

As confidentially submitted to the Securities and Exchange Commission on March 19, 2021.  
 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.**  
**170 Harbor Way, 3rd Floor**  
**South San Francisco, California 94080**  
**(650) 770-0077**

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

**Marshall Fordyce, M.D.**  
**Chief Executive Officer and President**  
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**South San Francisco, California 94080**  
**(650) 770-0077**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**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.

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.

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.

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

**CALCULATION OF REGISTRATION FEE**

| TITLE OF EACH CLASS OF<br>SECURITIES TO BE REGISTERED | PROPOSED<br>MAXIMUM<br>AGGREGATE<br>OFFERING PRICE (1) | AMOUNT OF<br>REGISTRATION FEE (2) |
|---|--|-----------------------------------|
| Common stock, par value \$0.0001 per share            | \$   | \$                                |

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) of the Securities Act of 1933, as amended. Includes the aggregate offering price of any additional shares that the underwriters have the option to purchase.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

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 nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED \_\_\_\_\_, 2021

PRELIMINARY PROSPECTUS

Shares



Common Stock

This is an initial public offering of shares of common stock by Vera Therapeutics, Inc. We are offering \_\_\_\_\_ shares of our common stock to be sold in the offering. The initial public offering price is expected to be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share.

Prior to this offering, there has been no public market for our common stock. We intend to apply to list our common stock on The Nasdaq Global Market under the symbol "VERA."

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.

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|  | PER SHARE | TOTAL    |
|--|-----------|----------|
| Initial public offering price                        | \$ _____  | \$ _____ |
| Underwriting discounts and commissions (1)           | \$ _____  | \$ _____ |
| Proceeds to Vera Therapeutics, Inc., before expenses | \$ _____  | \$ _____ |

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(1) See the section titled "Underwriting" beginning on page 174 for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to \_\_\_\_\_ additional shares of common stock at the initial public offering price, less the underwriting discounts and commissions.

Investing in our common stock involves a high degree of risk. See the section titled "[Risk Factors](#)" beginning on page 13.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on or about \_\_\_\_\_, 2021.

**Jefferies**

**Cowen**

**Evercore ISI**

Prospectus dated \_\_\_\_\_, 2021

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Through and including \_\_\_\_\_, 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

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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 shares of our common stock. 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 the shares of common stock and the distribution of this prospectus outside of the United States.

## 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 common stock. You should read this entire prospectus carefully, including the sections in this prospectus titled "Risk Factors," "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 clinical stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases. Our lead product candidate is atacicept, a fusion protein self-administered as a subcutaneous injection once weekly that blocks both B lymphocyte stimulator (BLyS) and a proliferation-inducing ligand (APRIL), which stimulate B cells and plasma cells to produce autoantibodies contributing to certain autoimmune diseases. We are conducting a Phase 2b clinical trial of atacicept in patients with immunoglobulin A nephropathy (IgAN), a disease with a high unmet medical need and no approved therapies. IgAN is a serious and progressive autoimmune disease of the kidney that is driven by the production of immunogenic galactose-deficient IgA1 (Gd-IgA1). IgAN patients with elevated Gd-IgA1 are at increased risk of kidney-related morbidity and mortality. As reported in a Phase 2a clinical trial, atacicept is the first and only molecule currently in development to demonstrate a 60% reduction in plasma Gd-IgA1, which we believe can be disease modifying. We plan to initiate patient screening for our Phase 2b clinical trial in IgAN in the second quarter of 2021, and we expect to report topline results in the fourth quarter of 2022. In addition, we are evaluating additional diseases where atacicept's reduction of autoantibodies may prove medically useful, including lupus nephritis (LN), a severe renal manifestation of systemic lupus erythematosus (SLE).

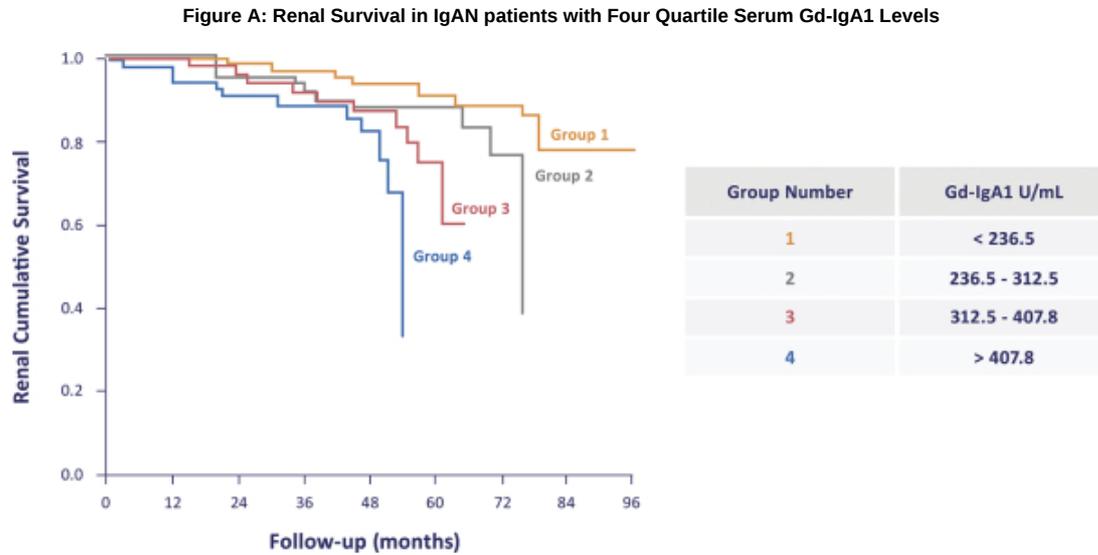
### Our Product Candidate: Atacicept

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 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 many immunologic diseases, including IgAN and LN. Atacicept has a large and established safety data set in which it has demonstrated an acceptable tolerability profile in clinical trials of over 1,500 patients to date.

### 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, there are currently no approved treatments indicated for IgAN. The current standard of care consists of off-label use of renin-angiotensin-aldosterone system (RAAS) inhibitors, including angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs), as well as 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 clinical trials 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 A below.

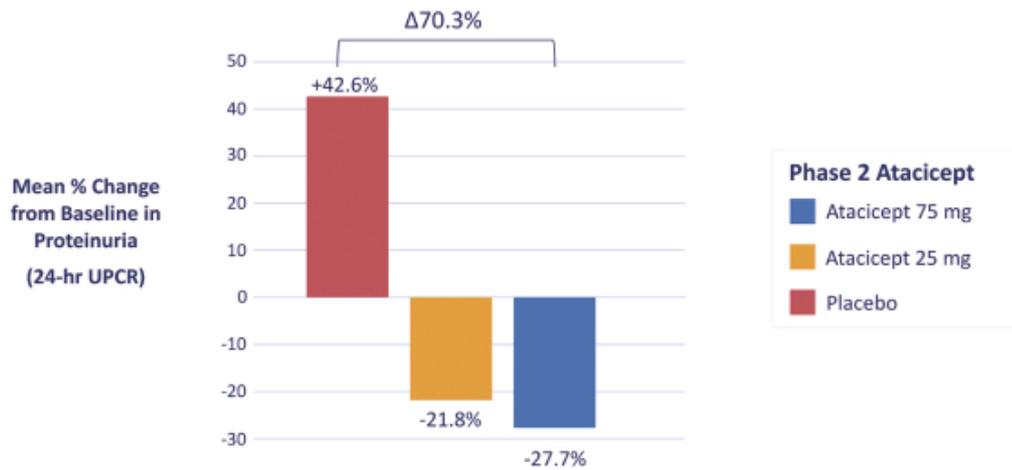


We believe that atacicept's mechanism has the potential to drive a high level of efficacy in IgAN and other immunologic diseases. BLYS inhibition has been clinically and commercially validated through the approval of Benlysta (belimumab) in both SLE and LN. Preclinical and clinical evidence supports that atacicept's mechanism of dual inhibition of BLYS and APRIL may provide better clinical efficacy than inhibiting either signal alone.

We have a worldwide, exclusive license to atacicept from Ares Trading S.A. (Ares), an affiliate of Merck KGaA, Darmstadt, Germany, which advanced atacicept in clinical trials for several autoimmune diseases in over 1,500 patients, in which it demonstrated an acceptable clinical safety and tolerability profile. We believe the large and established clinical data set for atacicept provides a competitive advantage for us versus other 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.

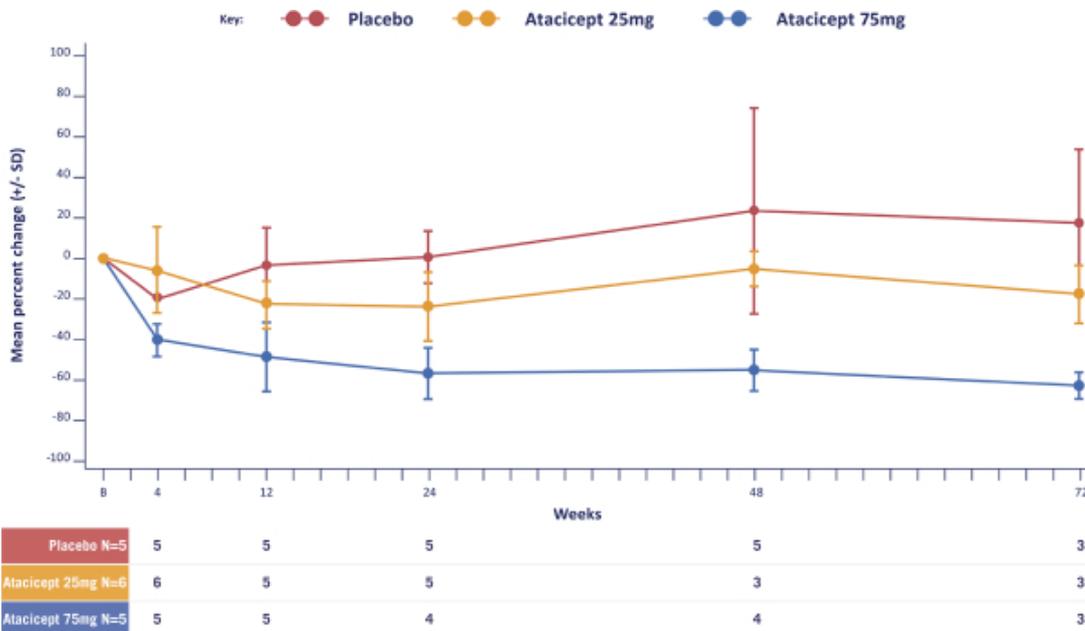
In IgAN, Ares conducted a randomized, double-blind, placebo-controlled Phase 2a clinical trial that enrolled 16 patients, known as JANUS. A clinically meaningful reduction in proteinuria was observed at week 24 in the atacicept group versus an increase in the placebo group, as shown in Figure B below.

**Figure B: Proteinuria at Week 24 in the Phase 2a JANUS Trial**



Atacicept 75 mg also showed a 60% of Gd-IgA1 reduction at 24 weeks (as shown in Figure C below), the largest magnitude in reduction of Gd-IgA1 by any molecule in development 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 C: 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 designed to evaluate 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 U.S. Food and Drug Administration (FDA) for primary glomerular diseases associated with significant proteinuria, including IgAN. The Phase 2b ORIGIN trial is powered to demonstrate a statistically significant difference between atacicept and placebo in decrease of proteinuria. Secondary endpoints include the difference in kidney function between treated and placebo patients as measured by estimated glomerular filtration rate and reduction in Gd-IgA1. We plan to initiate patient screening for our Phase 2b clinical trial in the second quarter of 2021 and we expect to report topline results from ORIGIN in the fourth quarter of 2022.

### **Atacicept in LN**

We are evaluating further development of atacicept 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 now 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. Positive clinical data on multiple measures, including reduction of renal flares, from a prior Phase 2 clinical trial of atacicept in SLE within the High Disease Activity patient segment supports atacicept's applicability in LN. Because both preclinical and clinical evidence suggests atacicept's dual inhibition of BlyS and APRIL may provide better clinical efficacy than inhibiting either signal alone, we believe there is a strong rationale to conduct a clinical trial of atacicept in LN. We intend to discuss our development plans for LN with the FDA in 2021 and expect to initiate a Phase 2b or Phase 3 clinical trial in 2022.

### **Our Patent Portfolio; Potential Market Exclusivity**

As of March 1, 2021, our licensed patent portfolio related to atacicept contains approximately 15 issued U.S. patents, as well as certain foreign counterparts of a subset of these patents in several foreign countries, including countries within the European Patent Convention and the Eurasian Patent Organization. Because atacicept is a biologic, marketing approval would also provide 12 years of market exclusivity from the approval date of a Biologics License Application 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 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 Merck KGaA, Darmstadt, Germany 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 key elements of our strategy to achieve our goal include:

- Complete global development of atacept in IgAN.
- Advance atacept in LN.
- Explore additional disease areas where atacept holds significant therapeutic promise.
- Build and scale organizational capabilities to support commercialization of atacept.
- 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 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 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; and Senior Vice President of Clinical Operations and Data Management, Tom Doan, who was formerly Executive Director of Clinical Operations and Therapeutic Area Head of Inflammation and Respiratory at Gilead. Our team is well positioned to leverage our collective experience and expertise in drug development and commercialization to optimize atacept development and provide a disease modifying option to patients.

### **Our Leading Life Sciences Investors**

In conjunction with the license agreement with Ares, we completed an approximately \$80.0 million Series C redeemable convertible preferred stock financing led by Abingworth LLP. 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.

### **Risks Related to Our Business**

Investing in our common stock 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, atacept, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We have incurred net losses since inception, and we expect to continue to incur net losses for the foreseeable future.
- Even if this offering is successful, we will require substantial additional capital to finance our operations.
- We are substantially dependent on the success of our only product candidate, atacept, which is currently in the early stages of clinical development. If we are unable to complete development of,

obtain regulatory approval for and commercialize atacicept 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 and significant competition for recruiting such patients in clinical trials.
- The incidence and prevalence for target patient populations of atacicept in specific indications are based on estimates and third-party sources. If the market opportunities for atacicept, or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.
- Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than us.
- Changes in methods of atacicept manufacturing or formulation may result in additional costs or delays.
- Atacicept, and any future product candidates we develop, 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 atacicept, or any product candidate we develop in the future, receives regulatory approval, it could be subject to significant post-marketing regulatory requirements and will be subject to continued regulatory oversight.
- Biosimilars to atacicept may provide competition sooner than anticipated.
- The outbreak of the novel coronavirus (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 atacicept and our other products, proprietary technologies and their uses, our business, financial condition, results of operations and prospects could be significantly harmed.
- If we breach our license agreement with Ares, an affiliate of Merck KGaA, Darmstadt, Germany, related to atacicept, we could lose the ability to continue the development and commercialization of atacicept.
- We may be required to make significant payments under our license agreement for atacicept.
- 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 or any future product candidates we may develop for an adequate amount of time.
- If third parties, on which we rely to conduct certain aspects of our nonclinical studies and clinical trials, 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 or future product candidates we may develop, and our business, financial condition, results of operations and prospects could be significantly harmed.

- The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of atacicept for clinical trials or our product for patients, if approved, could be delayed or prevented.
- The price of our stock may be volatile, and you could lose all or part of your investment.
- If the remediation of the material weakness in our internal control over financial reporting 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 common stock.
- Our principal stockholders and management own a significant percentage of our 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 170 Harbor Way, 3rd Floor, South San Francisco, California 94080, and our telephone number is (650) 770-0077. Our website address is [www.veratx.com](http://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 ® or TM 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) the last day of our fiscal year following the fifth anniversary of the completion of this offering; (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 smaller reporting company with less than \$100 million in annual revenue, 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

|   |  |
|---|--|
| <b>Common stock offered</b>   | shares   |
| <b>Underwriters' option to purchase additional shares</b>   | We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of our common stock at the initial offering price, less underwriting discounts and commissions.   |
| <b>Common stock to be outstanding immediately after this offering</b>   | shares (or shares if the underwriters exercise their option to purchase additional shares in full)   |
| <b>Use of proceeds</b>  | <p>We estimate that the net proceeds from this offering will be approximately \$ million (or approximately \$ million if the underwriters' option to purchase additional shares of our common stock from us is exercised in full), after deducting underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund the clinical development of atacicept in IgAN, LN and potential additional indications, and the remaining for working capital and other general corporate purposes. See the section titled "Use of Proceeds" for additional information.</p> |
| <b>Risk factors</b>   | See the section titled "Risk Factors" beginning on page 13 and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.  |
| <b>Proposed Nasdaq Global Market trading symbol</b>   | "VERA"   |
| The number of shares of our common stock to be outstanding after this offering is based on shares of common stock outstanding as of December 31, 2020 (including (i) shares issuable upon the conversion of all outstanding shares of our redeemable convertible preferred stock as of December 31, 2020 and (ii) shares of unvested restricted common stock subject to repurchase as of such date), and excludes:  |  |
| <ul style="list-style-type: none"><li>▪ shares of our common stock issuable upon the exercise of outstanding stock options as of December 31, 2020 under our 2017 Equity Incentive Plan, as amended (2017 Plan), with a weighted-average exercise price of \$ per share;</li><li>▪ shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to December 31, 2020 under our 2017 Plan, with a weighted-average exercise price of \$ per share;</li><li>▪ shares of our common stock reserved for future issuance under our 2021 Equity Incentive Plan (2021 Plan), which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2021 Plan and any shares underlying outstanding stock awards granted under (i) the PNA Innovations, Inc. 2011 Stock Plan (PNA Stock Plan), which we assumed in connection with our acquisition of PNA Innovations, Inc. (PNA) in</li></ul> |  |

February 2017 or (ii) 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

- shares of our common stock reserved for issuance under our 2021 Employee Stock Purchase Plan (ESPP), which will become effective once the registration statement of which this prospectus forms a part is declared effective, and any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP.

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

- a -for- reverse stock split of our common stock to be effected prior to the closing of this offering;
- the conversion of all Class A common stock and Class B common stock into shares of common stock;
- the automatic conversion of all outstanding shares of our redeemable convertible preferred stock as of December 31, 2020 into an aggregate of shares of our common stock upon the closing of this offering;
- no exercise of the outstanding options described above;
- no exercise by the underwriters of their option to purchase additional shares of common stock from us in this offering;
- an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus; and
- the filing and effectiveness of our amended and restated certificate of incorporation immediately after the closing of this offering, and the adoption of our amended and restated bylaws upon the closing of this offering.

