalty Term for such Product in such country) will be determined by <u>dividing</u>: (x) the total amount of royalties that would be payable under <u>Section 8.5(a)</u> with respect to worldwide aggregate annual Net Sales of all Products (excluding Net Sales of any Product in any country that occur after the date of the expiration of the Royalty Term for such Product in such country), <u>without giving effect to any royalty reduction or adjustment that may be available under Section 8.6(a) or 8.6(b); by (y) the total amount of worldwide aggregate annual Net Sales of any Product in any country that occur after the date of the expiration of the Royalty Term for such Product in any country that occur after the date of the expiration of the Royalty Term for such Product in such country), <u>without giving effect to any royalty reduction or adjustment that may be available under Section 8.6(a) or 8.6(b); by (y) the total amount of worldwide aggregate annual Net Sales of all Products (excluding Net Sales of any Product in any country that occur after the date of the expiration of the Royalty Term for such Product in such country); expressed as a percentage (such percentage, the "Effective Royalty Rate"). [\*\*\*]</u></u>
  - (ii) Any available royalty reduction under <u>Section 8.6(a)</u> or <u>8.6(b)</u> with respect to Net Sales of a particular Product in a particular country would be calculated by applying (x) the applicable percentage reduction under the relevant provision of <u>Section 8.6(a)</u> or <u>8.6(b)</u>, to (y) the amount of royalties determined by multiplying the Net Sales of such Product in such country by the Effective Royalty Rate.

# 8.7 Sublicense Consideration

(a) In addition to the other payment obligations of Company hereunder, in further consideration for the license and other rights granted to Company hereunder, Company shall pay to Novartis the Sublicense Percentage of any up-front, milestone, or other payments received by Company or its Affiliates as consideration for the grant of any sublicense hereunder, excluding [\*\*\*] For clarity, in a case where the Company receives payments from a sublicensee in a given Calendar Quarter in respect of an

interest in a profit-share or similar payments based on Product revenues, such payments will be considered Sublicense Consideration, but the amount payable to Novartis under this <u>Section 8.7(a)</u> in respect thereof will be reduced by [\*\*\*]

- (b) Notwithstanding Section 8.7(a), in the case of any milestone payments received by Company or its Affiliates from a sublicensee in respect of achievement of the milestones set forth in Sections 8.3 and 8.4, Company shall pay to Novartis the greater of (i) the Sublicense Percentage of the milestone payment received by Company or its Affiliate from such sublicensee, or (ii) the Milestone Payment set forth in Section 8.3 or 8.4, as applicable. If Company receives a milestone payment from a sublicensee for milestones not included in Section 8.3 or 8.4, Novartis shall be entitled to receive the Sublicense Percentage of such milestone payments, without offset or reduction of any Milestone Payment under Section 8.3 or 8.4.
- (c) Within [\*\*\*] Company will provide notice to Novartis thereof. Novartis will submit an Invoice to Company with respect to the Sublicense Consideration payable in respect thereof, and Company will pay such Sublicense Consideration within [\*\*\*].

#### 8.8 Payments.

- (a) All payments from Company to Novartis will be made by wire transfer in US Dollars to the credit of such bank account as may be designated by Novartis in this Agreement or in writing to Company. Any payment which falls due on a date which is not a business day in the location from which the payment may be made is payable on the next succeeding business day in such location. Unless otherwise provided in this Agreement, all amounts payable hereunder will be due [\*\*\*] after such amounts accrue.
- (b) All payments under this Agreement will be payable in US Dollars. When conversion of payments from any foreign currency is required to be undertaken by Company, the US Dollar equivalent will be calculated using Company's then-current standard exchange rate methodology as applied in its external reporting. If there is no standard exchange rate methodology applied by Company in its external reporting in accordance with Accounting Standards, then any amount in a currency other than US Dollars shall be converted to US Dollars using the exchange rate most recently quoted in the *Wall Street Journal* in New York as of the last Business Day of the applicable Calendar Quarter.
- (c) Other than as provided in this Section 8.8(c), each Party shall be responsible for its own Taxes, including any Tax, fee, assessment or other charge based on or measured by the capital or net income, or any other Tax imposed by any jurisdiction. Each Party will reasonably assist the other Party in lawfully claiming exemptions from and minimizing such deductions or withholdings under double taxation laws or similar circumstances. To the extent such exemptions are unavailable, Company shall be entitled to deduct and withhold (or cause to be deducted or withheld) from any consideration payable or otherwise deliverable pursuant to this Agreement, such amounts as are required to be deducted or withheld therefrom under any provision of

U.S. federal, state, local or non-U.S. Tax law or under any applicable legal requirement. To the extent such amounts are deducted or withheld and paid over to the appropriate governmental authority, such amounts shall be treated for all purposes under this Agreement as having been paid to the Person to whom such amounts would otherwise have been paid. To the extent that such amounts are not so deducted and withheld, Company shall indemnify Novartis and its Affiliates for any amounts imposed on Novartis or such Affiliate by a governmental entity, together with any related Losses. Additionally, all charges made hereunder for the supply of Product by Novartis to Company is exclusive of any sales, use, value added or similar tax customarily borne by a purchaser, which will be the exclusive responsibility of Company.

(d) Without limiting any other rights or remedies available to Novartis hereunder, if Company does not pay any amount due on or before the due date, any such payment shall bear interest at a rate of [\*\*\*] computed from the date such payment was due until the date Company makes the payment.

# 8.9 Records and Audit Rights.

- (a) Company will keep, and will cause its Affiliates and sublicensees to keep, complete, true and accurate books and records in accordance with its Accounting Standards in relation to Net Sales and royalties payable to Novartis hereunder. Company will keep, and will cause its Affiliates and sublicensees to keep, such books and records for at least [\*\*\*] following the delivery of the Sales & Royalty Report for the Calendar Quarter to which they pertain.
- (b) Novartis may, upon written notice to Company, appoint an internationally-recognized independent accounting firm (which is reasonably acceptable to Company) (the "<u>Auditor</u>") to inspect the relevant reports, statements, records or books of accounts (as applicable) of Company or its Affiliates or sublicensees to verify the accuracy of any Sales & Royalty Report. Before beginning its audit, the Auditor will execute an undertaking reasonably acceptable to Company by which the Auditor will keep confidential all Confidential Information reviewed during such audit. The Auditor will have the right to disclose to Novartis its conclusions regarding any payment owed under this Agreement.
- (c) Company will, and will cause its Affiliates and sublicensees to, make their records available for inspection by such Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from Novartis. The records will be reviewed solely to verify the accuracy of the Sales & Royalty Reports. Such inspection right will not be exercised more than [\*\*\*] and not more frequently than [\*\*\*]. In addition, Novartis will only be entitled to audit the relevant books and records of Company relating to a Sales & Royalty Report for a period of [\*\*\*] after receipt of the applicable Sales & Royalty Report. Novartis will hold in confidence in accordance with <u>Section 10</u> all Confidential Information received and all Confidential Information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or if disclosure is required by Applicable Law.

- (d) The Auditor will provide its audit report and basis for any determination to Company at the time such report is provided to Novartis, before it is considered final.
- (e) In the event that the final result of the inspection reveals an undisputed underpayment or overpayment by Company, the underpaid or overpaid amount will be settled promptly.
- (f) Novartis will pay for any such audits, as well as its own expenses associated with enforcing its rights with respect to any payments hereunder, except that in the event there is any upward adjustment in aggregate amounts payable for any Calendar Quarter shown by such audit of more than [\*\*\*] of the amount paid, Company will pay for such audit.
- **8.10** No Projections. Novartis and Company acknowledge that nothing in this Agreement will be construed as representing an estimate or projection of anticipated sales of any Product, and that the Milestones and Net Sales levels set forth above or elsewhere in this Agreement or that have otherwise been discussed by the Parties are merely intended to define the Milestone Payments and royalty obligations to Novartis in the event such Milestones or Net Sales levels are achieved.