## SUMMARY FINANCIAL DATA

The following tables set forth a summary of our financial data as of, and for the periods ended on, the periods indicated. We have derived the summary statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2020, and balance sheet data as of December 31, 2020, from our audited financial statements included elsewhere in this prospectus. 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 this prospectus.

|   | Year Ended<br>December 31, |                   |
|---|----------------------------|-------------------|
|   | 2019                       | 2020              |
| (in thousands, except share<br>and per share data)  |                            |                   |
| <b>Operating expenses:</b>  |                            |                   |
| Research and development  | \$ 7,290                   | \$ 45,206         |
| General and administrative  | 4,410                      | 4,039             |
| Restructuring costs   | 261                        | 2,996             |
| <b>Total operating expenses</b>   | <b>11,961</b>              | <b>52,241</b>     |
| Loss from operations  | <u>(11,961)</u>            | <u>(52,241)</u>   |
| <b>Other income (expense):</b>  |                            |                   |
| Interest income   | 159                        | 8                 |
| Interest expense  | (51)                       | (166)             |
| Gain on the issuance of convertible notes   | —                          | 63                |
| Change in fair value of convertible notes   | —                          | (1,076)           |
| <b>Total other income (expense), net</b>  | <b>108</b>                 | <b>(1,171)</b>    |
| Loss before provision for income taxes  | <u>(11,853)</u>            | <u>(53,412)</u>   |
| Provision for income taxes  | <u>(1)</u>                 | <u>(1)</u>        |
| <b>Net loss and comprehensive loss(1)</b>   | <b>(11,854)</b>            | <b>(53,413)</b>   |
| Net loss per common share, basic and diluted(1)   | <u>\$ (3.46)</u>           | <u>\$ (14.40)</u> |
| Weighted-average shares used to compute net loss per common share, basic and diluted(1)                       | <u>3,422,676</u>           | <u>3,708,152</u>  |
| Pro forma net loss per common share, basic and diluted (unaudited)(2)   |                            | <u>\$ (1.13)</u>  |
| Weighted-average shares used to compute pro forma net loss per common share, basic and diluted (unaudited)(2) |                            | <u>47,233,275</u> |

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

(2) The unaudited pro forma net loss per common share for the year ended December 31, 2020 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of redeemable convertible preferred stock into shares of Class A common stock, as if such conversion had occurred at the beginning of the period, or their issuance dates, if later. The unaudited pro forma net loss per common share does not include the shares expected to be sold in, and related proceeds to be received from, the Company's initial public offering of Class A common stock.

|  | AS OF DECEMBER 31, 2020 |                  |  |
|--|-------------------------|------------------|--|
|  | ACTUAL                  | PRO<br>FORMA (1) | PRO FORMA<br>AS<br>ADJUSTED (2)<br>(3) |
| <b>(In thousands)</b>                  |                         |                  |  |
| <b>Balance Sheet Data:</b>             |                         |                  |  |
| Cash and cash equivalents              | \$ 53,654               | \$               | \$                                     |
| Working capital (4)                    | 51,855                  |                  |  |
| Total assets                           | 54,554                  |                  |  |
| Total liabilities                      | 4,326                   |                  |  |
| Redeemable convertible preferred stock | 139,576                 |                  |  |
| Accumulated deficit                    | (91,447)                |                  |  |
| Total stockholders' deficit            | (89,348)                |                  |  |

- (1) The pro forma column in the balance sheet data gives effect to (i) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of \_\_\_\_\_ shares of common stock which will occur upon the closing of this offering and the related reclassification of the carrying value of our redeemable convertible preferred stock to permanent equity upon the closing of this offering, and (ii) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately after the closing of this offering.
- (2) The pro forma as adjusted column in the balance sheet data gives effect to (i) the items described in footnote (1) above and (ii) the issuance and sale of \_\_\_\_\_ shares of our common stock in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share after deducting underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) The pro forma as adjusted information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase or decrease, as applicable, each of cash and cash equivalents, working capital, total assets and total stockholders' deficit by \$ \_\_\_\_\_ million, assuming that the number of shares 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 of 1.0 million shares in the number of shares of common stock offered by us would increase or decrease, as applicable, each of cash and cash equivalents, working capital, total assets, and total stockholders' deficit by \$ \_\_\_\_\_ million, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.
- (4) We define working capital as current assets less current liabilities. See our 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 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 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 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 for you to evaluate our current business and predict our future success and viability.***

We are a clinical-stage biotechnology company and we have no products approved for commercial sale, have not generated any revenue from product sales and have incurred losses since inception. To date, we have devoted substantially all of our resources and efforts to organizing and staffing our company, business planning, executing partnerships, raising capital, acquiring, developing and securing our lead technology and product candidate, atacicept, and initiating a Phase 2b study to further evaluate atacicept in patients with IgAN. We have not yet demonstrated our ability to successfully complete any clinical trials with respect to atacicept, 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 for you 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 clinical-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 only product 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, atacicept. With only one product candidate in development, we anticipate incurring significant costs associated with the development of atacicept. 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, 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. Following this offering, we also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of December 31, 2020, we had \$53.7 million in cash and cash equivalents. Based on our current operating plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will

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be sufficient to fund our operating expenses and capital expenditures requirements for at least the next . 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 our product candidate, atacicept, for the treatment of IgAN and LN;
- initiate nonclinical studies and clinical trials for atacicept and any additional product candidates that we may pursue in the future;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- 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;
- 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 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 atacicept.

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, have not generated any revenue from product sales to date and have financed our operations principally through private financings. We have incurred net losses of \$11.9 million and \$53.4 million for the years ended December 31, 2020 and 2019. We had an accumulated deficit of \$91.4 million as of December 31, 2020. 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

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resulting from our efforts to develop gamma-PNA chemistry and triplex gene editing for therapeutic use, which we discontinued in September 2020. Our only product candidate, atacicept, is in early-stage clinical trials. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing atacicept 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 atacicept 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 atacicept. 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 atacicept. 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 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 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 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.

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

***We are substantially dependent on the success of our only product candidate, atacicept, which is currently in the early stages of clinical development. If we are unable to complete development of, obtain regulatory approval for and commercialize atacicept 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 atacicept, our only product candidate. 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. We are investing significant efforts and financial resources in the research and development of atacicept, 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 atacicept before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. Should our planned clinical development of atacicept in patients with IgAN fail to be completed in a timely manner or at all, we will need to rely on clinical development of atacicept 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 atacicept will be completed in a timely manner, or at all, or that we will be able to obtain approval for atacicept from the FDA or comparable foreign regulatory authorities. If we are unable to complete development of, obtain regulatory approval for and commercialize atacicept 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 for atacicept or submitted a Biologics License Application (BLA) to the FDA or similar drug approval filings to comparable foreign authorities. If we are ultimately unable to obtain regulatory approval for atacicept, 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 of atacicept and any future product candidates we may develop 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.

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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 atacicept or product candidates we may develop in the future 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 atacicept or product candidates we may develop. 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 atacicept or any future product candidates we may develop.

We do not know whether our current clinical trial of atacicept or any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market atacicept or any future product candidates we may develop. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. If we are unable to bring atacicept or any future 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 contract research organizations (CROs) and other third parties for regulatory submissions for atacicept. 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 atacicept or any future product candidates we may develop. 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 atacicept or any future product candidates we may develop. Even if regulatory approval is secured for atacicept, the terms of such approval may limit the scope and use of atacicept, which may also limit its 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 atacicept, including and any other indication we are seeking for approval under atacicept.

***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 atacicept or any future product candidate we may develop. 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;

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- 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 for the indication for which we are developing atacicept, 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 atacicept or any future product candidate we may develop 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, in 2020 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 atacicept or product candidates we may develop in the future, 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

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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 of atacicept or any product candidates we may develop in the future, the commercial prospects of atacicept or any product candidates we may develop in the future will be harmed, and our ability to generate product revenues from atacicept or any product candidates we may develop in the future will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down atacicept's or any product candidates we may develop in the future's development and approval process 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 of atacicept or any product candidates we may develop in the future. 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 or any product candidates we may develop in the future and our competitors may be able to bring products to market before we do, and the commercial viability of atacicept or any product candidates we may develop in the future could be significantly reduced. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

***Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with IgAN and significant competition for recruiting such 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 and the significant competition for recruiting patients with IgAN in clinical trials, 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 for our Phase 2b clinical trial, 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 atacept, and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.***

We may develop atacept and future product candidates in combination with one or more currently approved therapies. Even if atacept, 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 atacept 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 atacept 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 atacept or any other product candidate we develop, we may be unable to obtain approval of or market atacept or any other product candidate we develop.

***The incidence and prevalence for target patient populations of atacept in specific indications are based on estimates and third-party sources. If the market opportunities for atacept, 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 atacept 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 atacept, 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

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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 common stock after this offering.

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, atacicept or any future product candidates we may develop 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. There are currently no approved therapies for IgAN and current standard-of-care consists of treatment with renin-angiotensin-aldosterone system inhibitors, including angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers, to control blood pressure, or steroids with or without other immunosuppressive agents to non-specifically reduce inflammation. We do not expect to compete directly with these non-specific approaches, but rather atacicept may be an appropriate option where these therapies are not well tolerated and/or where a patient's disease progression remains uncontrolled despite these approaches. Among emerging therapies, we consider our most direct competitors with respect to atacicept in IgAN to be the programs in Phase 3 clinical development: Calliditas Therapeutics AB, Novartis Pharmaceuticals Corporation (Novartis), Omeros Corporation, Traverre 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 & Co. 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, CYC, rituxumab, 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 the following companies with programs in Phase 3 clinical development: Roche Holding AG and Novartis, and the following companies with programs in Phase 2 clinical development: BeiGene Ltd., Janssen Pharmaceuticals, Inc., AstraZeneca, Alexion, Omeros Corporation, Kezar Life Science Inc., Bristol Myers Squibb, Boehringer, and Novartis.

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 candidate 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 candidate 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 atacept manufacturing or formulation may result in additional costs or delays.***

As atacept progresses 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 atacept 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 atacept and jeopardize our ability to commercialize atacept, 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 atacept or any future product candidates we may develop, 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 atacept 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 atacept 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 of atacept 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 atacept's risk-benefit ratio for its proposed indication is acceptable;

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- 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 atacicept, which would significantly harm our business, financial condition, results of operations and prospects.

In addition, even if we obtain approval of atacicept for a lead indication, regulatory authorities may not approve atacicept 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 atacicept 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 of atacicept, 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, atacicept may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.***

Even if atacicept receives regulatory approval, it may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance 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;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of atacicept, 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 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 atacicept from treatment guidelines established by various physician groups;
- unfavorable publicity relating to atacicept 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 atacept, 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.

***Atacept, and any future product candidates we develop, 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 atacept 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 atacept or any future product candidates we may develop 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 atacept in patients with active LN, receiving newly initiated corticosteroids (CS) and mycophenolate mofetil (MMF). Two weeks before the initiation of atacept, significant decreases in IgG levels began unexpectedly with initiation of MMF and high-dose CS, and persisted upon initiation of atacept, 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 atacept or any future product candidates we may 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. atacept or any future product candidates we may develop, 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 atacept or any future product candidates we may develop, are used in combination with other therapies, atacept 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 atacept or any future

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candidates we may develop, may also be undergoing surgical, radiation, chemotherapy or other treatments, which can cause side effects or adverse events that are unrelated to atacept or any future product candidates we may develop, 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, if atacept obtains marketing approval, toxicities associated with atacept and not seen during clinical testing may also develop after such approval 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 atacept 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 atacept, or any product candidate we develop in the future, in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of atacept, or any product candidate we develop in the future, in other jurisdictions.***

Obtaining and maintaining regulatory approval of atacept, or any product candidate we develop in the future, 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 atacept, or any product candidate we develop in the future, will be harmed.

***Even if atacept, or any product candidate we develop in the future, 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 atacept, or any product candidate we develop in the future, 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 atacept, 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

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the FDA or applicable foreign regulatory authorities approve atacicept 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 for atacicept 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, 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 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 (EMA) 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.

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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.

***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 or future product candidates we may develop. For example, if the results from our planned 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 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. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. 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, 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 would result in a longer time period to commercialization of such product candidate, could increase the cost of development of atacicept and could harm our competitive position in the marketplace.

***Biosimilars to atacicept 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.

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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 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, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of atacicept. 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 atacicept will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for atacicept 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 atacicept, or any future product candidate we may develop, 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 atacicept or any future product candidates we may develop. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (CMS) an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our product to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Factors payors consider in determining reimbursement are based on whether the product is:

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

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Governmental payors, as well as other third-party payors, including pharmacy benefit managers, have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and/or biosimilars. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are

increasingly examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our product. Nonetheless, atacicept 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 or any future product candidates we may develop. In many countries, particularly the countries of the European Union, 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 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 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 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, various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court. Although the Supreme Court has not yet ruled on the

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constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs 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 also unclear how the Supreme Court ruling, other such litigation 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 2030, unless additional congressional action is taken. COVID-19 pandemic relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. 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.

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 released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance 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. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 2020, HHS published 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

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pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. 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 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 atacicept or any future product candidates we may develop, if any, 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 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 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 privacy and security laws (including 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 candidate 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 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

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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 (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) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and other transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; 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 European Union. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of EU Member States, and the Bribery Act 2010 in the 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.

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

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

***We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, 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 United Kingdom. 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

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be required to implement additional mechanisms to comply with the GDPR. These mechanisms may be onerous and, if our efforts to comply with 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 United Kingdom's (UK) 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 European Union 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 European Union'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 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 United Kingdom will continue to remain lawful under the GDPR in light of Brexit. Pursuant to a post-Brexit trade deal between the United Kingdom and the EU, transfers of personal information from the European Economic Area to the United Kingdom 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 United Kingdom before the end of that period, the United Kingdom will be considered a "third country" under the GDPR and transfers of European personal information to the United Kingdom will require an approved compliance mechanism to render such transfers lawful under the GDPR. Although the United Kingdom's primary data protection legislation is designed to be consistent with the GDPR, uncertainty remains regarding how data transfers to and from the United Kingdom 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

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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 anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.***

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

In addition, our product and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our product, or our failure to obtain any

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

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

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

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

***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;

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- 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 atacept 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, and more 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 rapidly 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 affects 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.

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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 atacept 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 atacept or any product candidate we may develop in the future, we may not be able to successfully sell or market atacept 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 atacept 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 atacept 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 atacept 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 atacept 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 atacept 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 atacept 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

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organization will be expensive and time-consuming and could delay the launch of atacicept 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 atacicept 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 March 1, 2021, we had eight full-time employees, including four employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating 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 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. 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 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 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 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 South San Francisco, 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 charges, and could increase our future U.S. tax expense. 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 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 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 net operating loss carryforwards as of December 31, 2020, that do not expire as a result of recent tax law changes. Our net operating loss (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 to offset taxable income 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 this offering or 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

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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 atacept 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 atacept 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 atacept, 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 atacept 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 candidate or any future product candidates or products that are substantially similar to our product candidate 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 atacept 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

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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 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 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, we could lose the ability to continue the development and commercialization of atacicept.***

We are dependent on patents, know-how and proprietary technology licensed or sublicensed to us from Ares. Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidate or any future product candidates and use our and our licensor's proprietary technologies without infringing the proprietary rights of third parties. Ares may have the right to terminate the license agreement in full in the event we materially breach or default in the performance of any of the obligations under the license agreement. A termination of the license agreement with Ares 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 from Ares and in the event the agreement between Ares and any such third party 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, as well as 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 candidate 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, under which we currently license intellectual property. The Ares Agreement is 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 the Ares 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

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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 agreement for atacept.***

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. 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 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. 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 atacept 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 atacept 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

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they are aware for the patent examiner to consider in addition to independent searches that the patent examiner is required to do. Also, in the United States and certain other jurisdictions, third parties are entitled to submit prior art to patent offices for consideration during examination.

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

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or other jurisdictions, or become involved in post-grant challenges such as opposition, derivation, revocation, reexamination, post-grant review (PGR) and *inter partes* review (IPR), or other similar proceedings, or in litigation, challenging our patent rights, including by challenging the validity or the claim of priority of our patents. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize atacicept 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 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, 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 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;

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- 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 atacept 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 atacept 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 atacept 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 atacept 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 atacept, or any future product candidates we may develop, may be subject to claims of infringement of the patent rights of third parties.

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

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

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing atacicept 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 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 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 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 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 atacept, 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 atacept and any future product candidates we may develop. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could significantly harm our business, financial condition, results of operations and prospects.

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

Competitors or other third parties may infringe, misappropriate or otherwise violate our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement or other intellectual property claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we may in-license in the future or own is not valid, is unenforceable, and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our owned or in-licensed patents do not cover the technology in question. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at atacept 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

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have sufficient financial or other resources to conduct such litigation or proceedings adequately. Our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

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

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

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

***Derivation proceedings may be necessary to determine 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 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

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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) 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 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 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 European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended 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 atacept or any future product candidates we may develop, without any available recourse.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Because the legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceutical products, it could be difficult for us to stop the infringement, misappropriation or violation of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our intellectual property and other proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly, could put our patent applications or the patent applications of our licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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.

***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.

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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 atacept 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 candidate 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 atacept or any future product candidates we may develop. 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.

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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 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 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 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 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. As a result, our results of operations and the commercial prospects for atacicept 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

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delay development and commercialization of atacept 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.

***We contract with third parties for the manufacture of atacept for our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of atacept or other drugs necessary for the development or commercialization of atacept 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 atacept for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of atacept for clinical trials under the guidance of members of our organization. We do not have long-term supply agreements for atacept. Furthermore, the raw materials for atacept are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of atacept 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 atacept 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 atacept, 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 atacept according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over atacept 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 atacept according to our specifications;

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- 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 atacicept, 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 atacicept, 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 atacicept or other drugs necessary for the development or commercialization of atacicept 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 atacicept are unable to produce sufficient quantities for clinical trials or for commercialization of atacicept, 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 atacicept or other drugs necessary for the development or commercialization of atacicept 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 atacicept 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.

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***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 atacicept. If those collaborations are not successful, we may not be able to capitalize on the market potential of atacicept.***

In the future, we may partner with third-party collaborators for the development and commercialization of atacicept. 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 atacicept. 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 atacicept or any future product candidate 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 atacicept 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 atacicept 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;

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- 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 atacicept 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 atacicept 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 atacicept or any future product candidates we may develop. 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 atacicept or any future product candidates we may develop or bring them to market and generate product revenue.

## Risks related to this offering and ownership of our common stock

***There has been no prior public market for our common stock. We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be, and as a result, it may be difficult for you to sell your shares of our common stock.***

Prior to this offering, no public market for shares of our common stock existed and an active trading market for our common stock may never develop or be sustained following this offering. We will determine the initial public offering price for our common stock through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. 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 common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration.

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

The trading price of our common stock following this offering is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

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

- 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;
- the timing and results of nonclinical studies and clinical trials of atacept or any future product candidates we may develop or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our product candidate or our competitors' products;
- 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;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- 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 common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions.

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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 rapidly 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 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 common stock.***

Prior to the completion of this offering, we have been 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 are in the process of adding additional accounting personnel and 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 will be 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 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our fifth annual report following this offering, which will be our year ending December 31, 2024, 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 Jumpstart Our Business Startups Act of 2012 (JOBS Act). 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

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the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

***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 ataccept 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 ataccept or any future product candidate 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 ataccept 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 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 stock and will be able to exert significant control over matters subject to stockholder approval.***

Prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately % of our voting stock and, upon the closing of this offering, that same group will beneficially own approximately % of our outstanding voting stock (based on the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and assuming no exercise of the underwriters' option to purchase additional shares) and without giving effect to any purchases that certain of these holders may make through our directed share program. Therefore, even after this offering these stockholders will be 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 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

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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 common stock, and might affect the prevailing market price for our common stock.