# 9. INTELLECTUAL PROPERTY.

**9.1 Inventions and Know-How.** All inventions, whether or not reduced to practice, and Know-How, including data and results, arising from activities conducted by or on behalf of a Party under this Agreement, including any Patent Rights covering such inventions that arise from such activities after the Effective Date, will be owned by such Party.

#### 9.2 Patent Prosecution and Maintenance Following the Effective Date.

- (a) Company will control prosecution and maintenance of the Novartis Patents at Company's sole cost and expense, using counsel reasonably acceptable to Novartis. Company will regularly consult with Novartis regarding important issues relating to the prosecution and maintenance of the Novartis Patents, and will furnish to Novartis copies of documents materially relevant to such prosecution and maintenance in sufficient time, but no later than [\*\*\*], prior to the filing of such document to allow for review and comment by Novartis, and Company will reasonably consider all of such comments.
- (b) Company will notify Novartis of any decision not to continue to pay the expenses of prosecution and maintenance of any Novartis Patent, which notice must be delivered within [\*\*\*] or any other due date that requires action in connection with such Patent Right. In such event, Company shall permit Novartis, at its sole discretion and expense, to file or to continue prosecution or maintenance of such Patent Right. If Novartis undertakes such prosecution and maintenance, (c) Company will provide Novartis all reasonable assistance and cooperation in relation thereto, including providing any

necessary powers of attorney and any other required documents or instruments to effect such transfer, and **(b)** the license granted to Company to such Novartis Patent in such country shall thereupon terminate.

- (d) Each Party will be solely responsible for filing, prosecuting, and maintaining all Patent Rights under intellectual property arising from such Party's activities under this Agreement and solely owned by such Party, at its own cost and expense.
- (e) For the avoidance of doubt, the provisions of this <u>Section 9.2</u> relate solely to Novartis Patents other than Manufacturing Patents. Novartis retains all rights and obligations to maintain and prosecute Manufacturing Patents.

#### 9.3 Third Party Infringement.

- (a) Each Party will promptly notify the other of any actual, suspected, or threatened infringement by a Third Party of any of the Novartis Patents or misappropriation of any Novartis Know-How of which it becomes aware, including any "patent certification" filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions, of any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability, or non-infringement of any Novartis Patents, or any filing of any abbreviated Regulatory Filing for a Biosimilar Product in any jurisdiction. Each Party shall provide the other Party with all available evidence supporting such infringement, suspected infringement, unauthorized use or misappropriation or suspected unauthorized use or misappropriation (collectively, "Third Party Infringement").
- (b) Company will have the first right, but not the obligation, to bring and control any legal action in connection with Third Party Infringement at its own expense as it reasonably determines appropriate, and Novartis shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If Company fails to bring an action or proceeding with respect to, or to terminate infringement of, any Novartis Patent [\*\*\*], Novartis will have the right to bring and control any such action at its own expense and by counsel of its own choice, and Company will have the right, at its own expense, to be represented in any such action by counsel of its own choice; provided, however, that if Company notifies Novartis in writing prior to [\*\*\*] then Company shall be obligated to file such action before the time limit, and Novartis will not have the right to bring and control such action.
- (c) At the request of the Party controlling the Third Party Infringement claim, the other Party will provide assistance in connection therewith, including by executing reasonably appropriate documents, access to such Party's premises and employees, cooperating reasonably in discovery and joining as a party to the action if required.
- (d) In connection with any such proceeding, neither Party will enter into any settlement admitting the invalidity of, or otherwise impairing the other Party's rights in, the Novartis Technology without the prior written consent of the other Party, which will not be unreasonably withheld or delayed.

- (e) Any recoveries resulting from such an action relating to a Third Party Infringement will be first applied against payment of each Party's costs and expenses in connection therewith. In the event that Company brought such action, any remainder will be retained by Company; *provided, however*, any such amount will be considered Net Sales hereunder and will be subject to the royalties and Net Sales Milestones payable to Novartis under this Agreement. In the event that Novartis brought such action, the remainder will be retained by Novartis.
- **9.4** Third Party Patent Invalidity Claim. If a Third Party at any time asserts a claim that any Novartis Patent is invalid or otherwise unenforceable (an "Invalidity Claim"), whether as a defense in an infringement action brought by a Party pursuant to Section 9.4, in a declaratory judgment action or any patent office proceeding anywhere in the world (*e.g.*, inter-partes review or European opposition), Company shall have the first right, but not the obligation, to defend such Invalidity Claim and Novartis shall cooperate with Company in preparing and formulating a response to such Invalidity Claim. If Company does not defend an Invalidity Claim brought against a Novartis Patent, Novartis may defend such Invalidity Claim and the coordination provisions of Section 9.3(c) will apply to such Invalidity Claim, *mutatis mutandis* as they apply to Third Party Infringement suits. No Party may, without the consent of the other Party, settle or compromise any Invalidity Claim in any manner which would (a) have an adverse effect on such other Party's rights or obligations hereunder or (b) be an admission of liability on behalf of the other Party; *provided, however*, that the Party initiating such suit may settle such suit without such consent if such settlement involves only the receipt of money from, or the payment of money to, such Third Party and the Party settling such suit makes all such payments to such Third Party. To the extent such Invalidity Claim is raised as a defense in an infringement action brought by a Party pursuant to Section 9.3, the expense provisions of <u>Section 9.3</u> will apply and counsel to the Party controlling the infringement action shall act as the ministerial liaison with the court.
- **9.5 Company Patent Invalidity Claim**. The Parties have determined the value of the Novartis Technology based on their understanding of the validity and enforceability of the relevant Patent Rights and Know-How. If Company or any Affiliate thereof at any time asserts an Invalidity Claim in a declaratory judgment action or any patent office proceeding anywhere in the world and such challenge does not result in a material diminution of the scope of the relevant Novartis Patent, then the terms of this Agreement shall continue in full force and effect, but all payment amounts set forth in <u>Section 8.3</u>, <u>Section 8.4</u>, and <u>Section 8.5</u> shall be multiplied by [\*\*\*].
- **9.6 Defense of Infringement Claims by Third Parties.** If any Third Party asserts a claim, demand, action, suit or proceeding against a Party (or any of its Affiliates), alleging that any Product (other than with respect to the use or practice of the Manufacturing Technology) or the use or practice of the Novartis Technology infringes, misappropriates or violates the intellectual property rights of any Person (any such claim, demand, action, suit or proceeding being referred to as an "<u>Infringement Claim</u>"), the Party first having notice of the Infringement

Claim shall promptly notify the other Party thereof in writing specifying the facts, to the extent known, in reasonable detail and the following shall apply:

- (a) In the case of any such Infringement Claim against either Party individually or against both Novartis and Company, in each case, with respect to the Product, Company shall assume control of the defense of such Infringement Claim. Novartis, upon the request of Company and if required by Applicable Law, will join in any such litigation at Company's expense, and in any event to reasonably cooperate with Company at Company's expense. Novartis will have the right to consult with Company concerning such Infringement Claim and to participate in and be represented by independent counsel in any litigation in which Company is a party, at its own expense. Company shall not have the right to settle any Infringement Claim to the extent such settlement would adversely affect Novartis rights in and to the Novartis Technology or Manufacturing Technology without the written consent of Novartis, not to be unreasonably withheld, conditioned or delayed.
- (b) During the period in which such Infringement Claim is pending and following the resolution thereof, Company shall bear all costs incurred in connection therewith (including litigation costs, attorneys' fees, costs of settlement) including damage awards, and any other payment resulting therefrom. In the event Company is required to obtain a license from any Third Party under any patent or other intellectual property right of such Third Party, Company shall be solely responsible for any costs, fees, royalties, damages or other payments associated with such license.
- **9.7 Trademarks**. Company will have the right to brand the Products using Company related trademarks and any other trademarks and trade names it determines appropriate for the Products, which may vary by country or within a country ("<u>Product Marks</u>"). Company will own all rights in the Product Marks and register and maintain the Product Marks in the countries and regions it determines reasonably necessary.

### 9.8 Patent Extensions.

- (a) If requested by Company, Novartis will cooperate in obtaining patent term restoration (including under the Drug Price Competition and Patent Term Restoration Act), supplemental protection certificates or their equivalents, and patent term extensions with respect to the Novartis Patents in any country or region where applicable. Novartis will provide all reasonable assistance requested by Company, including permitting Company to proceed with applications for such in the name of Novartis, if deemed appropriate by Company, and executing documents and providing any relevant information to Company.
- (b) As between the Parties, Company will in its sole discretion determine which, if any, Novartis Patents, it will apply to extend; *provided*, *however*, that Company will give Novartis [\*\*\*] before doing so and reasonably consider any input from Novartis with respect to the extension of any Novartis Patents.

#### 10. CONFIDENTIALITY AND PUBLICITY

**10.1 Duty of Confidence**. Subject to the other provisions of this <u>Article 10</u>, all Confidential Information disclosed by a Party or its Affiliates under this Agreement will be maintained in



confidence and otherwise safeguarded by the recipient Party. The recipient Party may only use the Confidential Information for the purposes of this Agreement and pursuant to the rights granted to the recipient Party under this Agreement. Subject to the other provisions of this <u>Article 10</u>, each Party will hold as confidential such Confidential Information of the other Party or its Affiliates in the same manner and with the same protection as such recipient Party maintains its own confidential information, but in no event using less than reasonable care. Subject to the other provisions of this <u>Article 10</u>, a recipient Party may only disclose Confidential Information of the other Party to employees, agents, contractors, consultants and advisers of the Party and its Affiliates and sublicensees and to Third Parties to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; *provided* that such Persons are bound to maintain the confidentiality of the Confidential Information in a manner consistent with the confidentiality provisions of this Agreement.

- **10.2 Exceptions.** The obligations under this <u>Article 10</u> will not apply to any Confidential Information to the extent the recipient Party can demonstrate by competent evidence that such Confidential Information:
  - (a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the recipient Party or its Affiliates;
  - (b) was known to, or was otherwise in the possession of, the recipient Party or its Affiliates prior to the time of disclosure by the disclosing Party or any of its Affiliates;
  - (c) is disclosed to the recipient Party or an Affiliate on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party or any of its Affiliates; or
  - (d) is independently developed by or on behalf of the recipient Party or its Affiliates, as evidenced by its written records, without reference to the Confidential Information disclosed by the disclosing Party or its Affiliates under this Agreement.

Specific aspects or details of Confidential Information will not be deemed to be within the public domain or in the possession of the recipient Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the recipient Party. Further, any combination of Confidential Information will not be considered in the public domain or in the possession of the recipient Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the recipient Party unless the combination and its principles are in the public domain or in the possession of the recipient Party.

# 10.3 Authorized Disclosures.

(a) In addition to disclosures allowed under <u>Sections 10.1</u> and <u>10.2</u>, and except as set forth in <u>Section 2.5</u>, either Party may disclose Confidential Information belonging to the other Party or its Affiliates to the extent such disclosure is necessary in the following instances: (i) filing or prosecuting Patent Rights as permitted by this Agreement; (ii) in

connection with Regulatory Filings for Products; (iii) prosecuting or defending litigation as permitted by this Agreement; (iv) complying with Applicable Law or the inquiries of Regulatory Authorities; (v) to a bona fide potential acquirer, investor, collaborator, partner, sublicensee under reasonable and customary written confidentiality obligations; or (vi) otherwise to the extent otherwise necessary or appropriate in connection with exercising the license and other rights granted to or performing the obligations imposed on such Party hereunder. Notwithstanding anything in this Agreement to the contrary, each Party will be entitled to disclose, without the consent of or any notification to the other Party, any pharmacovigilance information originating from itself, its Affiliates, and the other Party to Regulatory Authorities, investigators, ethical committees and internal review boards, and any other Third Parties that have a need to know such information according to each Party's Risk Management and Adverse Event Reporting requirements.

- (b) Novartis will be entitled to publish with respect to research and Development of any Antibody or Product with Company's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed). Company acknowledges that certain Third Parties (*e.g.*, academic institutions that have received an Antibody from Novartis) may have the right to publish information relating to Antibodies or Products, and any such disclosure will not be deemed to be a breach of Novartis' obligations of confidentiality, *provided* that Novartis provides notice of such publication to Company and seeks the Company's prior written consent to such publication (such consent not to be unreasonably withheld, conditioned or delayed), in each case, to the extent Novartis or any of its Affiliates has notice or consent rights with respect to such publication by such Third Party.
- (c) Company will be entitled to publish with respect to research and Development of any Antibody or Product without consent of Novartis, *provided* that if such publication contains Confidential Information of Novartis, Company shall obtain Novartis' prior written consent (such consent not to be unreasonably withheld, conditioned or delayed).
- (d) In the event the recipient Party is required to disclose Confidential Information of the disclosing Party by Applicable Law or in connection with a *bona fide* legal process, such disclosure will not be a breach of this Agreement; *provided* that the recipient Party (i) informs the disclosing Party as soon as reasonably practicable of the required disclosure; (ii) limits the disclosure to the required purpose; and (iii) at the disclosing Party's request and expense, assists in an attempt to object to or limit the required disclosure or to otherwise receive "confidential" or "trade secret" treatment with respect to relevant portions of such disclosure.
- **10.4 Ongoing Obligation for Confidentiality**. The provisions of this <u>Article 10</u> shall survive the termination or expiration of this Agreement in accordance with <u>Section 12.2</u>. Upon early termination of this Agreement for any reason, each Party and its Affiliates will immediately return to the other Party or destroy any Confidential Information disclosed by the other Party, except for one copy which may be retained in its confidential files for archive purposes and except as otherwise required by Applicable Law.

**10.5 Publicity**. Neither Party shall issue any other press release, trade announcement or make any other public announcement or statement with regard to the transactions contemplated by this Agreement without the other Party's prior written consent, except as such announcement or statement may be required, based upon the reasonable advice of counsel, by Applicable Law or the rules and regulations of any stock exchange upon which the securities of Novartis or Company or their respective direct or indirect parent entities are listed, or the requirements of any self-regulatory body, in which case the Party requested to make the statement or announcement shall, to the extent reasonably practicable under the circumstances, allow the other Party reasonable time to review and comment upon such statement or announcement in advance of such issuance. Without limiting the foregoing, to the extent any Party is obligated by Applicable Law to file a copy of this Agreement with the SEC or other governmental authority, such Party shall provide the other Party with reasonable opportunity to review and request confidential treatment of portions of this Agreement pursuant to Applicable Law (including the Securities Exchange Act of 1934 and the Freedom of Information Act and the rules promulgated thereunder) by means of filing a copy of this Agreement redacted to remove such terms as are reasonably requested by the other Party. The Party so obligated shall give due consideration to the other Party's request, and, if agreed by the Parties, use reasonable efforts to obtain such confidential treatment or permission to redact such exhibit.