***If you purchase shares of our common stock in our initial public offering, you will experience substantial and immediate dilution.***

The initial public offering price is substantially higher than the net tangible book value per share of our outstanding common stock immediately following the closing of this offering. Based on the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, if you purchase shares of common stock in this offering, you will experience substantial and immediate dilution in the pro forma as adjusted net tangible book value per share of \$ \_\_\_\_\_ per share as of December 31, 2020. That is because the price that you pay will be substantially greater than the pro forma net tangible book value per share of the common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares of our capital stock. You will experience additional dilution when those holding stock options or warrants exercise their right to purchase common stock under our equity incentive plans or when we otherwise issue additional shares of common stock. See the section titled "Dilution."

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

Our common stock price could decline as a result of sales of a large number of shares of common stock 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.

Upon the closing of this offering, \_\_\_\_\_ shares of common stock (including (i) \_\_\_\_\_ shares issuable upon the conversion of all outstanding shares of our redeemable convertible preferred stock as of December 31, 2020 and (ii) \_\_\_\_\_ shares of unvested restricted common stock subject to repurchase as of such date) will be outstanding ( \_\_\_\_\_ shares if the underwriters exercise their option to purchase additional shares from us in full), based on the number of shares outstanding as of December 31, 2020.

All shares of common stock expected to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended (Securities Act), unless held by our "affiliates" as defined in Rule 144 under the Securities Act. The resale of the remaining \_\_\_\_\_ shares, or \_\_\_\_\_ % of our outstanding shares of common stock following this offering, is currently prohibited or otherwise restricted as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders 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 181 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. Shares issued upon the exercise of stock options and warrants outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and/or lock-up agreements, as well as Rules 144 and 701 under the Securities Act. For more information, see the section titled "Shares Eligible for Future Sale" herein.

Upon the closing of this offering, the holders of approximately \_\_\_\_\_ shares of common stock, or \_\_\_\_\_ % of our outstanding shares following this offering, assuming no exercise of the underwriters' option to purchase additional shares, will have rights, subject to certain conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We also intend to register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Once we register the offer and sale of shares for the holders of registration rights and shares that may be issued under our equity incentive plans, these shares will be able to be sold in the public market upon issuance, subject to applicable securities laws and the lock-up agreements described under the section titled "Underwriters" herein.

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

***Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to atacccept 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 atacccept 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 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 of 2002 (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 common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock 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) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

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 intend to take 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.

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Pursuant to Section 404 of the Sarbanes-Oxley Act (Section 404) we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC or a smaller reporting company with less than \$100 million in annual revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We could be an EGC for up to five years. 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 common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock 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 common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.***

We have never declared or paid any cash dividends on our equity securities. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of our common stock, which is not certain.

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

Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our

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board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

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

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

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

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine or otherwise related to our internal affairs.

These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation and our amended and restated bylaws will further provide 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

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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. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation and our amended and restated bylaws. 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 either exclusive forum provision contained in our amended and restated certificate of incorporation or amended and restated bylaws 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—Recent Accounting Pronouncements."

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

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

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

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

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. We do not currently have and may never obtain research coverage by securities or industry analysts. If no or few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. In the event we obtain securities or industry analyst coverage, 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. 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 atacept or any other product candidates we may develop, and conducting nonclinical studies and clinical trials, including our atacept Phase 2b clinical trial;
- the timing and costs involved in obtaining and maintaining regulatory approval of atacept or any other product candidates we may develop, 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 atacept and any other product candidates we may develop, 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 atacept or any other product candidates we may develop;
- the size of the market opportunity for atacept or any other product candidates we may develop in each of the diseases we target;
- our reliance on third parties to conduct nonclinical research activities, and for the manufacture of atacept and any other product candidates we may develop;
- the beneficial characteristics, safety, efficacy and therapeutic effects of atacept and any other product candidates we may develop;
- 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 atacept and any other product candidates we may develop, and other positive results;
- the success of competing therapies that are or may become available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;

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- our plans relating to the further development and manufacturing of atacept and any other product candidates we may develop, 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 atacept and any other product candidates we may develop for clinical trials and for commercial use, if approved;
- the rate and degree of market acceptance of atacept and any other product candidates we may develop, as well as the pricing and reimbursement of atacept and any other product candidates we may develop, if approved;
- our continued reliance on third parties to conduct additional clinical trials of atacept and any other product candidates we may develop, 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 atacept 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 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 may not be achieved or occur and actual results could differ materially from those projected in the 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 common stock is exercised in full) based on the assumed initial public offering price of \$            per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$            per share 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 1.0 million shares in the number of shares of common stock offered by us would increase or decrease, as applicable, the net proceeds to us from this offering by approximately \$            million, assuming the initial public offering price of \$            per share remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our common stock and facilitate our future access to the public capital markets.

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

- approximately \$            to fund clinical development of atacicept in IgAN;
- approximately \$            to fund clinical development of atacicept in LN and potential additional indications; and
- the remainder for general corporate purposes, including working capital, operating expenses and capital expenditures.

We may also use a portion of the remaining net proceeds and our existing cash and cash equivalents to in-license, acquire, or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

We believe, based on our current operating plan, that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least the next            months. In particular, we expect that the net proceeds from this offering will allow us to            for atacicept in patients with IgAN, and            for atacicept in patients with LN and potential additional indications. 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 through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of atacicept in IgAN, LN, 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, and we do not anticipate paying any cash dividends in the foreseeable future. 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, 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 December 31, 2020 on:

- an actual basis;
- a pro forma basis, giving effect to the (i) automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of \_\_\_\_\_ shares of our common stock which will occur upon the closing of this offering, and the related reclassification of the carrying value of our redeemable convertible preferred stock to permanent equity upon the closing of this offering, (ii) the conversion of all Class A common stock and Class B common stock into common stock, and (iii) filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately after the closing of this offering; and
- a pro forma as adjusted basis, giving effect to the (i) pro forma adjustments set forth above and (ii) our receipt of net proceeds from the sale of \_\_\_\_\_ shares of common stock in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price 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," "Description of Capital Stock" and our financial statements and related notes included elsewhere in this prospectus.

|   | <u>AS OF DECEMBER 31, 2020</u> |                      |                        |
|---|--------------------------------|----------------------|------------------------|
|   | <u>ACTUAL</u>                  | <u>PRO<br/>FORMA</u> | <u>AS<br/>ADJUSTED</u> |
| <b>(In thousands, except share and per share amounts)</b>   |                                |                      |                        |
| Cash and cash equivalents   |                                |                      |                        |
| 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 |                                |                      |                        |
| Stockholders' deficit   |                                |                      |                        |
| Common stock, \$0.001 par value; 23,000,000 and 295,580,527 shares authorized as of December 31, 2019 and 2020, respectively; 3,731,682 and 4,117,498 shares issued and outstanding as of December 31, 2019 and 2020, respectively                              |                                |                      |                        |
| Additional paid-in capital  |                                |                      |                        |
| Accumulated deficit   |                                |                      |                        |
| Total stockholders' deficit   |                                |                      |                        |
| Total capitalization  |                                |                      |                        |

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase (decrease) each of our pro forma 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 1.0 million shares in the number of shares common stock offered by us would increase (decrease) each of our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit)

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and total capitalization by approximately \$            million, assuming the assumed initial public offering price of \$            per share remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock to be issued and outstanding, pro forma and pro forma as adjusted in the table above is based on            shares of common stock outstanding as of December 31, 2020 (including (i)            shares issuable upon the conversion of all outstanding shares of our redeemable convertible preferred stock as of December 31, 2020 and (ii)            shares of unvested restricted common stock subject to repurchase as of such date), and excludes:

- shares of our common stock issuable upon the exercise of outstanding stock options as of December 31, 2020 under our 2017 Plan, with a weighted-average exercise price of \$            per share;
- shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to December 31, 2020 under our 2017 Plan, with a weighted-average exercise price of \$            per share;
- shares of our common stock reserved for future issuance under our 2021 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2021 Plan and any shares underlying outstanding stock awards granted under our PNA Stock Plan or 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
- shares of our common stock reserved for issuance under our 2021 Employee Stock Purchase Plan (ESPP), which will become effective once the registration statement of which this prospectus forms a part is declared effective, and any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP.

## DILUTION

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

As of December 31, 2020, we had a historical net tangible book value of \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share of common stock based on the \_\_\_\_\_ shares of common stock outstanding as of such date, including \_\_\_\_\_ shares subject to repurchase as of such date. Our historical net tangible book value per share represents total tangible assets less total liabilities and convertible preferred stock, which is not included within permanent equity, divided by the number of shares of common stock outstanding as of December 31, 2020, including \_\_\_\_\_ shares subject to repurchase as of such date.

Our pro forma net tangible book value as of December 31, 2020 was \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share. Pro forma net tangible book value per share represents the amount of our total tangible assets less our total liabilities, divided by \_\_\_\_\_ shares of common stock outstanding as of such date, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of \_\_\_\_\_ shares of our common stock and the related reclassification of the carrying value of our convertible preferred stock to permanent equity upon the closing of this offering, and (ii) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately after the closing of this offering.

After giving effect to the sale by us of \_\_\_\_\_ shares of common stock in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2020 would have been \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of \$ \_\_\_\_\_ per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of \$ \_\_\_\_\_ per share to investors purchasing common stock in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash paid by an investor for a share of common stock in this offering. The following table illustrates this dilution on a per share basis:

|   |          |
|---|----------|
| Assumed initial public offering price per share   | \$ _____ |
| Historical net tangible book value (deficit) per share as of December 31, 2020  | \$ _____ |
| Pro forma increase in historical net tangible book value per share attributable to the pro forma transactions described in the preceding paragraphs | _____    |
| Pro forma net tangible book value per share as of December 31, 2020   | _____    |
| Increase in pro forma as adjusted net tangible book value per share attributable to investors purchasing shares in this offering                    | _____    |
| Pro forma as adjusted net tangible book value per share after this offering   | _____    |
| Dilution in pro forma 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 initial public offering price and other terms of this offering. Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase or decrease, as applicable, our pro forma as adjusted net tangible book value per share after this offering by \$ \_\_\_\_\_ per share and increase or decrease, as applicable, the dilution to investors purchasing shares in this offering by \$ \_\_\_\_\_ per share, in each case assuming the number of shares of common 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, each increase or decrease of 1.0 million shares in the number of shares of common stock offered by us would increase or decrease our pro forma as adjusted net tangible book value by approximately \$ \_\_\_\_\_ per share and decrease or

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increase, as applicable, the dilution to investors purchasing shares in this offering by approximately \$ \_\_\_\_\_ per share, in each case assuming the assumed initial public offering price of \$ \_\_\_\_\_ per share 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 common stock in full, the pro forma 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.

The foregoing discussion and tables above (other than the historical net tangible book value calculation) are based on \_\_\_\_\_ shares of common stock outstanding as of December 31, 2020 (including (i) \_\_\_\_\_ shares issuable upon the conversion of all outstanding shares of our convertible preferred stock as of December 31, 2020 and (ii) \_\_\_\_\_ shares of unvested restricted common stock subject to repurchase as of such date), and excludes:

- \_\_\_\_\_ shares of our common stock issuable upon the exercise of outstanding stock options as of December 31, 2020 under our 2017 Plan, with a weighted-average exercise price of \$ \_\_\_\_\_ per share;
- \_\_\_\_\_ shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to December 31, 2020 under our 2017 Plan, with a weighted-average exercise price of \$ \_\_\_\_\_ per share;
- \_\_\_\_\_ shares of our common stock reserved for future issuance under our 2021 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2021 Plan and any shares underlying outstanding stock awards granted under our PNA Stock Plan or 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
- \_\_\_\_\_ shares of our common stock reserved for issuance under our ESPP, which will become effective once the registration statement of which this prospectus forms a part is declared effective, and any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP.

To the extent that any outstanding options are exercised or new options are issued under our stock-based compensation plans, or we issue additional shares of 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 clinical stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases. Our lead product candidate is atacicept, a fusion protein self-administered as a subcutaneous injection once weekly that blocks both B lymphocyte stimulator (BLyS) and a proliferation-inducing ligand (APRIL), which stimulate B cells and plasma cells to produce autoantibodies contributing to certain autoimmune diseases. We are conducting a Phase 2b clinical trial of atacicept in patients with immunoglobulin A nephropathy (IgAN), a disease with a high unmet medical need and no approved therapies. IgAN is a serious and progressive autoimmune disease of the kidney that is driven by the production of immunogenic galactose-deficient IgA1 (Gd-IgA1). IgAN patients with elevated Gd-IgA1 are at increased risk of kidney-related morbidity and mortality. As reported in a Phase 2a clinical trial, atacicept is the first and only molecule currently in development to demonstrate a 60% reduction in plasma Gd-IgA1, which we believe can be disease modifying. We plan to initiate patient screening for our Phase 2b clinical trial in IgAN in the second quarter of 2021, and we expect to report topline results in the fourth quarter of 2022. In addition, we are evaluating additional diseases where atacicept's reduction of autoantibodies may prove medically useful, including lupus nephritis (LN), a severe renal manifestation of systemic lupus erythematosus (SLE).

Since our inception, we have devoted substantially all of our resources to our research and development efforts, pre-clinical studies, 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, if they ever occur, will take a number of years. We also do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for nonclinical and clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing approval. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

To date, we have funded our operations primarily through proceeds from the sale of shares of our common stock, redeemable convertible preferred stock and convertible promissory notes. As of December 31, 2020, we had \$53.7 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, will be sufficient to fund our planned operating expenses and capital expenditure requirements for at least the next

We have incurred significant operating losses since the commencement of our operations. Our net losses were \$11.9 million and \$53.4 million for the years ended December 31, 2019 and 2020, and we expect to incur significant and increasing losses for the foreseeable future as we continue to advance our product candidate, atacicept, and as we transition to operating as a public company. Our net losses may fluctuate significantly from

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period to period, depending on the timing of expenditures on our research and development activities. As of December 31, 2020, we had an accumulated deficit of \$91.4 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 is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and other current liabilities.

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 candidate, atacicept, for the treatment of iGAN and LN;
- initiate nonclinical studies and clinical trials for atacicept and any additional product candidates that we may pursue in the future;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- 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;
- 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 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 recent 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 temporarily reduced the presence of our employees 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 planned clinical trial and other development timelines, as well as on our industry and the healthcare system.

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

- 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;
- 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;
- 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.

[Table of Contents](#)**Results of Operations****Comparisons of the Years Ended December 31, 2019 and 2020**

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

| (dollars in thousands)                    | YEAR ENDED<br>DECEMBER 31, |                   | CHANGE            |          |
|---|----------------------------|-------------------|-------------------|----------|
|   | 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           | <u>\$(11,854)</u>          | <u>\$(53,413)</u> | <u>\$(41,559)</u> | 351%     |

\* 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. Through September 2020, our research and development expenses were incurred resulting from our efforts to develop gamma-PNA chemistry and triplex gene editing for therapeutic use. 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.

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

| (dollars in thousands)                     | YEAR ENDED<br>DECEMBER 31, |          | CHANGE   |       |
|--|----------------------------|----------|----------|-------|
|  | 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

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.

| (dollars in thousands)     | YEAR ENDED<br>DECEMBER 31, |         | CHANGE   |      |
|----------------------------|----------------------------|---------|----------|------|
|                            | 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.

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### **Restructuring Costs**

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

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| (dollars in thousands) | YEAR ENDED<br>DECEMBER 31, |          | CHANGE   |        |
|------------------------|----------------------------|----------|----------|--------|
|                        | 2019                       | 2020     | AMOUNT   | %      |
| Restructuring costs    | \$ 261                     | \$ 2,996 | \$ 2,735 | 1,048% |

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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)**

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| (dollars in thousands)       | YEAR ENDED<br>DECEMBER 31, |            | CHANGE     |          |
|------------------------------|----------------------------|------------|------------|----------|
|                              | 2019                       | 2020       | AMOUNT     | %        |
| Total other income (expense) | \$ 108                     | \$ (1,171) | \$ (1,279) | (1,184)% |

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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. From our inception through December 31, 2020, we have raised aggregate net cash proceeds of \$141.6 million from the issuance and sale of redeemable convertible preferred stock and convertible notes. 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 atacept, 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. We expect that our research and development and general and administrative costs will increase in connection with conducting additional clinical trials and clinical trials for our current and future 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.

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As of December 31, 2020, we had unrestricted cash and cash equivalents balance of \$53.7 million. We expect that our existing cash and cash equivalents, together with the proceeds from this offering, will be sufficient to fund our operations through at least the next

### **Cash Flows**

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

| (In thousands)  | YEAR ENDED<br>DECEMBER 31, |                  |
|---|----------------------------|------------------|
|   | 2019                       | 2020             |
| Net cash used in operating activities                                 | \$(10,289)                 | \$(34,809)       |
| Net cash used in investing activities                                 | (125)                      | (42)             |
| Net cash provided by (used in) financing activities                   | (137)                      | 85,290           |
| Net increase (decrease) in cash, cash equivalents and restricted cash | <u>\$(10,551)</u>          | <u>\$ 50,439</u> |

### **Operating Activities**

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 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 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 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.

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### Contractual Obligations

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

| (In thousands)   | PAYMENTS DUE BY PERIOD |                     |           |           |                      |
|------------------|------------------------|---------------------|-----------|-----------|----------------------|
|                  | TOTAL                  | LESS THAN<br>1 YEAR | 1-3 YEARS | 3-5 YEARS | MORE THAN<br>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 ends 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 addition to the office leases, we have future minimum lease payments of \$0.6 million for leases on research and laboratory equipment.

### 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. Although we have already taken some steps to remediate this material weakness, if we are unable to remediate the material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business."

### 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 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 are a privately-held company and do not have any 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.

We expect to incur stock-based compensation of approximately \$ million to \$ million over the next to years as a result of all compensatory equity issuances made in fiscal year 2021.

We expect to incur stock-based compensation of approximately \$ million to \$ million in fiscal year 2022 as a result of all compensatory equity issuances outstanding as of March 31, 2021.

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The intrinsic value of all outstanding options as of December 31, 2020 was \$ \_\_\_\_\_, \$ \_\_\_\_\_ million of which related to unvested options as of such date, based on the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

### **Fair Value of Common Stock**

Historically, for all periods prior to this initial public offering, 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.

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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 this offering, the fair value of each share of the underlying common stock will be determined based on the closing price as reported on the date of grant on the primary stock exchange on which our 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 a registration statement for an initial public offering, 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) the last day of the fiscal year following the fifth anniversary of completion of this offering.

### **Recent Accounting Pronouncements**

See Note 2 to our 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.

### **Quantitative and Qualitative Disclosures About Market Risk**

#### ***Interest Rate Risk***

As of December 31, 2020, we had cash and cash equivalents of \$53.7 million, which cash equivalents consisted of money market funds. Such interest-earning instruments carry a degree of interest rate risk. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash, cash equivalents, restricted cash, and investments.