#### 11. TERM AND TERMINATION

- **11.1 Term.** The term of this Agreement (the "<u>Agreement Term</u>") will commence upon the Effective Date and continue on a Product-by-Product and country-by-country basis until the expiry of the Royalty Term for such Product in such country, unless earlier terminated as permitted by this Agreement.
- **11.2 Termination for Cause**. If either Novartis or Company is in material breach of any material obligation hereunder, the non-breaching Party may give written notice to the breaching Party specifying the claimed particulars of such breach, and in the event such material breach is not cured within [\*\*\*] after such notice ([\*\*\*] in the case of breach of a payment obligation), the non-breaching Party will have the right (but not the obligation) thereafter to terminate this Agreement immediately by giving written notice to the breaching Party to such effect. Any termination by any Party under this Section and the effects of termination provided herein will be without prejudice to any damages or other legal or equitable remedies to which it may be entitled. The right to terminate in accordance with this <u>Section 11.2</u> may be exercised on a Product-by-Product or country-by-country basis.
- **11.3 Insolvency**. If an Insolvency Event occurs, **(a)** Company will give immediate (but in any event, not longer than [\*\*\*]) notice to Novartis of such occurrence, and **(b)** Novartis will have the right to immediately terminate this Agreement by written notice to Company.
- **11.4 Termination by Company Without Cause**. Company may terminate this Agreement without cause at any time after the Effective Date in its entirety or on a Product-by-Product or country-by-country basis at any time on 60 days' prior written notice.

# 12. EFFECT OF TERMINATION

- **12.1** Effect of Termination. Upon termination of this Agreement by either Party for any reason, in its entirety or with respect to a Product or country, except in each case for any Product in any country that is subject to a perpetual and irrevocable license pursuant to <u>Section 8.5(c)</u>:
  - (a) as of the effective date of the termination (the "<u>Termination Date</u>"), all licenses and other rights granted by Novartis to Company under the Novartis Technology and Manufacturing Technology will terminate with respect to the Terminated Product in the Terminated Territory, and Company shall not have any rights to use or exercise any rights under the Novartis Technology or Manufacturing Technology with respect to the Terminated Product in the Terminated Product in the Terminated Product in the Terminated Territory, and the sole right to prosecute and maintain all Novartis Patents with respect to the Terminated Product in the Terminated Territory shall be transferred to Novartis; *provided* that any sublicense granted by Company under the license set forth in <u>Section 2.1</u> in the applicable Terminated Territory shall survive the termination of this Agreement and become a direct license from Novartis to such sublicensee, *provided further* that, in the case of termination for Company's uncured material breach pursuant to <u>Section 11.2</u>, such sublicensee did not cause such uncured material breach of this Agreement, and *provided further* that Novartis shall have no obligations under such sublicense beyond its obligations set forth in this Agreement;
  - (b) at Novartis' written request, which must be delivered to Company not later than [\*\*\*] after receipt of the applicable notice of termination, the following provisions shall apply, except in the event of termination by Company pursuant to <u>Section 11.2</u>:
    - (i) within [\*\*\*] after receipt of such notice, Company will provide to Novartis a fair and accurate summary report of the status of the research, Development and Commercialization of the Terminated Product in each country in the Terminated Territory through the Termination Date;
    - (ii) Company will grant, and hereby does grant (effective on delivery of the notice), and will cause its Affiliates (and use Commercially Reasonable Efforts to cause its sublicensees, to the extent such sublicensees are not granted a direct license pursuant to <u>Section 12.1(a)</u>) to grant, to Novartis, solely for the Development and Commercialization of Terminated Products in the Field in the Terminated Territory, a perpetual, irrevocable, exclusive license in the Terminated Territory, with the right to grant sublicensees, under all Patent Rights and Know-How Controlled by Company and its Affiliates (and sublicensees, to the extent such sublicensees have agreed to grant such license and are not granted a direct license pursuant to <u>Section 12.1(a)</u>) as of the Termination Date that are specifically related to, and actually used and applied as of the Terminated Products in the Terminated Territory; *provided* that with respect to any Patent Rights and Know-How that are Controlled by Company and its Affiliates (and sublicensees, to the extent Such Sublicensees, to the extent Such Sublicensees, to the terminated Products, to Develop, and Commercialize the Terminated Products in the Terminated Territory; *provided* that with respect to any Patent Rights and Know-How that are Controlled by Company and its Affiliates (and sublicensees, to the extent such sublicensees have agreed to grant such license and are not granted a direct

license pursuant to <u>Section 12.1(a)</u>) pursuant to an agreement with a Third Party, Novartis will pay all amounts due under any such agreement as a result of Novartis' exercise of the rights granted thereunder and Novartis' rights will be subject to the terms of the applicable Third Party agreement.

- (iii) within [\*\*\*] after receipt of such notice, to the extent permitted by Applicable Law, Company will, and will cause its Affiliates to, provide Novartis or its designee, solely for the Development and Commercialization of Terminated Products in the Field in the Terminated Territory, an electronic copy of all documentation within the Know-How licensed to Novartis pursuant to Section 12.1(b)(ii); provided that if any such documentation is not available in electronic format, Company shall use its Commercially Reasonable Efforts to provide a hard copy of such documentation [\*\*\*] after receipt of such notice; provided further that the Parties acknowledge that the disclosure by Company of such Know-How will consist of the disclosure of data residing in Company's databases, and will not include any database architecture or require any experimental work performed by Company for the purpose of technology transfer;
- (iv) to the extent permitted by Applicable Law, Company will, and will cause its Affiliates (and use Commercially Reasonable Efforts to cause its sublicensees, to the extent such sublicensees are not granted a direct license pursuant to <u>Section 12.1(a)</u>) to, promptly transfer to Novartis or its designee all Regulatory Filings, Regulatory Approvals and Pricing Reimbursement Approvals, the contents of any global safety database, records of all interactions with Regulatory Authorities, in each case to the extent such sublicensees have agreed to grant such license and are not granted a direct license pursuant to <u>Section 12.1(a)</u>) Control as of the Termination Date; *provided, however*, that if Company is restricted under Applicable Law from transferring ownership of any of the foregoing items to Novartis or its designee, Company shall grant, and hereby does grant, and will cause its Affiliates (and use Commercially Reasonable Efforts to cause its sublicensees, to the extent such sublicensees are not granted in the transferring ownership of any of the foregoing items to Novartis or its designee, Company shall grant, and hereby does grant, and will cause its Affiliates (and use Commercially Reasonable Efforts to cause its sublicensees, to the extent such sublicensees are not granted a direct license pursuant to <u>Section 12.1(a)</u>) to grant, to Novartis (or its designee) a right of reference or use to such item. Company will take all permitted actions reasonably necessary to effect such transfer or grant of right of reference or use to Novartis or its designee;
- (v) to the extent reasonably requested by Novartis [\*\*\*] after receipt of such notice, Company will use Commercially Reasonable Efforts to assign or transfer to Novartis any license agreements or other contracts between Company or any of its Affiliates and any Third Party to the extent solely related to the Terminated Products in the Terminated Territory (including, as applicable, clinical trial and manufacturing agreements), to the extent such agreements are in effect as of Termination Date and such assignment or transfer is permitted, and to facilitate introductions of Novartis to the applicable subcontractors, licensors, manufacturing vendors, clinical trial sites, clinical trial investigators and the like;