## BUSINESS

### Overview

We are a clinical stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases. Our lead product candidate is atacicept, a fusion protein self-administered as a subcutaneous injection once weekly that blocks both B lymphocyte stimulator (BLyS) and a proliferation-inducing ligand (APRIL), which stimulate B cells and plasma cells to produce autoantibodies contributing to certain autoimmune diseases. We are conducting a Phase 2b clinical trial of atacicept in patients with immunoglobulin A nephropathy (IgAN), a disease with a high unmet medical need and no approved therapies. IgAN is a serious and progressive autoimmune disease of the kidney that is driven by the production of immunogenic galactose-deficient IgA1 (Gd-IgA1). IgAN patients with elevated Gd-IgA1 are at increased risk of kidney-related morbidity and mortality. As reported in a Phase 2a clinical trial, atacicept is the first and only molecule in development to demonstrate a 60% reduction in plasma Gd-IgA1, which we believe can be disease modifying. We plan to initiate patient screening for our Phase 2b clinical trial in IgAN in the second quarter of 2021, and we expect to report topline results in the fourth quarter of 2022. In addition, we are evaluating additional diseases where atacicept's reduction of autoantibodies may prove medically useful, including lupus nephritis (LN), a severe renal manifestation of systemic lupus erythematosus (SLE).

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, there are currently no approved treatments indicated for IgAN. The current standard of care consists of off-label use of renin-angiotensin-aldosterone system (RAAS) inhibitors, including angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs), as well as 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 clinical trials 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. We believe that atacicept's mechanism has the potential to drive a high level of 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 lupus nephritis (LN). Preclinical and clinical evidence supports that atacicept's mechanism of dual inhibition of BLyS and APRIL may provide better clinical efficacy than inhibiting either signal alone.

We have a worldwide, exclusive rights to atacicept from Ares Trading S.A. (Ares), an affiliate of Merck KGaA, Darmstadt, Germany, pursuant to a license agreement (Ares Agreement), which advanced atacicept in clinical trials for several autoimmune diseases in over 1,500 patients, in which it demonstrated an acceptable clinical safety and tolerability profile. In IgAN, Ares 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 on serum Gd-IgA1, proteinuria and key biomarkers, including serum immunoglobulin levels and a favorable safety profile. 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 designed to evaluate 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 U.S. Food and Drug Administration (FDA) for primary glomerular diseases associated with significant proteinuria,

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including IgAN. The ORIGIN trial is powered to demonstrate a statistically significant difference between atacicept and placebo in decrease of proteinuria. 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 plan to initiate patient screening for our Phase 2b clinical trial in the second quarter of 2021. We expect to report topline results from ORIGIN in the fourth quarter of 2022.

We are evaluating further development of atacicept 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 now 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. Positive clinical data on multiple measures, including reduction of renal flares, from a prior Phase 2 clinical trial of atacicept in SLE within the high disease activity (HDA) patient segment supports atacicept's applicability in LN. Because both preclinical and clinical evidence suggests atacicept's dual inhibition of BlyS and APRIL may provide better clinical efficacy than inhibiting either signal alone, we believe there is a strong rationale to conduct a clinical trial of atacicept in LN. We intend to discuss our development plans for LN with the FDA in 2021 and expect to initiate a Phase 2b or Phase 3 clinical trial in 2022.

As of March 1, 2021, our licensed patent portfolio related to atacicept contains approximately 15 issued U.S. patents, as well as certain foreign counterparts of a subset of these patents in several foreign countries, including countries within the European Patent Convention and the Eurasian Patent Organization. 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.

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 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 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; and Senior Vice President of Clinical Operations and Data Management, Tom Doan, who was formerly Executive Director of Clinical Operations and Therapeutic Area Head of Inflammation and Respiratory at Gilead. Our team is well positioned to leverage our collective experience and expertise in drug development and commercialization to optimize atacicept development and provide a disease modifying option to patients.

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.

## 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 principle

- **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, present 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 to improve patients' lives.

These principles have guided us to the successful in-licensing of atacicept from Ares 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 key elements of our strategy to achieve our goal include:

- **Complete global development of atacicept in IgAN.** We plan to initiate patient screening for our Phase 2b clinical trial in IgAN in the second quarter of 2021. We expect to report topline results from ORIGIN in the fourth quarter of 2022. If these data are positive, we intend to initiate a pivotal Phase 3 clinical trial in 2023 with the aim of accelerated approval in the United States by the FDA and approval in the European Union by the EMA.
- **Advance atacicept in lupus nephritis (LN).** 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. We intend to discuss our development plans for LN with the FDA in 2021 and expect to initiate a Phase 2b or Phase 3 clinical trial in 2022.
- **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.
- **Build and scale organizational capabilities to support commercialization of atacicept.** Under the leadership of our experienced management team, we plan to build a specialized commercial organization to launch atacicept in the United States and other key markets, if approved. Within certain ex-U.S. markets, we may consider strategic collaborations for commercialization.
- **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

## Atacicept in IgAN

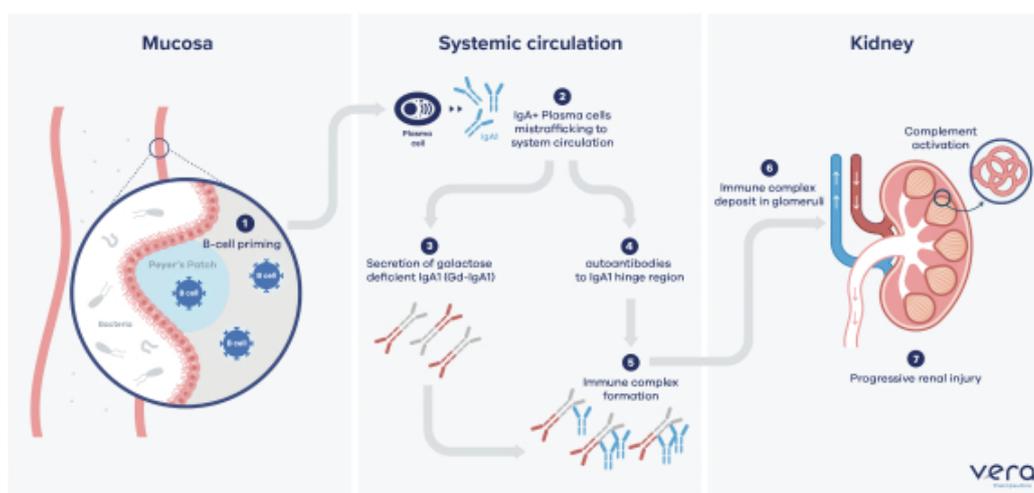
We are developing atacicept as a potential treatment for patients with IgAN, a disease with a high unmet medical need and currently no approved therapies. IgAN is a serious and progressive autoimmune disease of the kidney, that is driven by the production of pathogenic Gd-IgA1. IgAN patients with elevated Gd-IgA1 are at increased risk of kidney-related morbidity and mortality. As reported in the Phase 2a JANUS trial, atacicept is the first and only molecule in development to demonstrate a 60% reduction in plasma Gd-IgA1, suggesting atacicept targets the source of disease in these patients. Based on these encouraging results, we are initiating the randomized, 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 intend to initiate a pivotal Phase 3 clinical trial in 2023. We believe that atacicept has the potential to be the best-in-class and 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 represent a significant health economic burden estimated to be over \$40.0 billion annually in the United States. Despite this high level of morbidity, there is currently no approved treatment indicated for IgAN.

### Pathophysiology of IgAN

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

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

**Figure 1: IgAN Pathophysiology—Overview**



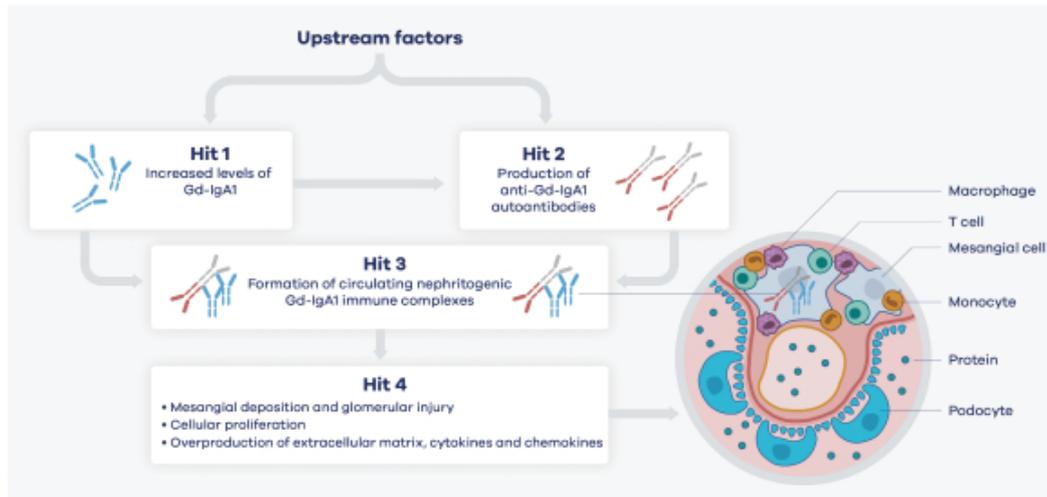
- 1 B cells, which mature into plasma cells, are abnormally primed in the Peyer's patch region of the ileum of the intestines, potentially due to a combination of genetic predisposition and environmental, bacterial or dietary factors. BLyS promotes B cell maturation and survival, increasing the number of disease causing B cells.
- 2 APRIL, a factor important for plasma cell survival, becomes upregulated, resulting in increased numbers of disease-causing plasma cells.
- 3 APRIL increases the number of plasma cells and increases antibody class switching, 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 2 below.)
- 4 The Gd-IgA1 antibodies are immunogenic when found in the systemic circulation, which triggers autoantibodies, or antibodies created by the body in response to a constituent of its own tissue. (See "Hit 2" in Figure 2 below.)
- 5 Autoantibodies against Gd-IgA lead to the formation of pathogenic immune complexes, or clusters of antibodies. (See "Hit 3" in Figure 2 below.)

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- 6 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 2 below.)
- 7 As the glomeruli are destroyed, the kidney's ability to remove waste products from the blood is reduced, which can result in potentially life-threatening complications that lead to the need for dialysis or kidney transplant in many patients.

Similarly, IgAN has also been described as having a multi-hit pathogenesis, as shown in Figure 2 below, and referenced in the steps 3-6 above.

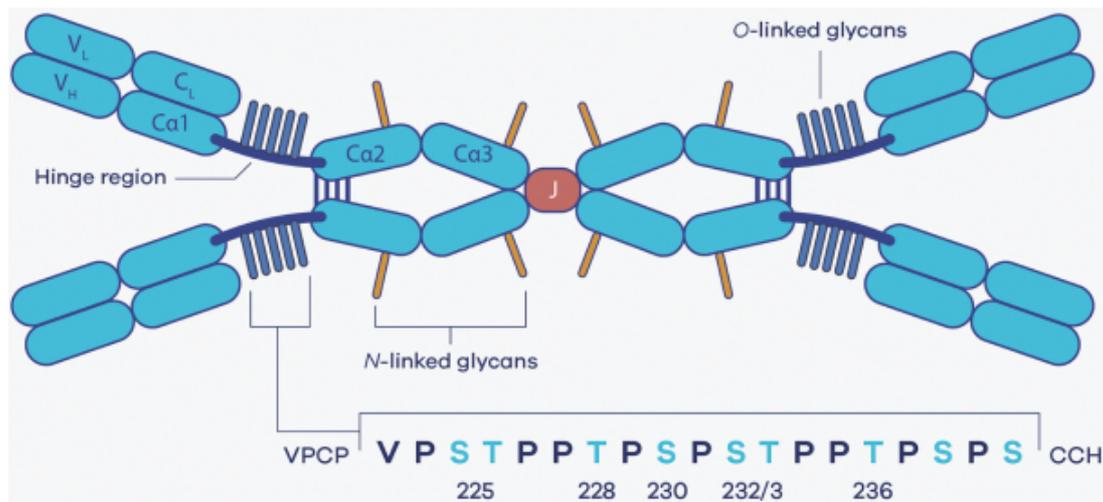
**Figure 2: IgAN Pathophysiology—Downstream Effects of Elevated Gd-IgA1**



### ***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 3 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 immunoglobulin G (IgG) antibodies with specificity for the hinge region.

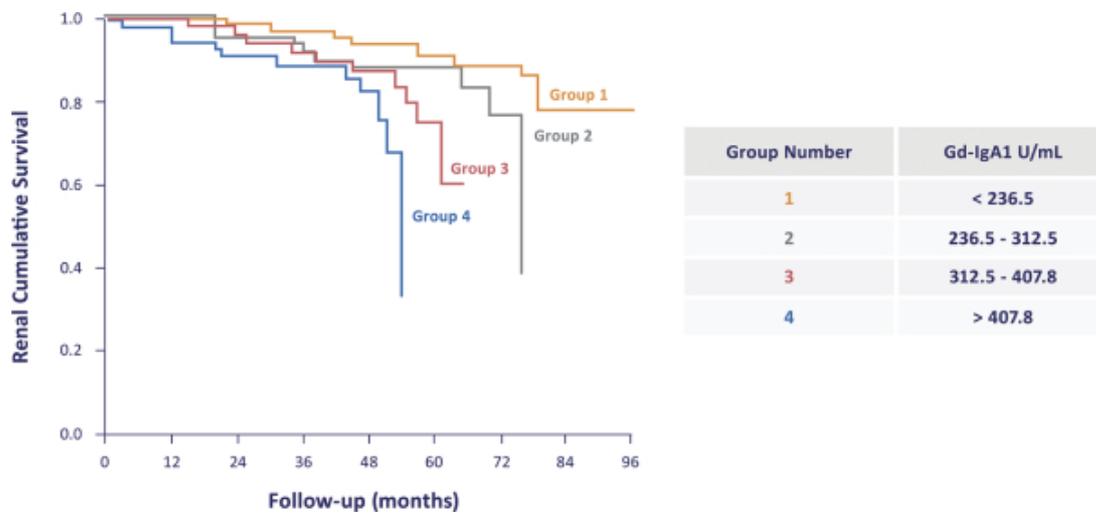
**Figure 3: Components of Gd-IgA1**



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 4 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.

**Figure 4: Renal Survival in IgAN Patients with Four Quartile Serum Gd-IgA1 Levels**



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In addition, high serum APRIL levels correlate with increased expression of serum Gd—IgA1 in IgAN patients and high serum BLYS 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***

There are currently no approved therapies indicated for IgAN. However, the two following 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**

Though there are no currently approved therapies indicated for IgAN, 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 and only agent currently in development that has demonstrated a 60% reduction of Gd-IgA1, the upstream source of IgAN pathogenesis.

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

**Glucocorticoid Receptor Agonists.** Glucocorticoid receptor agonists are a well-known class of molecules that have broad anti-inflammatory effects, and well established acute and chronic side effects. Though reduction in the risk of eGFR decline was shown in clinical trials, there is no consensus on whether 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 immune-complex deposition in glomeruli may contribute to complement activation, though the exact mechanism is not well understood. Several agents that inhibit complement activation are in clinical development for IgAN. Modest reduction of proteinuria has been observed in early clinical trials. As complement inhibition works downstream of immune complex formation, these agents are not expected to impact the upstream cause of disease and reduce Gd-IgA1 or the resulting immune complexes that cause inflammation and complement activation in the kidney.

**B-cell Modulators.** B-cell modulators, including atacicept, are an important category of emerging therapies for IgAN. The disease causing Gd-IgA1 is predominantly produced by B cells and plasma cells. Therefore, control of B-cell activation may reduce production of Gd-IgA1 and the downstream formation of autoantibodies and immune 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. 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.

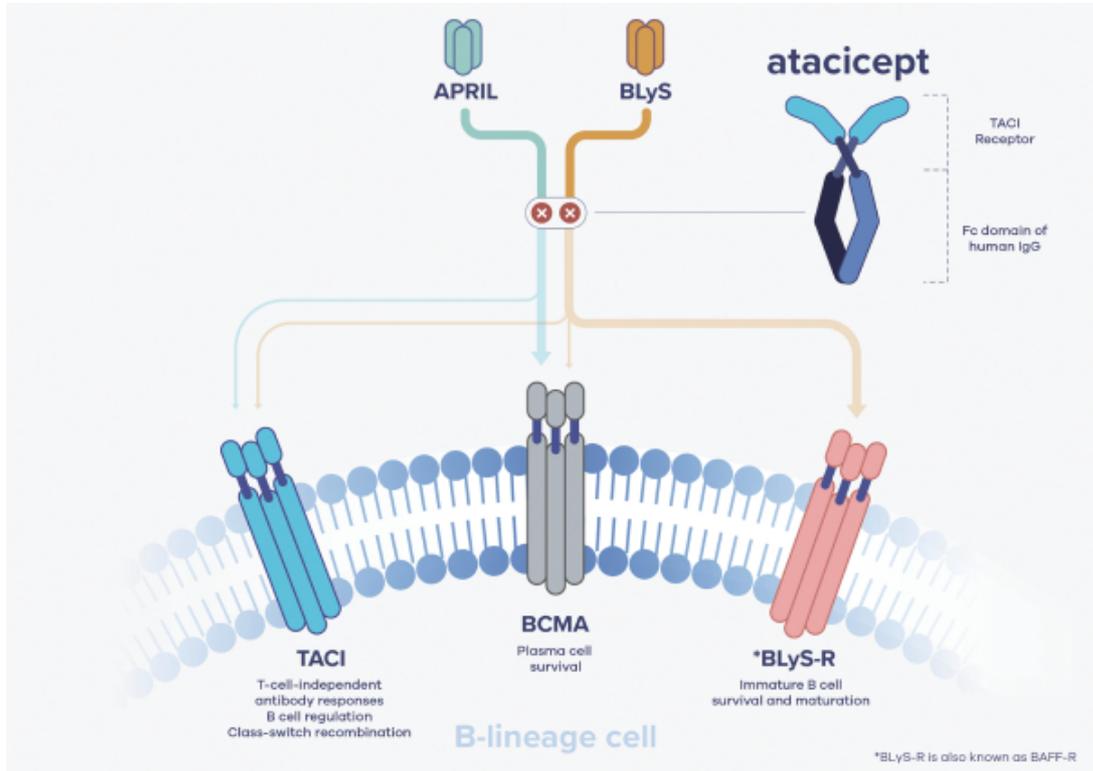
#### **Our Solution: Atacicept**

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 subcutaneous injection. As a result, we believe atacicept has the potential to be the first disease modifying therapy for IgAN. Atacicept has a large and established safety data set in which it has demonstrated an acceptable tolerability profile in clinical trials of over 1,500 patients to date. In a Phase 2a clinical trial in patients with IgAN, atacicept substantially reduced Gd-IgA1 and demonstrated a clinically meaningful reduction in proteinuria and eGFR parameters at week 24. We plan to initiate patient screening for our Phase 2b clinical trial in IgAN in the second quarter of 2021, and we expect to report topline results in the fourth quarter of 2022.