- (vi) to the extent requested by Novartis [\*\*\*]after receipt of such notice, Novartis will have the right to purchase from Company all of the inventory of the Terminated Products held by Company and its Affiliates for use in the Terminated Territory as of the Termination Date at a price equal to Company's actual, fully-burdened manufacturing cost, determined in accordance with Accounting Standards, plus, in the case of termination by the Company pursuant to Sections 11.2 or 11.3, a mark-up of [\*\*\*]; and
- (vii) for a period of [\*\*\*] following receipt of such notice, Company will provide such assistance as may be reasonably necessary to transfer manufacturing documents and materials that are Controlled by Company and its Affiliates (or their subcontractor(s)) and actually used as of the Termination Date in the manufacture of Terminated Products for use in the Field in the Terminated Territory, and cooperate with Novartis in reasonable respects to transfer to Novartis, or Novartis' designated contract manufacturer, the manufacturing technologies (including all relevant Know-How) that are used in the manufacture of the Terminated Products for use in Field in the Terminated Territory, in each case, in the manner set forth in Section 4.2 as if Novartis were Company and Company were Novartis, *mutatis mutandis*;
- (c) except as set forth in this Section 12.1 and in Section 12.2, the rights and obligations of the Parties hereunder will terminate as of the Termination Date; and
- (d) Company shall return to Novartis or, on Novartis's request, destroy all records and materials in its possession or control that contain or comprise Novartis Know-How, Manufacturing Know-How, or other Confidential Information of Novartis solely related to the Terminated Product in the Terminated Territory, except for one copy which may be retained in its confidential files for archive purposes and except as otherwise required by Applicable Law.
- 12.2 Survival. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the provisions of <u>Article 1</u>, <u>Sections 2.3</u> (except for the Non-Compete), <u>2.4</u>, <u>2.5</u>, <u>4.3</u>, <u>4.4</u>, <u>6.2</u>, <u>8.8</u> (as specified therein), <u>8.9</u>, <u>9.1</u>, <u>11.2</u> (but only the last sentence thereof), <u>Article 12</u>, <u>Section 13.6</u>, <u>Article 14</u>, and <u>Article 15</u> will survive expiration or termination of this Agreement. The provisions of <u>Article 10</u> (Confidentiality) will survive the termination or expiration of this Agreement for a period of [\*\*\*].
- **12.3 Termination Not Sole Remedy**. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as agreed to otherwise herein. Nothing in this Agreement shall obligate a Party to terminate this Agreement in the event that the other Party breaches any obligation of this Agreement, and failure to terminate this Agreement shall not prohibit or modify the recovery of damages pursuant to <u>Section 15.5</u>.

**12.4 Rights Upon Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction, licenses of rights to "intellectual property" as defined under such laws.

#### 13. REPRESENTATIONS, WARRANTIES AND COVENANTS

- 13.1 Representations and Warranties by Each Party. Each Party represents and warrants to the other as of the Effective Date that:
  - (a) it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;
  - (b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;
  - (c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles and public policy constraints (including those pertaining to limitations and/or exclusions of liability, competition laws, penalties and jurisdictional issues including conflicts of laws);
  - (d) all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained;
  - (e) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and will not (i) conflict with or result in a breach of any provision of its organizational documents; (ii) result in a breach of any agreement to which it is a party; or (iii) violate any Applicable Law; and
  - (f) neither such Party nor, to the knowledge of the associates of such Party responsible for such matters, any employee, agent or subcontractor of such Party involved or to be involved in the research, Development or Commercialization of the Antibodies or the Products has been debarred under Subsection (a) or (b) of Section 306 of the Federal Food, Drug and Cosmetic Act (21 USC §§ 335a) (the "<u>FDC Act</u>"), and upon any discovery thereof, such Person shall be removed from performing under this Agreement.

# 13.2 Covenants by Company. Company covenants that:

- (a) no Person who is known by Company (i) to have been debarred under Subsection (a) or (b) of Section 306 of the FDC Act, or (ii) to be on any of the FDA clinical investigator enforcement lists will be employed by or on behalf of Company or its Affiliates or otherwise participate in the performance of any activities hereunder;
- (b) Company will, prior to its initiation of any clinical trials in any country in the Territory, maintain an insurance policy that is customary for similarly situated companies in such country to address claims that could reasonably arise from the research, Development, Manufacture, and Commercialization of the Antibodies or Products (and in any event, with combined limits of not less than [\*\*\*]. At Novartis' written request, Company will provide Novartis with evidence of Company's insurance. Company will provide to Novartis at least [\*\*\*] prior written notice of any change to Company's insurance program that is not consistent with Company's obligations hereunder or cancellation to Company's insurance program; and
- (c) Company will conduct its research, Development, Manufacture, and Commercialization activities relating to the Antibodies or Products in accordance with Applicable Law (including data privacy laws, current international regulatory standards, including, as applicable, GMP, GLP, GCP, and other rules, regulations and requirements), and will cause any collaborators and sublicensees to comply with such Applicable Laws.
- 13.3 Representations and Warranties by Novartis. Novartis represents and warrants to Company as of the Effective Date that:
  - (a) To the knowledge of the Novartis associates responsible for such matters, *Exhibit B* sets forth an accurate summary of all Know-How Controlled by Novartis or its Affiliates as of the Effective Date that relates primarily to any Antibody or Product, including the use thereof in the Field, and is reasonably necessary for the research, Development or Commercialization of any Antibody or Product;
  - (b) *Exhibit C* sets forth an accurate list of all Patent Rights Controlled by Novartis or its Affiliates as of the Effective Date that claim any Antibody, any Product or any high-affinity monoclonal antibody against BK virus protein VP1 that was identified or developed by or on behalf of Novartis or its Affiliates on or prior to the Effective Date, or the use thereof, or are necessary for the research, Development, or Commercialization of any Antibody or any Product;
  - (c) *Exhibit F* sets forth a true, complete, and correct list of all Regulatory Filings and Regulatory Approvals Controlled by Novartis or its Affiliates solely relating to any Antibody or Product;
  - (d) Novartis is the sole and exclusive owner, or exclusive licensee of all the rights, title and interest in and to all Novartis Technology and Manufacturing Technology free from any encumbrance;

- (e) Novartis has not received, nor do the associates of Novartis responsible for such matters have knowledge of, any written claims or allegations that (i) the research, Development or Commercialization of any Antibody or any Product infringes the Patent Rights or misappropriates the know-how of any Third Party, (ii) a Third Party has any right or interest in or to the Novartis Technology, or (iii) any of the Novartis Patents are invalid or unenforceable;
- (f) to the knowledge of the associates of Novartis responsible for such matters, there are no activities by Third Parties that would constitute infringement of the Novartis Patents or misappropriate of the Novartis Know-How;
- (g) Novartis has not initiated or been involved in any proceedings or Claims in which it alleges that any Third Party is or was infringing or misappropriating any Novartis Technology;
- (h) Novartis has filed and prosecuted patent applications within the Novartis Patents in good faith and complied with all duties of disclosure with respect thereto;
- (i) Novartis has taken reasonable precautions to preserve the confidentiality of the non-public information within the Novartis Know-How;
- (j) Novartis has not entered into a government funding relationship that would result in rights to any Antibody, Product or any Novartis Patents residing in the US Government, National Institutes of Health, National Institute for Drug Abuse or other agency, and the licenses granted hereunder are not subject to overriding obligations to the US Government as set forth in 35 USC §§ 200 to 204, as amended, or any similar obligations under the laws of any other country;
- (k) Novartis has the right to grant to Company the licenses and rights under <u>Section 2.1</u> and <u>Section 4.1(d)</u> that it purports to grant hereunder; and
- (I) Novartis has not granted rights to any Third Party under the Novartis Technology or the Manufacturing Technology that conflict with the rights granted to Company hereunder, and has not taken any action that would prevent it from granting the rights granted to Company under this Agreement, or that would otherwise materially conflict with or interfere or limit the rights granted to Company under this Agreement.