**Our Approach to IgAN: Reducing Gd-IgA1, the Source of Autoantibodies**

Atacept 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 5 below, atacept 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 by TACI has been shown to be more potent than blocking BLYS 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, atacept's mechanism acts directly on the source of IgAN, which we believe will significantly mitigate the downstream effects of the disease.

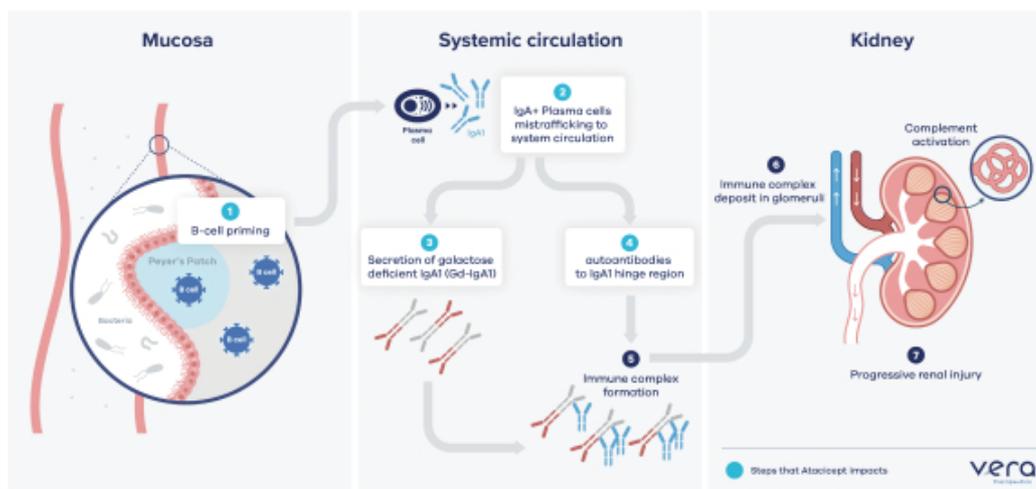
**Figure 5: Atacept Blocks Both BLYS and APRIL**



**Atacept: Potential to Address the Core Processes Underlying IgAN Pathogenesis**

Atacept's specific actions on IgAN disease pathogenesis are shown in Figure 6 below.

**Figure 6: Atacept Impact on IgAN Pathogenesis**



- 1 Atacept blocks BLYS, a factor important for B cell survival and maturation, resulting in reduced numbers of disease-causing B cells.
- 2 Atacept 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.
- 4 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.
- 7 Ultimately, progressive renal injury is reduced, which we believe will significantly lower the morbidity and mortality associated with IgAN.

Atacept's disease modifying mechanism addresses the upstream processes that cause IgAN, while most other molecules in development act downstream. Therefore, we believe that the efficacy and durability of atacept will be favorable to competitors, with a demonstrated safety and tolerability profile. Once weekly subcutaneous dosing also provides an attractive target product profile for patients.

**Atacept in IgAN: Clinical Development**

Atacept 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 Ares 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 clinical trial conducted by Merck KGaA, Darmstadt, Germany in patients with IgAN, atacept (25 mg and 75 mg doses) reduced Gd-IgA1 by 60% in IgAN patients. Atacept has been the first and only molecule observed to reduce Gd-IgA1, the presumed upstream source of the disease, by this magnitude. The 150 mg dose was not studied in the JANUS study. A clinically meaningful reduction in proteinuria and eGFR

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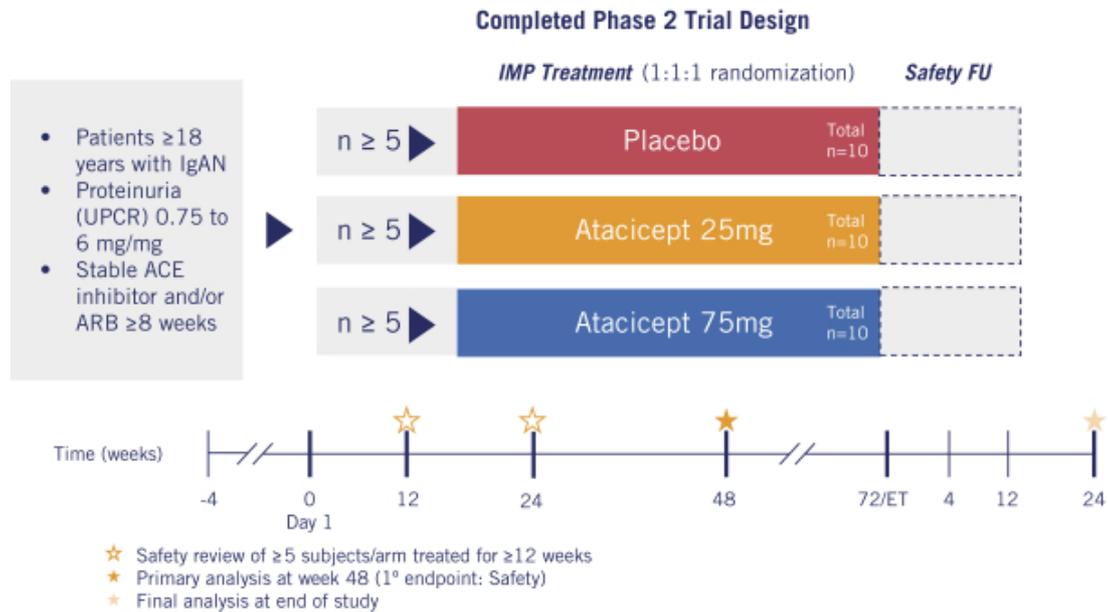
parameters was observed at week 24 for both the 25 mg and 75 mg doses. The clinically significant and robust reduction in Gd-IgA1 provides important corroborative evidence of the potential benefit of atacicept for patients with IgAN. Based on this encouraging data, we are initiating a Phase 2b ORIGIN clinical 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 through 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 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 7 below and the baseline patient characteristics shown in Figure 8 below. Results showed a dose dependent effect of atacicept on proteinuria as well as key biomarkers including serum immunoglobulin levels, and Gd-IgA1 alongside a favorable safety profile. The JANUS trial was terminated earlier than planned due to Ares' decision to deprioritize the program. Trial termination was not related to safety or efficacy.

Figure 7: Phase 2a JANUS Trial Design



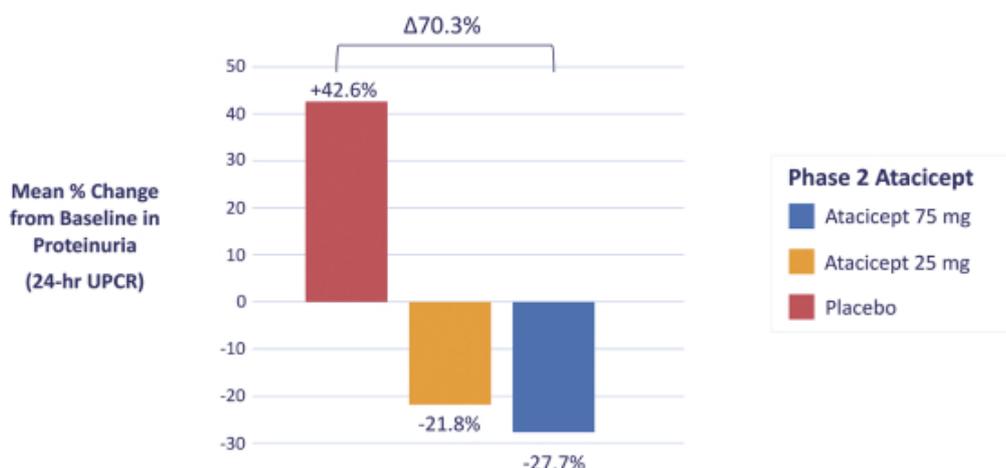
**Figure 8: Phase 2a JANUS Trial Baseline Characteristics**

|                     | Placebo<br>(n=5) | Atacicept 25 mg<br>(n=6) | Atacicept 75 mg<br>(n=5) | Total<br>(n=16) |
|---------------------|------------------|--------------------------|--------------------------|-----------------|
| <b>Age, mean±SD</b> |                  |                          |                          |                 |
| 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          |
| <b>Sex, n (%)</b>   |                  |                          |                          |                 |
| 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)        |
| <b>Race, n (%)</b>  |                  |                          |                          |                 |
| 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 9 below.

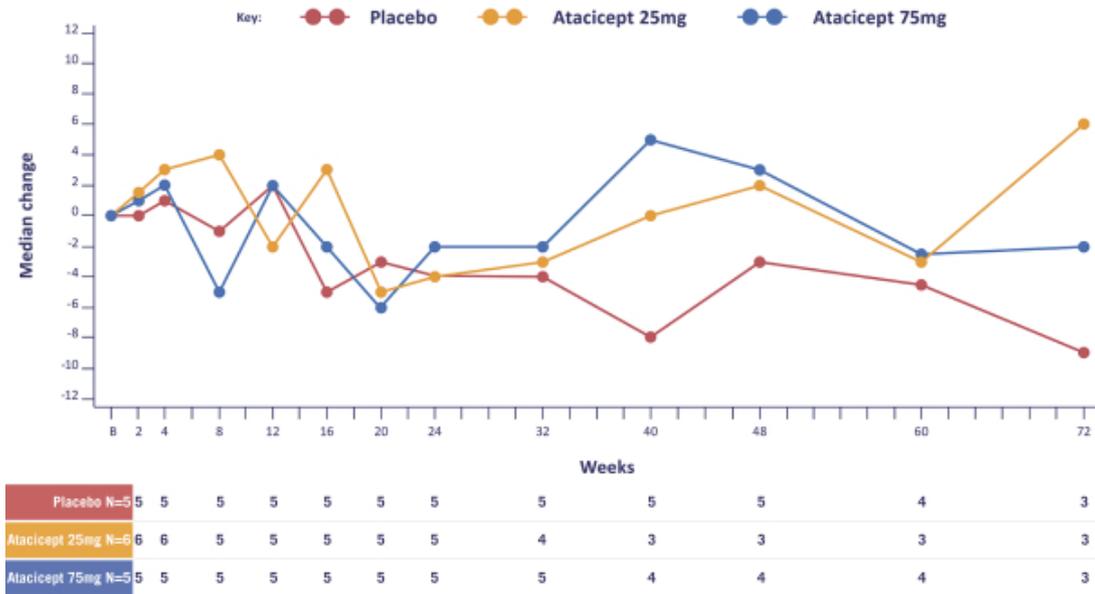
**Figure 9: Proteinuria at Week 24 in the Phase 2a JANUS Trial**



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.

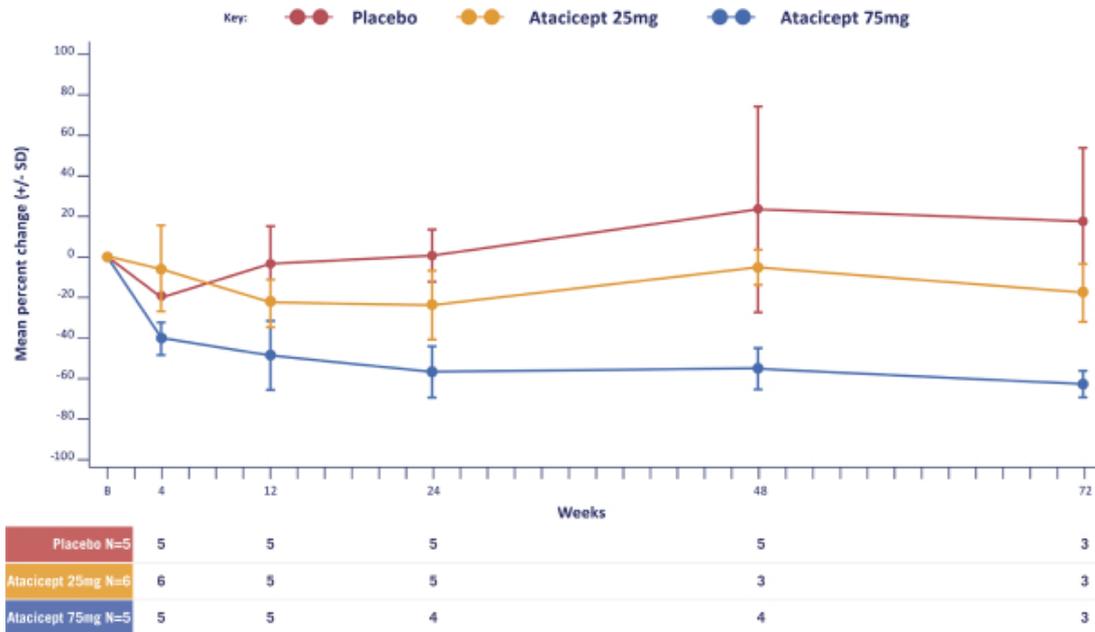
As seen in Figure 10 below, atacept also showed stable eGFR for greater than one year versus expected 25% decline, as was shown in the placebo arm.

**Figure 10: eGFR Over Time in the Phase 2a JANUS Trial**



Atacept 75 mg also showed a 60% of Gd-IgA1 reduction at 24 weeks, the largest magnitude in reduction in of any molecule in development for IgAN. Clear dose-dependent reductions of serum Gd-IgA1 were observed over the 72-week period studied (as shown in Figure 11 below), with atacept 75 mg reducing Gd-IgA significantly (60%) and durably.

**Figure 11: Serum Gd-IgA1 Levels Over Time in the Phase 2a JANUS Trial**



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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 demonstrated an acceptable tolerability profile in the Phase 2a JANUS trial, with treatment-emergent adverse events (TEAEs) shown in Figure 12 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 TEAE. Most TEAEs were graded as mild and were related to injection site events such as injection site bruising and erythema.

**Figure 12: Overview of Treatment-emergent Adverse Events by Severity in the Phase 2a JANUS Trial**

| Number of Subjects with:                   | Placebo<br>n=5 (100%) n (%) | Atacicept 25 mg<br>n=6 (100%) n (%) | Atacicept 75 mg<br>n=5 (100%) n (%) | Total<br>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 demonstrated to have an acceptable tolerability profile, characterized in Figure 13 below. We believe that this large and established data set is a competitive advantage for us versus other emerging therapies in development, many of which lack extensive safety data.

**Figure 13. Integrated Safety Analysis: Summary of Treatment-Emergent Adverse Events > 5% in Any Arm, by Dose**

| System organ class<br>Preferred term, n (%)          | Placebo<br>n=483 | Atacicept      |                |                 |                     | All subjects<br>n=1568 |
|--|------------------|----------------|----------------|-----------------|---------------------|------------------------|
|  |                  | 25 mg<br>n=129 | 75 mg<br>n=384 | 150 mg<br>n=572 | All doses<br>n=1085 |                        |
| 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)             |

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, IgAN, 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.

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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.

### **Planned Phase 2b ORIGIN Clinical Trial Design**

ORIGIN, our planned Phase 2b randomized, double-blinded, placebo-controlled, dose-ranging trial, will aim to 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 12-week safety follow-up period. The trial will assess multiple doses (25 mg, 75 mg, and 150 mg) of once weekly subcutaneous injections of atacicept by prefilled syringe 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.

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 at or after week 110. 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. 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 initiating the Phase 2b ORIGIN trial and expect to enroll a total of 105 patients at multiple global sites, commencing in the second quarter of 2021. We expect to report topline results from ORIGIN in the fourth quarter of 2022. If these data are positive, we intend to initiate a pivotal Phase 3 clinical trial in 2023.

### **Atacicept in LN: A Severe Renal Manifestation of SLE**

We are evaluating further development of atacicept 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 now 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. Positive clinical data on multiple measures, including reduction of renal flares, from a prior Phase 2 clinical trial of atacicept in SLE within the HDA patient segment further adds to our belief in atacicept's applicability in LN. Because both preclinical and clinical evidence suggests atacicept's dual inhibition of BLYS and APRIL may provide better clinical efficacy than inhibiting either signal alone, we believe there is a strong rationale to conduct a clinical trial of atacicept in LN. We intend to discuss our development plans for LN with the FDA in 2021 and expect to initiate a Phase 2b or Phase 3 clinical trial in 2022.

#### **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 strand 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.

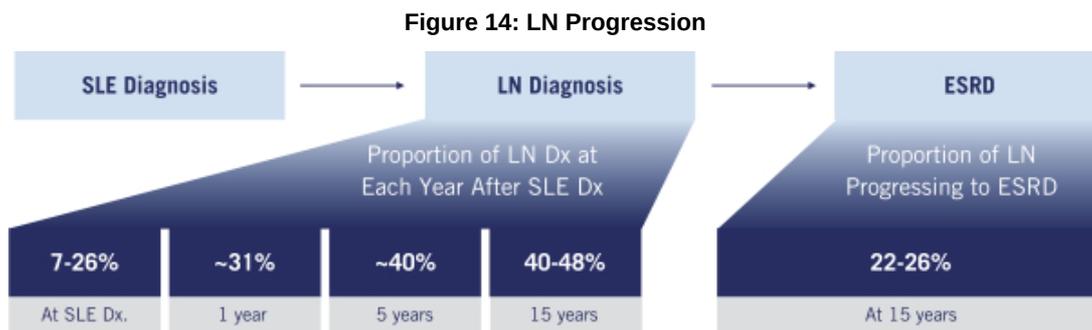
**LN Disease Burden and Diagnosis**

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



**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 14 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 mycophenolate mofetil (MMF) ± corticosteroids or cyclophosphamide (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: Ataccept / Scientific Rationale in LN**

**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 TAC1, BCMA and BLyS. Therefore, B cell blocking agents such as rituxan (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.

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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 higher efficacy than 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 robust efficacy in SLE patients with HDA (SLEDAI-2K <sup>3</sup>10) 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%) and ustekinumab (2%). 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 corticosteroids (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 safety and efficacy 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.

**Safety and Efficacy Profile of Atacicept In SLE**

Atacicept 75 mg and 150 mg, dosed once per week with subcutaneous auto-injection, have demonstrated clinical 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 (defined as Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) <sup>3</sup> 10 at screening) had an increase in SLE Responder Index (SRI)-6 response, attainment of low disease activity (LDA), or SLEDAI-2K  $\leq$  2, and a reduction of the risk of a first new severe flare (defined by SLEDAI Flare Index (SFI) or by BILAG A) when treated with atacicept 150 mg. Furthermore, the 024 long-term extension (LTE) trial showed durability of these effects through a median duration of treatment of 96 weeks.

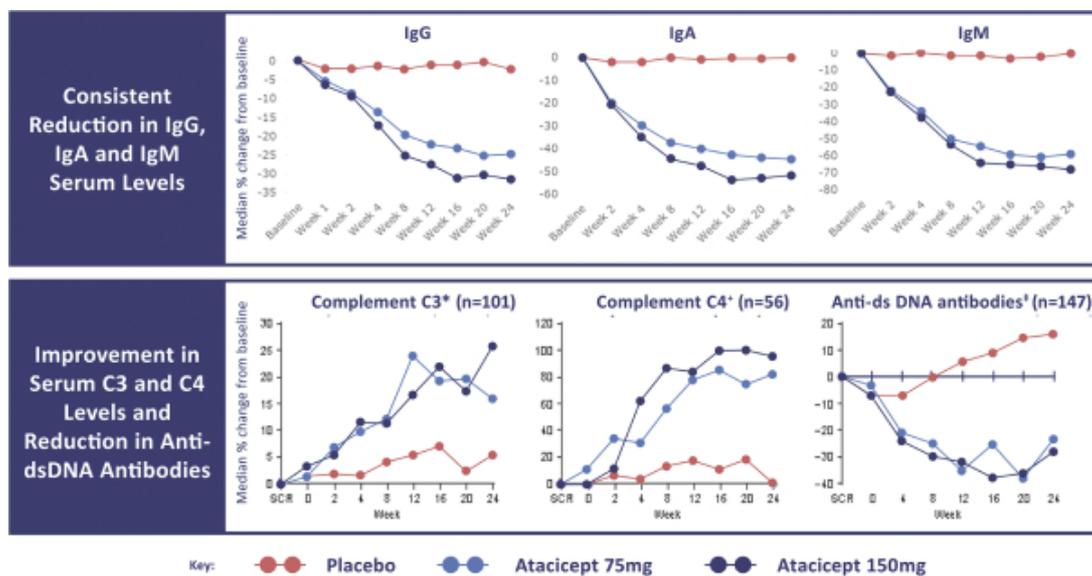
Following the release of the HDA data, Merck KGaA, Darmstadt, Germany pursued the planning and initiation of a global Phase 3 registrational program for atacicept 150 mg once per week in SLE. This program, including two large Phase 3 randomized placebo-controlled trials of atacicept 150 mg compared to placebo, were reviewed and endorsed 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 52 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 a LTE arm continuing an additional 96 weeks.

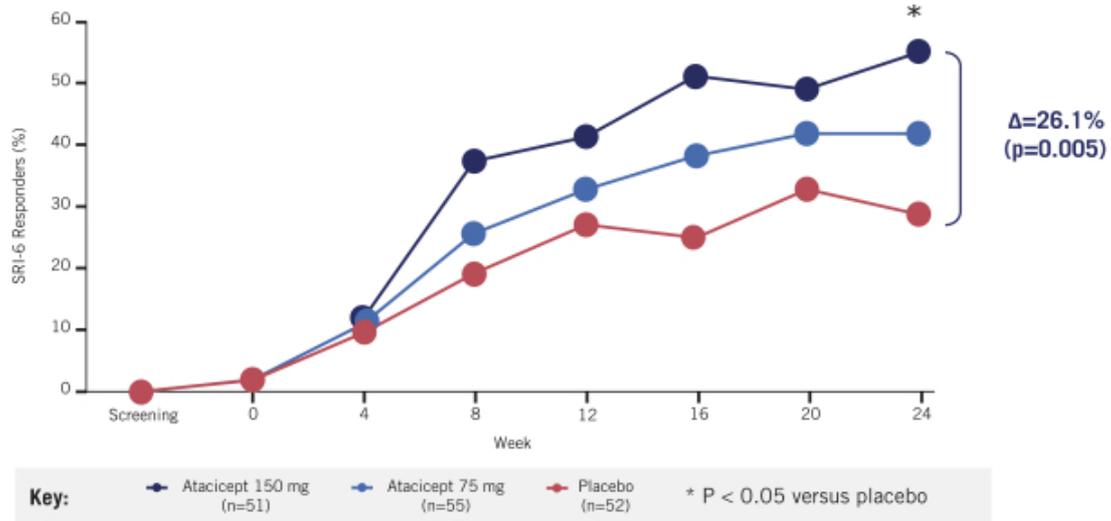
Atacicept demonstrated consistent reductions in IgG, IgA, and IgM serum levels, and reductions in anti-dsDNA antibodies, as well as improvements in serum C3 and C4 levels, as shown in Figure 15 below.

**Figure 15: Atacicept Impact on Key Biomarkers in the Phase 2 ADDRESS II Trial**



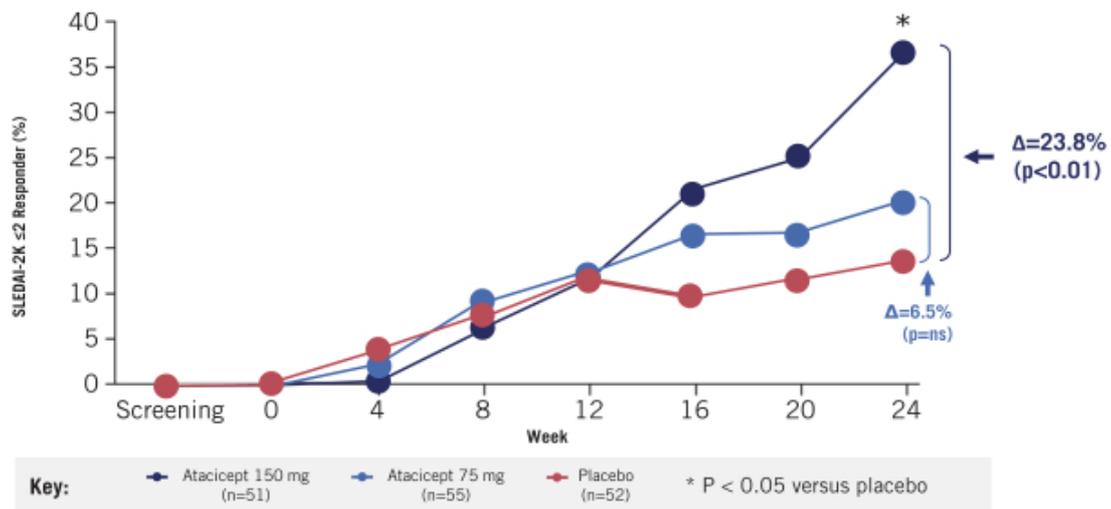
Though atacicept missed its primary endpoint of SRI-6 reduction versus placebo in all comers, in a pre-specified analysis within HDA patients, which comprised approximately half of those enrolled, atacicept 150 mg showed clinical efficacy across multiple measures, including a 26% improvement (p=0.005) by SRI-6 versus placebo, flare risk reduction, and serologic marker normalization. SRI-6 response is defined as  $\geq$ 6-point reduction in the SLENA-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 16: SRI-6 Response Among HDA Patients in the Phase 2 ADDRESS II Trial**



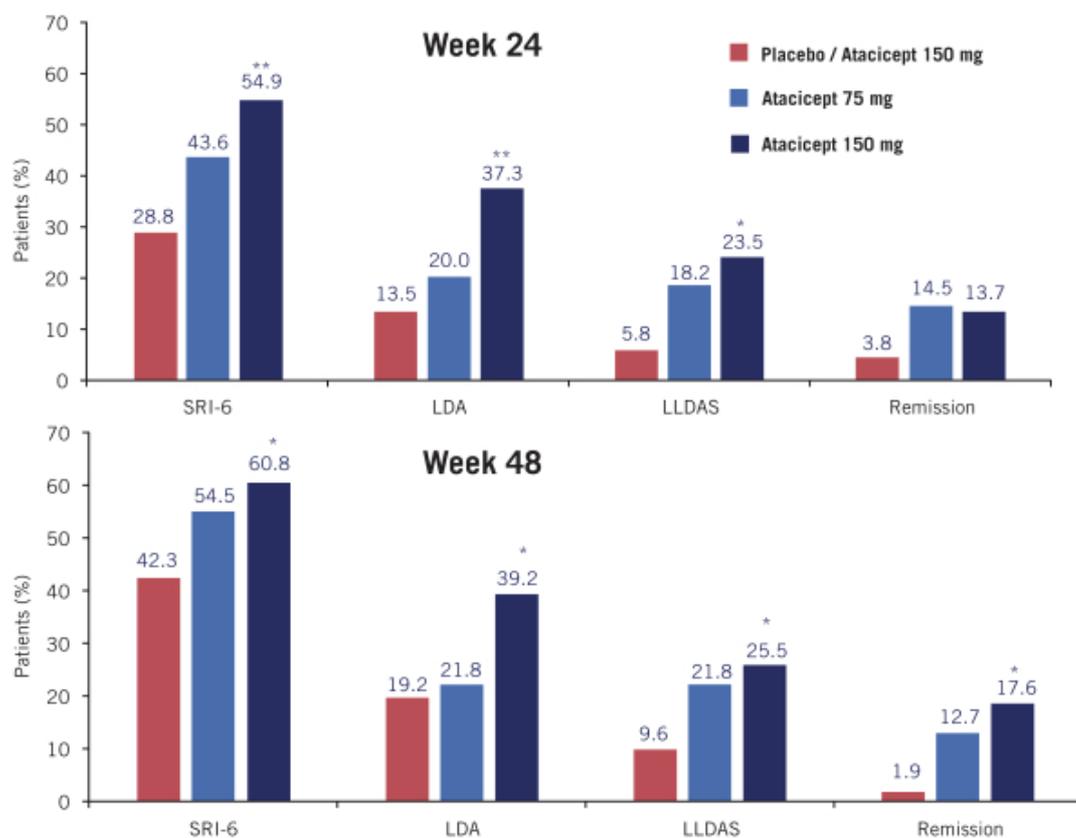
Also among this HDA patient segment, significantly more patients on the atacicept 150 mg arm reached LDA, as measured by SLEDAI-2K  $\leq$  2, as shown in Figure 17 below.

**Figure 17: HDA Patients Reaching LDA in the Phase 2 ADDRESS II Trial**



Furthermore, Figure 18 below demonstrates the durable clinical efficacy observed in the HDA segment: more patients reached LDA by multiple measures at both week 24 and week 48. Significantly more patients treated with atacicept 150 mg once weekly versus placebo demonstrated clinical improvement (as shown by SRI-6), achieved LDA, and remission.

**Figure 18: Durable Efficacy Observed in HDA Patients in the Phase 2 ADDRESS II Trial**



HDA, High disease activity; LDA, Low disease activity; LLDAS, Lupus Low Disease Activity State; SRI, SLE responder index; \*p<0.05 vs placebo; \*\*p<0.01 vs placebo

We believe that the clinical efficacy demonstrated on multiple measures within the HDA segment of the SLE population in the ADDRESS II trial – and the favorable safety 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.

**Exclusive License Agreement with Ares Trading S.A.**

On October 29, 2020, we entered into an Exclusive License Agreement with Ares, an affiliate of Merck KGaA, Darmstadt, Germany (Ares Agreement), 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.

### **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 October 29, 2020, we have licensed, including sublicenses, from Ares, an affiliate of Merck KGaA, Darmstadt, Germany, a patent portfolio related to atacept that contains approximately fifteen 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 atacept expiring in 2022.

In regards to atacept, we in-license a patent family that includes one issued U.S. patent with claims covering a method of purifying atacept 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 atacept 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.

Because atacept 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 atacept 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.

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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 commercial manufacturing organizations (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 Current Good Manufacturing Procedures (cGMP) 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 drug product presentation in a prefilled autoinjector has been developed and will be implemented for future clinical trials.

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.

### **Commercialization Plans**

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.

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

### **Competition**

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

There are currently no approved therapies for IgAN and current standard-of-care 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. 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 programs in Phase 3 clinical development: Calliditas Therapeutics AB, Novartis Pharmaceuticals Corporation (Novartis), Omeros Corporation, Travers Therapeutics, Inc., and Chinook Therapeutics Inc., and the following companies with programs in Phase 2 of clinical development: Chinook Therapeutics Inc., Anlylam 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 & Co. 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, CYC, rituxumab, 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 the following companies with programs in Phase 3 clinical development: Roche Holding AG and Novartis, and the following companies with programs in Phase 2 clinical development: BeiGene Ltd., Janssen Pharmaceuticals, Inc., AstraZeneca, Alexion, Omeros Corporation, Kezar Life Science Inc., Bristol Myers Squibb, Boehringer, and Novartis.

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 candidate 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

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compete effectively against these companies, then we may not be able to commercialize our product candidate 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.

### **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 institutional review board (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, good clinical practices (GCP) requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- preparation of and submission to the FDA of a BLA for marketing approval that includes sufficient evidence of establishing the safety, purity, and potency of the proposed biological product for its intended indication, including from results of nonclinical testing and clinical trials;
- payment of any user fees for FDA review of the BLA;
- a determination by the FDA within 60 days of its receipt of a BLA to 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 good manufacturing processes (cGMP) requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;

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- 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 Risk Evaluation and Mitigation Strategy (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.

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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](http://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

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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.

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

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

### ***Orphan Drug Designation***

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

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

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

### ***Expedited Development and Review Programs***

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

Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor of a new biologic candidate can request the FDA to designate

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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. The accelerated approval pathway is contingent on a sponsor's agreement to 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

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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. Ataccept in a prefilled autoinjector would be such a combination of therapeutic and delivery device.

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

### **Pediatric Information**

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

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

### **Post-Approval Requirements**

Once a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for

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

Adverse event reporting and submission of periodic safety summary reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects a biologic product's manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with required regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

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

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning or other enforcement-related letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

### ***U.S. Marketing Exclusivity***

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

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. "First licensure" typically

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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.

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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 General Data Protection Regulation (GDPR) (and in the United Kingdom (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 would market, sell and distribute our products. The healthcare laws that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, Affordable Care Act), to a stricter standard such that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.
- Federal civil and criminal false claims laws, such as the False Claims Act, which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the False

Claims Act in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims.

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA), among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.
- HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009 (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) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives.
- 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.

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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, the U.S. Supreme Court is currently reviewing the constitutionality of the Affordable Care Act, but it is unknown when a decision will be reached. Although the Supreme Court has not yet ruled on the constitutionality of the Affordable Care Act, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs 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 unclear how the Supreme Court ruling, other such litigation, 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 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic, absent additional congressional action. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. 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 released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health & Human Services (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 pending review by the Biden administration until March 22, 2021. On November 20, 2020, the Centers for Medicare & Medicaid Services (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. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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

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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**

We have a total of eight full time employees and 21 consultants on a part-time basis. Vera has in the past, and may in the future, retain additional expert consultants if required in connection with the Company's 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 leased 24,606 square feet of office and lab space at 170 Harbor Way in South San Francisco, CA. This space is currently subleased to Vaxart, Inc. through September 30, 2025.

### ***COVID-19 Impact on Facilities***

We are operating virtually to align with local COVID-19 guidelines, which we believe meets our operational needs for the time being as a clinical-stage organization. We plan to reassess our facilities needs on a quarterly basis and anticipate a future lease or flexible arrangement for office-only space.

## **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, Directors and Key Employees

The following table sets forth information regarding our executive officers and directors, including ages as of March 15, 2021.

| NAME                           | AGE | POSITION   |
|--------------------------------|-----|--|
| <i>Executive Officers:</i>     |     |  |
| Marshall Fordyce, M.D.         | 47  | President, Chief Executive Officer and Director              |
| Celia Lin, M.D.                | 46  | Chief Medical Officer  |
| Joanne Curley, Ph.D.           | 52  | Chief Development Officer                                    |
| Jonathan Wolter                | 70  | Chief Financial Officer                                      |
| <i>Other Key Employees</i>     |     |  |
| Lauren Frenz                   | 36  | Chief Business Officer                                       |
| Tom Doan                       | 49  | Senior Vice President, Clinical Operations & Data Management |
| Joseph Young                   | 49  | Senior Vice President, Finance                               |
| <i>Non-Employee Directors:</i> |     |  |
| Kurt von Emster, C.F.A. (3)    | 53  | Chairperson of the Board of Directors                        |
| Andrew Cheng, M.D., Ph.D. (1)  | 53  | Director   |
| Beth Seidenberg, M.D. (3)      | 63  | Director   |
| Maha Katabi, Ph.D., C.F.A. (1) | 47  | Director   |
| Patrick Enright (1)            | 59  | Director   |
| Scott Morrison (3)             | 63  | 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 Chief Executive Officer and President 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. We believe 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

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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 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.

**Jonathan Wolter** has served as our Chief Financial Officer since March 2020 through his capacity as a partner at FLG Partners, LLC, a Silicon Valley chief financial officer services firm. Mr. Wolter joined FLG Partners, where he is a partner, in July 2004. Through FLG Partners, Mr. Wolter has served public and private company clients as both permanent and interim chief financial officer. In connection with his role at FLG Partners, Mr. Wolter has been engaged by SmartRent.com, Inc., a smart home automation company, as Chief Financial Officer since August 2020. From June 2019 to March 2020, Mr. Wolter served as interim Chief Financial Officer at Amyris, Inc., a biotechnology company. From September 2017 to October 2019, Mr. Wolter served as Chief Financial Officer of Soleno Therapeutics, Inc., a biopharmaceutical company. From January 2016 to April 2019, Mr. Wolter served as Chief Financial Officer of Verana Health, Inc., a private technology company that partners with medical associations to assemble clinical databases in medicine. Mr. Wolter received a B.S. in business administration from the University of California, Berkeley and is a certified public accountant (inactive).

### **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, Clinical Operations & Data Management 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. From April 2006 to July 2020, Mr. Young held a number of senior leadership roles at Plexxikon Inc., a biotechnology company, and wholly-owned 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).

### **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, Trishula Therapeutics, Inc., an immunotherapy company, since December 2020, Orbus Therapeutics, Inc., a pharmaceutical company, since July 2020, SFJ Pharmaceuticals, Inc., a specialty

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pharmaceutical company, since April 2020, Jasper Therapeutics, Inc., a biotechnology company, since November 2019, Vaxcyte Inc. (Vaxcyte), a biopharmaceutical 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: 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.). We believe 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. We believe 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 Tesaro, Inc., and from December 2012 to June 2018 she served on the board of directors of ARMO 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. We believe 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., C.F.A.** has served on 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. 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., Amplex Pharmaceuticals, Inc., and NorthSea Therapeutics B.V. 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 Inc, 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. Dr. Katabi received a B.Sc. in biology and a Ph.D. in pharmacology from McGill University and is a Chartered Financial Analyst. We believe that Dr. Katabi is qualified to serve on our board of directors because of her extensive experience as an advisor and investor in the life sciences industry.

**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 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 also has significant life sciences operations experience including senior executive positions at Valentis, Inc., Boehringer Mannheim GmbH (acquired by Roche) and Sandoz (now known as Novartis Pharmaceuticals Corporation). 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), Codexis, Inc. (CDXS), Corcept Therapeutics Inc. (CORT), Esperion Therapeutics, Inc. (ESPR), Horizon Pharma plc (HZNP, renamed Horizon Therapeutics plc), MAP Pharmaceuticals, Inc. (MAPP, acquired by Allergan plc), Sequenom, Inc. (SQNM, acquired by LabCorp), Threshold Pharmaceuticals Inc. (THLD), 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. We believe 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, and Escape Bio, Inc., a biotechnology company, since October 2020. 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.