For purposes of this Section 13.3, "knowledge of the associates of Novartis responsible for such matters" includes the knowledge of Novartis' employees performing the functions of regulatory, CMC, clinical, and intellectual property with respect to Antibodies and Products.

- **13.4** Covenants of Novartis. Novartis covenants that:
  - (a) Novartis will not, during the Agreement Term, grant any interest in the Novartis Technology or Manufacturing Technology that conflict with the rights granted to Company hereunder, and will not take any action that would prevent it from granting the rights granted to Company under this Agreement or that would otherwise materially conflict with or adversely affect the rights granted to Company under this Agreement; and

(b) if, at any time after execution of this Agreement, the associates of Novartis responsible for such matters obtain knowledge that Novartis or any employee, agent or subcontractor of Novartis who participated in the research, Development or Manufacture of an Antibody or Product is on, or is being added to the FDA's Disqualified/Restricted List or to any of the FDA clinical investigator enforcement lists, it will provide written notice of this to Company promptly following this fact becoming known to it.

For purposes of this <u>Section 13.4</u>, "<u>FDA's Disqualified/Restricted List</u>" is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if the FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false information to the study sponsor or the FDA.

- **13.5** Additional Representations and Warranties by Novartis. Novartis represents and warrants to Company that the information with respect to the Manufacture of any Antibody Material set forth in any certificate of analysis delivered to Company pursuant to <u>Section 6.3(c)</u> is complete, true and accurate.
- 13.6 No Other Warranties. EXCEPT AS EXPRESSLY STATED IN THIS SECTION 13, (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF NOVARTIS OR ITS AFFILIATES OR COMPANY OR ITS AFFILIATES; AND (B) ALL OTHER REPRESENTATIONS, CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE HEREBY EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

# 14. INDEMNIFICATION; LIABILITY

- **14.1 Indemnification by Novartis**. Novartis will indemnify and hold Company, its Affiliates, and their respective officers, directors and employees ("<u>Company Indemnitees</u>") harmless from and against any and all Losses incurred by or imposed upon the Company Indemnitees or any of them in connection with any Claim, in each case, to the extent arising or resulting from:
  - (a) the research, Development, Manufacture or Commercialization of Terminated Products by or on behalf of Novartis, its Affiliates, or its sublicensees, including all product liability claims (whether arising during research, Development, Manufacture or Commercialization) relating to any Terminated Product (whether pursuant to design defect, manufacturing defect, failure to notify, or otherwise);
  - (b) the breach of any of the obligations, covenants, warranties or representations made by Novartis to Company under this Agreement; or

(c) the gross negligence or willful misconduct of Novartis or any of its Affiliates in performing activities under this Agreement;

*provided, however,* that Novartis will not be obliged to so indemnify and hold harmless the Company Indemnitees for any Claims for which Company has an obligation to indemnify Novartis Indemnitees pursuant to <u>Section 14.2</u> or to the extent that such Claims arise from the breach, gross negligence or willful misconduct of Company or the Company Indemnitees.

- **14.2 Indemnification by Company**. Company will indemnify and hold Novartis, its Affiliates, and their respective officers, directors and employees ("<u>Novartis Indemnitees</u>") harmless from and against any and all Losses incurred by or imposed upon the Novartis Indemnitees or any of them in connection with any Claim, in each case, to the extent arising or resulting from:
  - (a) the research, Development, Manufacture or Commercialization of Antibodies or Products by or on behalf of Company, its Affiliates, or its sublicensees, including all product liability claims (whether arising during research, Development, Manufacture or Commercialization) relating to any Antibody or Product (whether pursuant to design defect, manufacturing defect, failure to notify, or otherwise);
  - (b) the gross negligence or willful misconduct of Company or any of its Affiliates in performing activities under this Agreement; or
  - (c) the breach of any of the obligations, covenants, warranties, or representations made by Company to Novartis under this Agreement;

*provided, however,* that Company will not be obliged to so indemnify and hold harmless the Novartis Indemnitees for any Claims for which Novartis has an obligation to indemnify Company Indemnitees pursuant to <u>Section 14.1</u> or to the extent that such Claims arise from the breach, gross negligence or willful misconduct of Novartis or the Novartis Indemnitees.

#### 14.3 Indemnification Procedure.

- (a) All indemnification claims in respect of a Company Indemnitee or Novartis Indemnitee will be made solely by Company or Novartis, respectively.
- (b) A Party seeking indemnification hereunder ("Indemnified Party") will notify the other Party ("Indemnifying Party") in writing reasonably promptly after the assertion against the Indemnified Party of any Claim or fact in respect of which the Indemnified Party intends to base a claim for indemnification hereunder ("Indemnification Claim Notice"), but the failure or delay to so notify the Indemnifying Party will not relieve the Indemnifying Party of any obligation or liability that it may have to the Indemnified Party, except to the extent that the Indemnifying Party demonstrates that its ability to defend or resolve such Claim is materially and adversely affected thereby. The Indemnification Claim Notice will contain a description of the Claim and the nature and amount of the Claim (to the extent that the nature and amount of such Claim is known at such time). Upon the request of the Indemnifying Party, the Indemnified Party will furnish promptly to the Indemnifying Party copies of all correspondence, communications and official documents (including court documents) received or sent in respect of such Claim.

- (c) Subject to the provisions of <u>Sections (d)</u> and (e) below, the Indemnifying Party will have the right, upon written notice given to the Indemnified Party within [\*\*\*] after receipt of the Indemnification Claim Notice to assume the defense and handling of such Claim, at the Indemnifying Party's sole expense, in which case the provisions of <u>Section 14.3(e)</u> below will govern. The assumption of the defense of a Claim by the Indemnifying Party will not be construed as acknowledgement that the Indemnifying Party is liable to indemnify any indemnitee in respect of the Claim, nor will it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party's claim for indemnification. In the event that it is ultimately decided that the Indemnifying Party will reimburse the Indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any losses incurred by the Indemnifying Party in its defense of the Claim. If the Indemnifying Party does not give written notice to the Indemnified Party, within [\*\*\*] after receipt of the Indemnification Claim Notice, of the Indemnifying Party's election to assume the defense and handling of such Claim, the provisions of <u>Section 14.3(f)</u> below will govern.
- Upon assumption of the defense of a Claim by the Indemnifying Party: (i) the Indemnifying Party will have the right to and will assume (d) sole control and responsibility for dealing with the Claim; (ii) the Indemnifying Party may, at its own cost, appoint as counsel in connection with conducting the defense and handling of such Claim any law firm or counsel reasonably selected by the Indemnifying Party; (iii) the Indemnifying Party will keep the Indemnified Party informed of the status of such Claim; and (iv) if the Indemnifying Party acknowledges that it is liable to indemnify an indemnitee in respect of the Claim, the Indemnifying Party will have the right to settle the Claim on any terms the Indemnifying Party chooses; provided, however, that it will not, without the prior written consent of the Indemnified Party, agree to a settlement of any Claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder or which admits any wrongdoing or responsibility for the claim on behalf of the Indemnified Party. The Indemnified Party will cooperate with the Indemnifying Party and will be entitled to participate in, but not control, the defense of such Claim with its own counsel and at its own expense. In particular, the Indemnified Party will furnish such records, information and testimony, provide witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation will include access during normal business hours by the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Claim, and making the Indemnified Party, the Indemnitees and its and their employees and agents available on a mutually convenient basis to provide additional information and explanation of any records or information provided.