### **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 seven 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.

Certain members of our board of directors were elected under the provisions of our Amended and Restated Voting Agreement entered into in October 2020 (Voting Agreement), which will terminate upon the closing of this offering. Under the terms of our Voting Agreement, the stockholders who are party to the Voting Agreement have agreed to vote their respective shares to elect: (i) one director designated by Abingworth Bioventures 8 LP, currently Kurt von Emster; (ii) one director designated by Sofinnova Venture Partners X, L.P., currently Maha Katabi, Ph.D.; (iii) one director designated by Longitude Venture Partners IV, L.P., currently Patrick Enright; (iv) one director designated by the holders of our common stock, who shall be our then-current Chief Executive Officer, currently Marshall Fordyce, M.D.; and (v) three directors designated by a majority of the other members of the board of directors, currently Andrew Cheng, M.D., Ph.D., Beth Seidenberg, M.D. and Scott Morrison. The Voting Agreement will terminate upon the closing of this offering, and upon the closing of the offering no stockholder will have any special rights regarding the election or designation of the members of our board of directors. Our current directors elected to our board of directors pursuant to the Voting Agreement will continue to serve as directors until their successors are duly elected and qualified by holders of our common stock.

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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 to be filed in connection with this offering, immediately after this offering, our board of directors will be 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 will be divided among the three classes as follows:

- the Class I directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their terms will expire at the annual meeting of stockholders to be held in 2022;
- the Class II directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their terms will expire at the annual meeting of stockholders to be held in 2023; and
- the Class III directors will be \_\_\_\_\_ and \_\_\_\_\_, 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), independent directors must comprise a majority of our board of directors as a listed company within one year of the listing date.

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 \_\_\_\_\_ 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 intends to adopt a written charter that satisfies the application rules and regulation of the SEC and the Nasdaq Listing Rules, which we will post to our website at [www.veratx.com](http://www.veratx.com) upon the closing of this offering. 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, 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 Securities Exchange Act of 1934, as amended (Exchange Act). 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.

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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;
- 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, and Dr. Cheng. 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;
- reviewing and recommending to our board of directors the compensation paid to our directors;
- 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, change-of-control protections 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, including our overall compensation philosophy.

### **Nominating and Corporate Governance Committee**

Our nominating and corporate governance committee consists of \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_. The chair of our nominating and corporate governance committee is \_\_\_\_\_. 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;

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- 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

In connection with this offer, we intend to adopt 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 will be posted on our website at [www.veratx.com](http://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 financial 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 the 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, 2020 to each of our non-employee directors who served on our board of directors during 2020:

| NAME                       | FEES EARNED OR<br>PAID IN CASH<br>(\$) | OPTION AWARDS<br>(\$) <sup>(1)(2)</sup> | TOTAL<br>(\$) |
|----------------------------|--|---|---------------|
| Beth Seidenberg, M.D.      | —                                      | 172,880                                 | 172,880       |
| Andrew Cheng, M.D., Ph.D.  | —                                      | 137,978                                 | 137,978       |
| Scott Morrison             | —                                      | 157,530                                 | 157,530       |
| Brian Kotzin, M.D. (3)     | —                                      | 92,103                                  | 92,103        |
| Kurt von Emster            | —                                      | —                                       | —             |
| Maha Katabi, Ph.D.         | —                                      | —                                       | —             |
| Patrick Enright            | —                                      | —                                       | —             |
| Joseph Walton (4)          | —                                      | —                                       | —             |
| Krishna Yeshwant, M.D. (5) | —                                      | —                                       | —             |

(1) The amounts disclosed represent the aggregate grant date fair value of the stock options granted to our named executive officers during fiscal year 2020 under our 2017 Equity Incentive Plan, as amended (2017 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 7 to our audited financial statements 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 common stock held by our non-employee directors was: Dr. Seidenberg, 800,000; Dr. Cheng, 800,000, Mr. Morrison, 800,000; and Dr. Kotzin, 445,000.

(3) During fiscal year 2020, Dr. Kotzin received consulting fees equal to \$95,100, unrelated to his service as a member of our board of directors. Dr. Kotzin resigned from our board of directors in October 2020.

(4) Mr. Walton resigned from our board of directors in October 2020.

(5) Dr. Yeshwant resigned from our board of directors in October 2020.

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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 Chief Executive Officer, was also a director as of December 31, 2020, 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, 2020, 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, Joseph Walton, Krishna Yeshwant, M.D. and Brian Kotzin, M.D. Other than as set forth above, none of our non-employee directors earned any compensation in the year ended December 31, 2020 or held any equity awards as of December 31, 2020.

In January 2020, we granted a stock option to Dr. Cheng covering 50,000 shares of our common stock at an exercise price of \$0.20 per share, which vests monthly over three years following January 10, 2020, subject to Dr. Cheng’s continuous service to us. The vesting of this option will accelerate in full upon the closing of a change in control (as defined in our 2017 Plan).

In April 2020, we granted a stock option to Dr. Kotzin covering 40,000 shares of our common stock at an exercise price of \$0.55 per share, which vests monthly over three years following April 16, 2020, subject to Dr. Kotzin’s continuous service to us. The vesting of this option will accelerate in full upon the closing of a change in control (as defined in our 2017 Plan).

In April 2020, we also granted a stock option to Mr. Morrison covering 40,000 shares of our common stock at an exercise price of \$0.55 per share, which vests monthly over three years following April 16, 2020, subject to Mr. Morrison’s continuous service to us. The vesting of this option will accelerate in full upon the closing of a change in control (as defined in our 2017 Plan).

In December 2020, we granted a stock option to each of Dr. Seidenberg, Mr. Morrison, Dr. Cheng and Dr. Kotzin covering 800,000, 800,000, 710,000 and 445,000 shares of our common stock, respectively, at an exercise price of \$0.25 per share, each vesting monthly over three years following December 16, 2020, and each subject to such individual’s continuous service to us. The vesting of these options will accelerate in full upon the closing of a change in control (as defined in our 2017 Plan). The options issued to both Mr. Morrison and Dr. Kotzin were conditioned on the cancellation of an option covering 40,000 shares held by such individual, granted in April 2020.

Our board of directors adopted a non-employee director compensation policy in \_\_\_\_\_, 2021 that will become effective in connection with this offering and will be 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 \$ \_\_\_\_\_ ;
- an additional annual cash retainer of \$ \_\_\_\_\_ , \$ \_\_\_\_\_ and \$ \_\_\_\_\_ 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 \$ \_\_\_\_\_ , \$ \_\_\_\_\_ and \$ \_\_\_\_\_ for service as chair of the audit committee, compensation committee and the nominating and corporate governance committee, respectively;
- an initial option grant to purchase \_\_\_\_\_ shares of our 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 \_\_\_\_\_ shares of our 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 Equity Incentive Plan (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, 2020, 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;
- Joanne Curley, Ph.D., our Chief Development Officer;
- Jonathan Wolter, our Chief Financial Officer; and
- Allen Ebens, Ph.D., our former Chief Scientific Officer.

### 2020 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 year ended December 31, 2020.

| NAME AND PRINCIPAL POSITION                                      | FISCAL YEAR | SALARY (\$) | STOCK AWARDS (\$)(1) | OPTION AWARDS (\$)(2) | NON-EQUITY INCENTIVE PLAN COMPENSATION (\$)(3) | ALL OTHER COMPENSATION (\$) | TOTAL (\$) |
|--|-------------|-------------|----------------------|-----------------------|--|-----------------------------|------------|
| Marshall Fordyce, M.D.<br><i>Chief Executive Officer</i>         | 2020        | 360,000     | 316,323              | 2,441,982             | 108,000  | —                           | 3,226,305  |
| Joanne Curley, Ph.D.<br><i>Chief Development Officer (4)</i>     | 2020        | 286,458     | —                    | 318,212               | 105,000  | —                           | 709,670    |
| Jonathan Wolter<br><i>Chief Financial Officer (5)</i>            | 2020        | 205,300(6)  | —                    | —                     | —  | —                           | 205,300    |
| Allen Ebens, Ph.D.<br><i>Former Chief Scientific Officer (7)</i> | 2020        | 263,691     | —                    | —                     | —  | 133,333(8)                  | 397,025    |

- (1) In October 2020, in connection with the closing of our Series C redeemable convertible preferred stock financing, 575,132 outstanding shares of our 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.
- (2) The amounts disclosed represent the aggregate grant date fair value of the awards granted to our named executive officers during fiscal year 2020 under our 2017 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 7 to our audited financial statements included elsewhere in this prospectus. This amount does not reflect the actual economic value that may be realized by the named executive officer.
- (3) The amounts disclosed represent performance bonuses earned in 2020, but paid in the beginning of 2021. Dr. Curley's bonus was pro-rated to reflect her partial year of service.
- (4) Dr. Curley has served as our Chief Development Officer since March 2020.
- (5) Mr. Wolter has served as our Chief Financial Officer since March 2020, whereby we contracted with FLG Partners, LLC for his services.
- (6) The amounts disclosed represent consulting fees paid by the Company in consideration for Mr. Wolter's services as our Chief Financial Officer.
- (7) Dr. Ebens' employment was terminated as our Chief Scientific Officer effective October 2020 following a shift in our operations from preclinical to clinical development.
- (8) This amount represents severance payable to Dr. Ebens.

## 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. Upon the closing of this offering, the compensation committee will determine our executive officers' compensation and follow this process, but generally the compensation committee itself, rather than our board of directors, will approve 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 2020 annual base salaries for our named executive officers are set forth in the table below, except for Mr. Wolter. We pay FLG Partners a rate of \$400 per hour for Mr. Wolter's services as our Chief Financial Officer, to a maximum of \$25,000 per month.

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| <b>NAME</b>                | <b>2020 BASE SALARY</b> |
|----------------------------|-------------------------|
| Marshall Fordyce, M.D. (1) | \$ 400,000              |
| Joanne Curley, Ph.D. (2)   | \$ 350,000              |
| Allen Ebens, Ph.D. (3)     | \$ 320,000              |

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(1) Dr. Fordyce's base salary increased from \$300,000 to \$400,000 in December 2020.

(2) Dr. Curley began her employment with us in March 2020 with an annualized base salary of \$375,000, which was decreased to \$350,000 in September 2020.

(3) Dr. Ebens' employment was terminated as our Chief Scientific Officer effective October 2020 following a shift in our operations from preclinical to clinical development.

**Outstanding Equity Awards as of December 31, 2020**

The following table presents the outstanding equity incentive plan awards held by each named executive officer as of December 31, 2020. Mr. Wolter and Dr. Ebens did not have any outstanding equity incentive plan awards as of December 31, 2020.

| NAME                   | GRANT DATE     | OPTION AWARDS <sup>(1)</sup>  |   | OPTION EXERCISE PRICE PER SHARE (\$) <sup>(2)</sup> | OPTION EXPIRATION DATE |
|------------------------|----------------|---|---|---|------------------------|
|                        |                | NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS EXERCISABLE (#) | NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) |   |                        |
| Marshall Fordyce, M.D. | 01-16-2020 (3) | —   | 107,500   | 0.20  | 01-15-2030             |
|                        | 12-16-2020 (4) | —   | 12,829,162  | 0.25  | 12-15-2030             |
|                        | 12-16-2020 (5) | 400,000   | —   | 0.25  | 12-15-2030             |
| Joanne Curley, Ph.D.   | 04-01-2020 (6) | —   | 300,000   | 0.55  | 03-31-2030             |
|                        | 12-16-2020 (7) | —   | 765,000   | 0.25  | 12-15-2030             |
|                        | 12-16-2020 (8) | 275,000   | —   | 0.25  | 12-15-2030             |

- (1) All of the option and stock awards were granted under the 2017 Plan, the terms of which plan is described below under “—Equity Benefit Plans—2017 Equity Incentive Plan.”
- (2) All of the option awards were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our board of directors or compensation committee.
- (3) 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.
- (4) 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 150,000 shares granted to Dr. Fordyce on March 26, 2019 and an option covering 200,000 shares granted to Dr. Fordyce on February 7, 2018.
- (5) 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. The option award includes an early exercise feature. Dr. Fordyce exercised this option in full in February 2021. This option was conditioned on the cancellation of an option covering 150,000 shares granted to Dr. Fordyce on March 26, 2019 and an option covering 200,000 shares granted to Dr. Fordyce on February 7, 2018.
- (6) One-fourth of the shares subject to the option award vest on March 12, 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.
- (7) 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.
- (8) 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. The option award includes an early exercise feature. Dr. Curley exercised this option in full in February 2021.

Options held by certain of our named executive officers are eligible for accelerated vesting under specified circumstances. Please see the subsection titled “—Employment 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, 2020.

## **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, 2020.

## **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 13,229,162 shares of our common stock (in addition to shares of our stock that Dr. Fordyce held at the time we entered into his offer letter). 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.

*Dr. Curley.* In February 2020, we and Dr. Curley entered into an offer letter, which was amended in September 2020, and that governs the current terms of Dr. Curley’s employment with us. Pursuant to the agreement, Dr. Curley is entitled to an annual base salary of \$375,000 (which was decreased to \$350,000 in September 2020), 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 300,000 shares of our common stock. Dr. Curley 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. Curley’s employment is at will.

*Mr. Wolter.* In March 2020, we entered into a consulting agreement with FLG Partners, LLC setting forth the terms and conditions of Mr. Wolter’s service to the Company as our Chief Financial Officer. Pursuant to the consulting agreement, Mr. Wolter receives \$400 per hour for his services up to \$25,000 a month and no additional compensation. The term of the agreement is indefinite and either party may terminate upon thirty (30) days advance written notice.

*Dr. Ebens.* In July 26, 2018, we and Dr. Ebens entered into an offer letter that governed the terms of Dr. Ebens’ employment with us. Pursuant to the agreement, Dr. Ebens was entitled to an annual base salary of \$320,000, was eligible to receive an annual performance bonus with a target achievement of 25% of his base salary, as determined by our board of directors, and was granted an option exercisable for 375,000 shares of our common stock. Dr. Ebens was also entitled to certain severance benefits, and his employment was at will. Dr. Ebens’ employment was terminated as our Chief Scientific Officer effective October 2020 following a shift in our operations from preclinical to clinical development. In August 2020, we entered into a transition and separation agreement with Dr. Ebens. Pursuant to the agreement, we made a lump cash severance payment equal to five months of his base salary and the payment of COBRA premiums through a date no later than February 28, 2021. Dr. Ebens ceased vesting in his outstanding equity awards as of the date of his separation and did not receive any vesting acceleration in connection with his termination. The receipt of severance benefits was conditioned upon the execution of a release of claims in our favor and subject to his compliance with his obligations under the agreement, including those relating to confidentiality, non-disparagement, and return of company property.

**Potential Payments and Benefits Upon Termination or Change of Control**

*Dr. Fordyce.* Pursuant to Dr. Fordyce'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, 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 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 time-based 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 15 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.

For the purposes of Dr. Fordyce'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) as our 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; or (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 within 30 days after each occurrence of the event giving rise to good reason setting forth the basis for officer's resignation,

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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.

*Dr. Curley.* Pursuant to Dr. Curley's offer letter, as amended, 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. Curley will be entitled to receive severance in the form of 6 months of her then base salary, such amount to be paid in equal installments over a 6-month period after the date of termination, subject to applicable taxes and withholding, as well as up to 5 months of COBRA coverage. These severance benefits are conditioned upon Dr. Curley 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.

For the purposes of Dr. Curley'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) material breach of officer's duties to us; (d) intentional damage to any of our property; (e) misconduct, or other violation of our policy that causes harm; (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 breach of any the company policy, or of any statutory duty officer owes to us; or (g) conduct which in the good faith and reasonable determination of the company demonstrates gross unfitness to serve.
- "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), 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; or (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. In order to resign for good reason, officer must provide written notice to our board of directors 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**

Prior to the closing of this offering, we expect that our board of directors will adopt, and our stockholders will approve, our 2021 Plan. We expect our 2021 Plan will become effective on the date of the underwriting agreement related to this offering. Our 2021 Plan will come into existence upon its adoption by our board of directors, but no grants will be made under our 2021 Plan prior to its effectiveness. Once our 2021 Plan becomes effective, no further grants will be made under our 2017 Plan.

**Awards.** Our 2021 Plan will provide 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 common stock that may be issued under our 2021 Plan after it becomes effective will not exceed \_\_\_\_\_ shares of our common stock, which is the sum of (i) \_\_\_\_\_ new shares, plus (ii) an additional number of shares up to a maximum of \_\_\_\_\_ shares, which number consists of shares of our common stock subject to outstanding stock options or other stock awards granted under our 2017 Plan that, on or after our 2021 Plan becomes 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 common stock reserved for issuance under our 2021 Plan will automatically increase on January 1st 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) \_\_\_\_\_ % of the total number of shares of our common stock outstanding on December 31st 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 common stock that may be issued on the exercise of ISOs under our 2021 Plan will be \_\_\_\_\_ 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 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, will administer 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 will have 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 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 will have 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 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.

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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 12 months following the cessation of service. In the event 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 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 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 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 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 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

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agreement as will be determined by the administrator. Stock appreciation rights may be settled in cash or shares of our 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 will permit 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 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 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 common stockholders other than regular cash dividends; (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 will be permitted to grant other awards based in whole or in part by reference to our 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 \$ \_\_\_\_\_ in total value, except such amount will increase to \$ \_\_\_\_\_ 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

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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 (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 us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction); and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

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 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 consolidated 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 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.

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*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 adopts 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 provides 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.

The 2017 Plan will be terminated on the date the 2021 Plan becomes effective. However, any outstanding awards granted under the 2017 Plan will remain outstanding, subject to the terms of our 2017 Plan and award agreements, until such outstanding options are exercised or until any awards terminate or expire by their terms.

*Authorized Shares.* Upon the effective date of the 2021 Plan, we will no longer grant awards under our 2017 Plan. As of \_\_\_\_\_, options to purchase \_\_\_\_\_ shares were outstanding, and \_\_\_\_\_ shares of common stock remained available for future issuance under our 2017 Plan. The options outstanding as of \_\_\_\_\_ had a weighted-average exercise price of \_\_\_\_\_.

*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 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**

Prior to the closing of this offering, our board of directors intends to adopt, and we expect our stockholders will approve, our 2021 Employee Stock Purchase Plan (ESPP). Our ESPP will become effective immediately prior to and contingent upon the date of the underwriting agreement related to this offering. The purpose of our ESPP will be 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 will include two components. One component will be designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. The other component will permit 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.* Following this offering, our ESPP will authorize the issuance of \_\_\_\_\_ shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1st 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) \_\_\_\_\_ % of the total number of shares of our common stock outstanding on \_\_\_\_\_ of the immediately preceding year; and (ii) \_\_\_\_\_ 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 will administer our ESPP and may delegate its authority to administer our ESPP to our compensation committee. Our ESPP will be implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under our ESPP, our board of directors will be 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 common stock will be purchased for employees participating in the offering. Our ESPP will provide that an offering 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 \_\_\_\_\_ % of their earnings (as defined in our ESPP) for the purchase of our common stock under our ESPP. Unless otherwise determined by our board of directors, 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 common stock on the first day of an offering; or (ii) 85% of the fair market value of a share of our common stock on the date 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 common stock (based on the fair market value per share of our 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 will provide 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.

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*Corporate Transactions.* Our ESPP will provide 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 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 consolidated 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 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 will have 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, which will become effective immediately after the closing of this offering, will contain 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 will authorize us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws will 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 will 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.