- (e) If the Indemnifying Party does not give written notice to the Indemnified Party as set forth in <u>Section 14.3(d)</u> or fails to conduct the defense and handling of any Claim in good faith after having assumed such, the Indemnified Party may, at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Claim and defend or handle such Claim in such manner as it may deem appropriate. In such event, the Indemnified Party will keep the Indemnifying Party timely apprised of the status of such Claim and will not settle such Claim without the prior written consent of the Indemnifying Party, which consent will not be unreasonably withheld. If the Indemnified Party defends or handles such Claim, the Indemnifying Party will cooperate with the Indemnified Party, at the Indemnified Party's request but at no expense to the Indemnified Party, and will be entitled to participate in the defense and handling of such Claim with its own counsel and at its own expense.
- (f) In the case of any Infringement Claim, this <u>Section 14.3</u> shall be subject to the provisions of <u>Section 9.8</u>.
- **14.4 Mitigation of Loss**. Each Indemnified Party will take and will procure that its Affiliates take all such reasonable steps and action as are necessary or as the Indemnifying Party may reasonably require in order to mitigate any Claims (or potential Losses) under this <u>Section 14</u>. Nothing in this Agreement will or will be deemed to relieve any Party of any common law or other duty to mitigate any Losses incurred by it.
- 14.5 Special, Indirect and Other Losses. NO PARTY NOR ANY OF SUCH PARTY'S AFFILIATES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR FOR ANY ECONOMIC LOSS OR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS <u>ARTICLE 14</u> OR RESULT FROM EITHER PARTY'S BREACH OF <u>ARTICLE 10</u>.

# 15. GENERAL PROVISIONS

- **15.1 Assignment**. No Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that (i) either Party may, without such consent, assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; and (ii) either Party may, without such consent, assign its rights and obligations under this Agreement or any part hereof to a successor to all or substantially all of its business or assets to which this Agreement relates or to which any Antibody or Product relates. Any permitted assignee will assume all applicable obligations of its assignor under this Agreement. Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors, heirs and permitted assigns.
- **15.2** Extension to Affiliates. Each Party will have the right to extend the rights, immunities and obligations granted in this Agreement to one or more of its Affiliates. All applicable terms

and provisions of this Agreement will apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to such Party. The Party so extending the rights, immunities and obligations granted in this Agreement will remain primarily liable for any acts or omissions of its Affiliates.

- **15.3 Severability**. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then this Agreement will be construed as if such provision were not contained herein and the remainder of this Agreement will be in full force and effect, and the Parties will use their Commercially Reasonable Efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.
- **15.4 Governing Law and Jurisdiction**. This Agreement will be governed by and construed under the laws of the State of New York, USA, without giving effect to the conflicts of laws provision thereof. The United Nations Convention on Contracts for the International Sale of Goods (1980) will not apply to the interpretation of this Agreement.

#### 15.5 Dispute Resolution.

- (a) In the event of a dispute under this Agreement, the Parties will refer the dispute to the Alliance Managers for discussion and resolution. If the Alliance Managers are unable to resolve such a dispute within [\*\*\*] of the dispute being referred to them, either Party may require that the Parties forward the matter to the Senior Officers (or designees with similar authority to resolve such dispute), who will attempt in good faith to resolve such dispute. If the Senior Officers cannot resolve such dispute within [\*\*\*] of the matter being referred to them, either Party may initiate the arbitration proceeding outlined in Section 15.5(b) to resolve the matter.
- (b) Subject to Section 15.16, any unresolved disputes between the Parties relating to, arising out of or in any way connected with this Agreement or any term or condition hereof, or the performance by either Party of its obligations hereunder, whether before or after termination of this Agreement, shall be referred to and finally resolved by arbitration. Whenever a Party decides to institute arbitration proceedings, it will give written notice to that effect to the other Party. The seat of arbitration shall be located in New York, New York, in accordance with the arbitration rules of the International Chamber of Commerce ("ICC"). The arbitration will be conducted by a tribunal of three arbitrators appointed in accordance with ICC rules; *provided* that co-arbitrators appointed by each Party will, within [\*\*\*] of the confirmation of the appointment of the last co-arbitrator, select a third arbitrator as the chair of the arbitrator will be appointed in accordance with ICC rules. The tribunal will render their award within [\*\*\*] of the final arbitrator will be appointed in accordance with ICC rules. The tribunal will render their award within [\*\*\*] of the final arbitrator will be appointed in accordance with ICC rules. The tribunal will render their award within [\*\*\*] of the final arbitration hearing. The tribunal shall not have the power to award punitive damages. Decisions of the tribunal will be final and binding on the Parties. Judgment on the award so rendered may be entered in any court of competent jurisdiction. The Parties each consent to the personal jurisdiction of the U.S. federal courts for any case arising out of or otherwise related to this arbitration, its conduct and its enforcement. The language to be used in the arbitrat proceedings will be English.

- (c) Notwithstanding <u>Sections 15.4</u> and <u>15.5(b)</u>, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent Right covering the manufacture, use, importation, offer for sale or sale of any Antibody or Product or of any trademark rights relating to any Product shall be submitted to a court of competent jurisdiction in the country in which such Patent Right or trademark rights were granted or arose.
- (d) Each Party shall be responsible for all of its costs and expenses incurred with respect to any arbitration, litigation or other dispute resolution undertaken in accordance with this Agreement.
- **15.6** Force Majeure. In the event that either Party is prevented from performing its obligations under this Agreement (other than payment obligations) as a result of any contingency beyond its reasonable control ("<u>Force Majeure</u>"), including any actions of governmental authorities or agencies, war, hostilities between nations, civil commotions, riots, national industry strikes, lockouts, sabotage, shortages in supplies, energy shortages, fire, floods and acts of nature such as typhoons, hurricanes, earthquakes, or tsunamis, the Party so affected will not be responsible to the other Party for any delay or failure of performance of its obligations hereunder, for so long as Force Majeure prevents such performance. In the event of Force Majeure, the Party immediately affected thereby will give prompt written notice to the other Party specifying the Force Majeure event complained of, and will use Commercially Reasonable Efforts to resume performance of its obligations. Notwithstanding the foregoing, if such a Force Majeure induced delay or failure of performance continues for a period of more than [\*\*\*] either Party may terminate this Agreement upon written notice to the other Party.
- **15.7 Waivers and Amendments**. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver will be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.
- **15.8 Relationship of the Parties**. Nothing contained in this Agreement will be deemed to constitute a partnership, joint venture, or legal entity of any type between Novartis and Company, or to constitute one as the agent of the other. Moreover, each Party will not construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party will act solely as an independent contractor, and nothing in this Agreement will be construed to give any Party the power or authority to act for, bind, or commit the other.
- **15.9 Notices**. All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: **(a)** delivered by hand (with written confirmation of receipt); or **(b)** when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the

appropriate addresses set forth below (or to such other addresses as a Party may designate by notice):

If to Company:

Amplyx Pharmaceuticals, Inc. 12730 High Bluff Drive, Suite 160 San Diego, CA 92130 <u>Attn</u>: [\*\*\*]

with a required copy (which shall not constitute notice) to:

Cooley LLP 4401 Eastgate Mall San Diego, CA 92121 <u>Attn</u>: [\*\*\*]

If to Novartis:

Novartis International Pharmaceutical AG Lichtstrasse 35 CH-4065 Basel Switzerland

with a required copy (which shall not constitute notice) to:

Novartis Institutes for BioMedical Research, Inc. 250 Massachusetts Avenue Cambridge, MA 02139 USA <u>Attn</u>: [\*\*\*]

- **15.10** Further Assurances. Company and Novartis will execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary to carry out the intent and purposes of this Agreement.
- **15.11 Compliance with Law**. Each Party will perform its obligations under this Agreement in accordance with all Applicable Laws. No Party will, or will be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any Applicable Law.
- **15.12** No Third Party Beneficiary Rights. The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they will not be construed as conferring any rights to any Third Party (including any third party beneficiary rights), except that the indemnitees expressly identified in <u>Section 14.1</u> and <u>Section 14.2</u> shall be third party beneficiaries of <u>Article 14</u>.
- **15.13 Expenses.** Except as otherwise expressly provided in this Agreement, each Party will pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.

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- **15.14 Entire Agreement**. This Agreement, together with its Exhibits and schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including the prior confidentiality agreement. In the event of any conflict between a substantive provision of this Agreement and any Exhibit or schedule hereto, the substantive provisions of this Agreement will prevail.
- **15.15 Counterparts.** This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe Portable Document Format (.pdf) sent by electronic mail shall be deemed to be original signatures.
- 15.16 Specific Performance; Cumulative Remedies. Notwithstanding the dispute resolution procedures set forth in Section 15.5, the Parties hereby expressly recognize and acknowledge that (a) the other Party's Confidential Information includes highly sensitive trade secret information, (b) breach of Article 10 by a Party with respect to such information may cause immediate, extensive, and irreparable damage, for which monetary damages would not provide a sufficient remedy, and (c) in such case of breach of Article 10, notwithstanding the intent of the Parties to submit claims to arbitration in accordance with Section 15.5 and without the need to first proceed under Section 15.5, the non-breaching Party shall be entitled to equitable relief (including temporary or permanent restraining orders, specific performance or other injunctive relief) in any court of competent jurisdiction. In addition, and notwithstanding anything to the contrary set forth in this Agreement, in the event of any other actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including temporary or permanent restraining orders, specific performance or other injunctive relief) from any court of competent jurisdiction without first submitting to the dispute resolution procedures set forth in Section 15.5. No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Laws.

[Signature Page Follows]

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License Agreement - Signature Page

*IN WITNESS WHEREOF*, the Parties, intending to be bound, have caused this Agreement to be executed and delivered by their duly authorized representatives.

# NOVARTIS INTERNATIONAL PHARMACEUTICAL AG

By:	/s/ Simone Pfirter
Name:	Simone Pfirter
Title:	Authorized Signatory
By:	/s/ Sylvain Beltzung
Name:	Sylvain Beltzung

Title: Authorized Signatory

#### AMPLYX PHARMACEUTICALS, INC.

By:/s/ Ciara Kennedy, Ph.D.Name:Ciara Kennedy, Ph.D.

Title: President and Chief Executive Officer

EXHIBIT A

### ANTIBODY

### 1. GENERAL DESCRIPTION

[\*\*\*]

# 2. AMINO ACID SEQUENCE OF HEAVY AND LIGHT CHAIN

[\*\*\*]

Exhibit A - 1

EXHIBIT B-1

#### **NOVARTIS KNOW-HOW**

#### 1. Presentations

[\*\*\*]

#### 2. Technical Research and Development

2.1 Documents transferred after effective date of the agreement

{4 pages omitted}

[\*\*\*]

2.2. Documents transferred selection of CMO and partially redacted where needed to protect proprietary quantitative cell culture media compositions

#### [\*\*\*]

2.3. Other Documents

[\*\*\*]

2.4. Transfer of materials (if any available)

[\*\*\*]

#### 3. Pre-Clinical documents

[\*\*\*]

#### 4. Clinical

# 4.1. Trial master Files

{11 pages omitted}

[\*\*\*]

#### 4.2. Additional clinical documents

[\*\*\*]

### 4.3. Databases (where applicable)

[\*\*\*]

Exhibit B-1 - 1

**EXHIBIT B-2** 

#### TRANSFER ASSISTANCE

# Transfer documents (redacted where needed)

[\*\*\*]

### **Overview of CMC-related Know-How Transfer assistance provided by Novartis**

{2 pages omitted}

[\*\*\*]

Exhibit B-2 - 1

EXHIBIT C

### NOVARTIS PATENTS

Exhibit C - 1

EXHIBIT D

# ANTIBODY MATERIALS

The table below lists the Inventory Novartis will provide to Company

[\*\*\*]

Exhibit D - 1

EXHIBIT E

# PROJECT-SPECIFIC CELL BANK

The table below lists the MCB Inventory Novartis will provide to Company's chosen by Company.

[\*\*\*]

Exhibit E - 1

EXHIBIT F

### **REGULATORY FILINGS AND REGULATORY APPROVALS**

Note 1; the table below does not list all documents nor gives it the same level of detail on document groups in order to keep the table easier to review. All regulatory documents available to Novartis will be shared.

[\*\*\*]

Exhibit F - 1

# Certain identified information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[\*\*\*]".

#### AMENDMENT NO. 1 TO LICENSE AGREEMENT

This Amendment No. 1 to the License Agreement, dated as of September 24, 2019 (this "<u>Amendment</u>"), is entered into by and between Novartis International Pharmaceutical AG, a corporation organized under the laws of Switzerland ("<u>Novartis</u>"), and Amplyx Pharmaceuticals, Inc., a corporation organized and existing under the laws of Delaware ("<u>Company</u>"). Novartis and Company are each referred to individually as a "<u>Party</u>" and together as the "<u>Parties</u>". Except as otherwise expressly provided, capitalized terms used in this Amendment that are not otherwise defined herein shall have the meanings provided in the License Agreement (as defined below).

#### RECITALS

WHEREAS, the Parties entered into that certain License Agreement on August 26, 2019 (the "License Agreement"); and

WHEREAS, the Parties desire to amend the License Agreement to delete Exhibit C thereto and replace it with a new Exhibit C.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual agreements and covenants set forth herein, for other good and valuable consideration and intending to be legally bound, the Parties hereby agree as follows:

#### 1. AMENDMENT

1.1 Exhibit C to the License Agreement is hereby deleted and replaced with the Exhibit C set forth in <u>Annex A</u> to this Amendment.

#### 2. MISCELLANEOUS

- 2.1 <u>Scope of Amendment</u>. Except as expressly set forth in this Amendment, the terms of the License Agreement shall remain in full force and effect.
- 2.2 <u>Counterparts</u>. This Amendment may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe Portable Document Format (.pdf) sent by electronic mail shall be deemed to be original signatures.
- 2.3 <u>Governing Law and Jurisdiction</u>. This Amendment will be governed by and construed under the laws of the State of New York, USA, without giving effect to the conflicts of laws provision thereof. The United Nations Convention on Contracts for the International Sale of Goods (1980) will not apply to the interpretation of this Amendment.

[Signature Page Follows]

Amendment No. 1 to License Agreement - Signature Page

IN WITNESS WHEREOF, the Parties, intending to be bound, have caused this Amendment to be executed and delivered by their duly authorized representatives.

# NOVARTIS INTERNATIONAL PHARMACEUTICAL AG

By:	/s/ Simone Pfirter
Name:	Simone Pfirter
Title:	Authorized Signatory
By:	/s/ Charlotte Retzler
5	/s/ Charlotte Retzler Charlotte Retzler

AMPLYX PHARMACEUTICALS, INC.

By: /s/ Ciara Kennedy Name: CEO

### ANNEX A

EXHIBIT C

### **NOVARTIS PATENTS**

[\*\*\*]

Exhibit C - 1