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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 of 1933, as amended (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 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 180 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.

## 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, 2018 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.

### 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).

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.

| <b>PARTICIPANTS (1)</b>  | <b>PRINCIPAL AMOUNT AND INTEREST OF<br/>2020 NOTES</b> |              |
|--|--|--------------|
| 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 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.

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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<br>PREFERRED STOCK<br>PURCHASED FOR CASH (#) | AGGREGATE<br>CASH<br>PURCHASE<br>PRICE | SHARES OF SERIES C<br>PREFERRED STOCK<br>ISSUED UPON<br>CONVERSION OF<br>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  | \$ 9,999,999.68                        | —   |
| 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 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 Mt. Vernon Street Trust: Fidelity Growth Company K6 Fund, (v) 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 partner at 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 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 an exclusive worldwide license agreement with Ares, an affiliate of Merck KGaA, Darmstadt, Germany. Under this license agreement (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 atacept 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. 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 will grant Dr. Ebens an option covering 445,000 shares of our 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 grants 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 imposes 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 will terminate in connection with the closing of this offering.

## **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.

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Pursuant to the Voting Agreement, each of Abingworth Bioventures 8 LP, Longitude Venture Partners IV, L.P. and Sofinnova Venture Partners X, L.P. has 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 will terminate by its terms in connection with the closing of this offering and none of our stockholders will have any continuing rights regarding the election or designation of members of our board of directors following this offering.

### **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 have 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 are granted certain rights of first refusal and co-sale in respect of such sale. The Co-Sale Agreement will terminate in connection with the closing of this offering.

### **Indemnification Agreements**

Our amended and restated certificate of incorporation will contain provisions limiting the liability of directors, and our amended and restated bylaws will provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board. In addition, we have entered into or intend to enter into an indemnification agreement with each of our directors and executive officers, which will require us to indemnify them. For more information regarding these agreements, see the section titled “Executive Compensation—Limitations on Liability and Indemnification.”

### **Policies and Procedures for Transactions with Related Persons**

Prior to closing of this offering, we intend to adopt 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.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock as of January 31, 2021 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our 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 186,889,870 shares of our common stock outstanding as of January 31, 2021, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into 182,772,372 shares of our common stock in connection with the closing of this offering and including \_\_\_\_\_ shares of our unvested restricted common stock subject to repurchase as of such date.

Applicable percentage ownership after the offering is based on \_\_\_\_\_ shares of common stock outstanding immediately after the closing of this offering, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into \_\_\_\_\_ shares of our common stock in connection with the closing of this offering and including \_\_\_\_\_ shares of our unvested restricted common stock subject to repurchase as of \_\_\_\_\_. 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 January 31, 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.

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Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Vera Therapeutics, Inc., 170 Harbor Way, 3rd Floor, South San Francisco, California 94080.

| NAME OF BENEFICIAL OWNER  | NUMBER OF<br>SHARES<br>BENEFICIALLY<br>OWNED<br>(#) | PERCENTAGE OF SHARES<br>BENEFICIALLY OWNED |                          |
|---|---|--|--------------------------|
|   |   | BEFORE<br>OFFERING<br>(%)                  | AFTER<br>OFFERING<br>(%) |
| <b>Greater than 5% Holders:</b>                                   |   |  |                          |
| Abingworth Bioventures 8 LP (1)                                   |   |  |                          |
| Entities affiliated with Fidelity (2)                             |   |  |                          |
| Longitude Venture Partners IV, L.P. (3)                           |   |  |                          |
| Sofinnova Venture Partners X, L.P. (4)                            |   |  |                          |
| Ares Trading S.A. (5)   |   |  |                          |
| Citadel Multi-Strategy Equities Master Fund Ltd. (6)              |   |  |                          |
| KPCB Holdings, Inc., as nominee (7)                               |   |  |                          |
| Entities affiliated with GV (8)                                   |   |  |                          |
| <b>Directors and Named Executive Officers:</b>                    |   |  |                          |
| Marshall Fordyce, M.D. (9)  |   |  |                          |
| Jonathan Wolter   |   |  |                          |
| Joanne Curley, Ph.D. (10)   |   |  |                          |
| Allen Ebens, Ph.D. (11)   |   |  |                          |
| Kurt von Emster, C.F.A. (1)                                       |   |  |                          |
| Andrew Cheng, M.D., Ph.D. (12)                                    |   |  |                          |
| Beth Seidenberg, M.D. (7)(13)                                     |   |  |                          |
| Maha Katabi, Ph.D. (4)  |   |  |                          |
| Patrick Enright (3)   |   |  |                          |
| Scott Morrison (14)   |   |  |                          |
| All directors and executive officers as a group (10 persons) (15) |   |  |                          |

\* Represents beneficial ownership of less than 1%.

- (1) Consists of \_\_\_\_\_ shares of common stock issuable upon conversion of Series C preferred stock held by Abingworth Bioventures 8, LP (ABV 8). 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 Abingworth GP. ABV 8 (acting by its general partner Abingworth GP, acting by its general partner Abingworth General Partner 8 LLP) has delegated to Abingworth LLP, all investment and dispositive 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 GP, Abingworth GP 8, and each member of the investment committee disclaims beneficial ownership of the shares held by ABV 8. The address for ABV 8 is Abingworth Bioventures 8 LP c/o Abingworth LLP, 38 Jermyn Street, London, SW1Y 6DN, UK.
- (2) Consists of (i) \_\_\_\_\_ shares of common stock issuable upon conversion of Series C preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund, (ii) \_\_\_\_\_ shares of common stock issuable upon conversion of Series C preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund, (iii) \_\_\_\_\_ shares of common stock issuable upon conversion of Series C preferred stock held by Fidelity Growth Company Commingled Pool, (iv) \_\_\_\_\_ shares of common stock issuable upon conversion of Series C preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company K6 Fund, (v) \_\_\_\_\_ shares of common stock issuable upon conversion of Series C preferred stock held by Fidelity Select Portfolios: Biotechnology Portfolio, and (vi) \_\_\_\_\_ shares of common stock issuable upon conversion of Series C preferred stock held by Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund. The address for the entities listed in (i), (iii) and (v) is Mag & Co., c/o Brown Brothers Harriman & Co., Attn: Corporate Actions/Vault, 140 Broadway, New York, NY 10005. The address for the entities listed in (ii) and (iv) is BNY Mellon, PO Box 392002, Pittsburgh, PA 15230. The address for the entity listed in (vi) is State Street Bank & Trust, PO Box 5756, Boston, MA 02206, Attn: Bangle & Co fbo Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund.
- (3) Consists of \_\_\_\_\_ shares of common stock issuable upon conversion of Series C preferred 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. The address for this entity is 2470 Sand Hill Road, 2<sup>nd</sup> Floor, Menlo Park, CA 94025.

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- (4) Consists of \_\_\_\_\_ shares of common stock issuable upon conversion of Series C preferred 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.
- (5) Consists of \_\_\_\_\_ shares of common stock issuable upon conversion of Series C preferred 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 \_\_\_\_\_ shares of common stock issuable upon conversion of Series C preferred stock held by Citadel Multi-Strategy Equities Master Fund Ltd. (Citadel). 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 address for this entity is 131 S Dearborn St, 32nd Floor, Chicago, IL 60603.
- (7) Consists of (i) \_\_\_\_\_ shares of our Series A preferred stock held by Kleiner Perkins Caufield & Byers XVI, LLC (KPCB XVI) and \_\_\_\_\_ shares held by KPCB XVI Founders Fund, LLC (XVI Founders), (ii) \_\_\_\_\_ shares of our Series B preferred stock held by KPCB XVI and \_\_\_\_\_ shares held by XVI Founders and (iii) \_\_\_\_\_ shares of our Series C Preferred Stock held by KPCB XVI and \_\_\_\_\_ shares held by XVI Founders. All shares are held for convenience in the name of "KPCB Holdings, Inc., as nominee" for the accounts of such individuals and entities. 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. The principal business address for all entities and individuals affiliated with Kleiner Perkins Caufield & Byers is c/o Kleiner Perkins Caufield & Byers, LLC, 2750 Sand Hill Road, Menlo Park, CA 94025.
- (8) Consists of (i) \_\_\_\_\_ shares of common stock issuable upon conversion of Series B convertible preferred stock (Series B preferred stock) held by GV 2017, L.P. and (ii) \_\_\_\_\_ shares of common stock issuable upon conversion of Series C preferred stock held by GV 2019, L.P. The address for these entities is 1600 Amphitheater Parkway, Mountain View, CA 94043.
- (9) Consists of (i) \_\_\_\_\_ shares of common stock held directly by Dr. Fordyce, (ii) \_\_\_\_\_ shares of common stock subject to options exercisable within 60 days of January 1, 2021 held by Dr. Fordyce, \_\_\_\_\_ of which are vested as of such date, and (iii) \_\_\_\_\_ shares of our Series C preferred stock held by James W. Fordyce, as Trustee of the James W. Fordyce 2005 Revocable Trust.
- (10) Consists of \_\_\_\_\_ shares of common stock subject to options exercisable within 60 days of January 1, 2021 held by Dr. Curley, \_\_\_\_\_ of which are vested as of such date.
- (11) Consists of \_\_\_\_\_ shares of common stock held directly by Dr. Ebens. Dr. Ebens' employment was terminated as our Chief Scientific Officer effective October 2020.
- (12) Consists of (i) \_\_\_\_\_ shares of common stock issuable upon conversion of Series C preferred stock held by Dr. Cheng, as trustee of the Andrew Cheng 2010 Trust UA 10-26-2010 and (ii) \_\_\_\_\_ shares of common stock subject to options exercisable within 60 days of January 1, 2021 held by Dr. Cheng.
- (13) Consists of \_\_\_\_\_ shares of common stock subject to options exercisable within 60 days of January 1, 2021 held by Dr. Seidenberg.
- (14) Consists of \_\_\_\_\_ shares of common stock subject to options exercisable within 60 days of January 1, 2021 held by Mr. Morrison.
- (15) Consists of (i) \_\_\_\_\_ shares beneficially owned by our current executive officers and directors, and (ii) \_\_\_\_\_ shares subject to options exercisable within 60 days of January 31, 2021, all of which are vested as of such date.

## 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, which will become effective immediately after the closing of this offering, and the amended and restated bylaws, which will become effective upon the closing of this offering. Copies of these documents have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will be in effect upon the closing of this offering.

Upon filing of our amended and restated certificate of incorporation and the closing of this offering, our authorized capital stock will consist of \_\_\_\_\_ shares of common stock, par value \$0.0001 per share, and \_\_\_\_\_ shares of preferred stock, par value \$0.0001 per share. All of our authorized shares of preferred stock will be undesignated.

As of December 31, 2020, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into \_\_\_\_\_ shares of our common stock in connection with the closing of this offering and including \_\_\_\_\_ shares of our unvested restricted common stock subject to repurchase as of such date, there were \_\_\_\_\_ shares of common stock outstanding and held of record by \_\_\_\_\_ stockholders.

### Common Stock

#### Voting Rights

The common stock is entitled to one vote per share on any matter that is submitted to a vote of our stockholders. Our amended and restated certificate of incorporation does not provide for cumulative voting for the election of directors. 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, 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 66 $\frac{2}{3}$ % 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, the size of our board of directors, removal of directors, director liability, vacancies on our board of directors, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

#### Economic Rights

Except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law, all shares of 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 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 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.

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### **No Preemptive or Similar Rights**

The holders of our shares of common stock are not entitled to preemptive rights, and are not subject to conversion, 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 common stock to be issued under this offering will be fully paid and non-assessable.

### **Preferred Stock**

Upon the closing of this offering, all of our currently outstanding shares of redeemable convertible preferred stock will convert into common stock and we will not have any redeemable convertible preferred stock outstanding. Immediately after the closing of this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of redeemable convertible preferred stock. Under the amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to \_\_\_\_\_ 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 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 common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

### **Stock Options**

As of December 31, 2020, \_\_\_\_\_ shares of common stock were issuable upon the exercise of outstanding stock options, at a weighted-average exercise price of \$ \_\_\_\_\_ per share. For additional information regarding terms of our equity incentive plans, see the section titled "Executive Compensation—Equity Benefit Plans."

### **Registration Rights**

Upon the closing of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, certain holders of shares of our common stock, including those shares of our common stock that will be issued upon the conversion of our redeemable convertible preferred stock in connection with this offering, will initially be 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 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 this offering.

### **Demand Registration Rights**

Upon the closing of this offering, holders of an aggregate of \_\_\_\_\_ shares of our common stock will be entitled to certain demand registration rights. At any time beginning 180 days after the closing of this offering, the holders of \_\_\_\_\_ % of these shares may request that we register all or a portion of their shares. We are not required to effect more than \_\_\_\_\_ registration statements which are declared or ordered effective. Such request for registration must cover shares with an anticipated aggregate offering price of at least \$ \_\_\_\_\_ million. With certain

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exceptions, we are not required to effect the filing of a registration statement during the period starting with 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, the holders of an aggregate of \_\_\_\_\_ shares of our common stock were 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. After this offering, 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***

Upon the closing of this offering, holders of an aggregate of \_\_\_\_\_ shares of common stock will be entitled to certain Form S-3 registration rights. Holders of \_\_\_\_\_ % 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 if the reasonably anticipated aggregate net proceeds of the shares offered would equal or exceed \$ \_\_\_\_\_ million. We will not be required to effect more than \_\_\_\_\_ 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 common stock will be able to elect all of our directors. Our amended and restated certificate of incorporation, to be effective immediately after the closing of this offering, and our amended and restated bylaws, to be effective upon the closing of this offering, will provide for stockholder actions at a duly called meeting of stockholders or, before the date on which all shares of 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 will 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 to be filed in connection with this offering, immediately after this offering, our board of directors will be 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 Delaware General Corporation Law (DGCL), which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, subject to certain exceptions.

### **Choice of Forum**

Our amended and restated certificate of incorporation to be effective immediately after the closing of this offering will provide that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our bylaws (as each may be amended from time to time); (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. This choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction, or the Securities Act.

Our amended and restated certificate of incorporation to be effective upon the closing of this offering will further provide 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 to be effective immediately after the closing of this offering will provide 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 common stock is currently not listed on any securities exchange. We intend to apply to have common stock approved for listing on The Nasdaq Global Market under the symbol "VERA."

### **Transfer Agent and Registrar**

Upon the closing of this offering, the transfer agent and registrar for our common stock will be

## SHARES ELIGIBLE FOR FUTURE SALE

Before the closing of this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock, including shares issued on the exercise of outstanding options, in the public market after this offering, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital.

Based on our shares outstanding as of December 31, 2020, upon the closing of this offering, a total of \_\_\_\_\_ shares of common stock will be outstanding, assuming the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into \_\_\_\_\_ shares of our common stock in connection with the closing of this offering and \_\_\_\_\_ shares of unvested restricted common stock subject to repurchase. Of these shares, all of the common stock sold in this offering by us, plus any shares sold by us on exercise of the underwriters' option to purchase additional common stock, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by "affiliates," as that term is defined in Rule 144 under the Securities Act (Rule 144).

The remaining shares of common stock will be, and shares of common stock subject to stock options will be on issuance, "restricted securities," as that term is defined in Rule 144. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. Restricted securities may also be sold outside of the United States to non-U.S. persons in accordance with Rule 904 of Regulation S.

Subject to the lock-up agreements described below and the provisions of Rule 144 or Regulation S under the Securities Act, as well as our insider trading policy, these restricted securities will be available for sale in the public market after the date of this prospectus.

### Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares of common stock from us; or
- the average weekly trading volume of our common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

## **Rule 701**

Rule 701 of the Securities Act (Rule 701) generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below.

## **Form S-8 Registration Statements**

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC to register the offer and sale of shares of our common stock that are issuable under the PNA Stock Plan, 2017 Plan, 2021 Plan and ESPP. These registration statements will become effective immediately on filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below, and Rule 144 limitations applicable to affiliates.

## **Lock-up Arrangements**

We, and all of our directors, executive officers and the holders of substantially all of our common stock and securities exercisable for or convertible into our common stock outstanding immediately upon the closing of this offering, have agreed with the underwriters that, until 180 days after the date of the underwriting agreement related to this offering, we and they will not, without the prior written consent of the representatives of the underwriters, subject to certain exceptions, directly or indirectly, 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 any of our shares of common stock, or any securities convertible into or exercisable or exchangeable for shares of our common stock, or enter into any hedging, swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the securities, whether any such swap or transaction is to be settled by delivery of our common stock or other securities, in cash or otherwise. These agreements are described in the section titled "Underwriting." The representatives of the underwriters may, in their sole discretion, release any of the securities subject to these lock-up agreements at any time.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including the amended and restated investors' rights agreement, our standard form of option agreement and our standard form of restricted stock agreement, that contain market stand-off provisions or incorporate market stand-off provisions from our equity incentive plan imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

## **Registration Rights**

Upon the closing of this offering, pursuant to our amended and restated investors' rights agreement, the holders of \_\_\_\_\_ shares of our common stock, or their transferees, will be entitled to certain rights with respect to the registration of the offer and sale of their shares under the Securities Act, subject to the terms of the lock-up agreements described under the section titled "—Lock-Up Arrangements" above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately on the effectiveness of the registration. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

## 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 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 common stock pursuant to this offering and who hold our 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 common stock through the exercise of an option or otherwise as compensation;
- qualified foreign pension funds as defined in Section 897(l)(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 common stock;
- persons who have elected to mark securities to market; and
- persons holding our 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 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 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 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 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 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 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 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 common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under the section titled “—Gain on Disposition of Our 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 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 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 common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our 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 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 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 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 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 common stock, and our 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 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 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 common stock and would have applied also to payments of gross proceeds from the sale or other disposition of our 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 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 common stock.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

## UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated \_\_\_\_\_, 2021, among us, Jefferies LLC, Cowen and Company, LLC and Evercore Group L.L.C, as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us the respective number of shares of common stock shown opposite its name below:

| <u>UNDERWRITER</u>     | <u>NUMBER OF<br/>SHARES</u> |
|------------------------|-----------------------------|
| Jefferies LLC          |                             |
| Cowen and Company, LLC |                             |
| Evercore Group L.L.C.  |                             |
| Total                  |                             |

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

### Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of \$ \_\_\_\_\_ per share of common stock. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of \$ \_\_\_\_\_ per share of common stock to certain brokers and dealers. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

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The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

|   | PER SHARE  |   | TOTAL  |   |
|---|--|---|--|---|
|   | WITHOUT<br>OPTION TO<br>PURCHASE<br>ADDITIONAL<br>SHARES | WITH<br>OPTION TO<br>PURCHASE<br>ADDITIONAL<br>SHARES | WITHOUT<br>OPTION TO<br>PURCHASE<br>ADDITIONAL<br>SHARES | WITH<br>OPTION TO<br>PURCHASE<br>ADDITIONAL<br>SHARES |
| Public offering price                             | \$   | \$  | \$   | \$  |
| Underwriting discounts and commissions paid by us | \$   | \$  | \$   | \$  |
| Proceeds to us, before expenses                   | \$   | \$  | \$   | \$  |

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$ .

### **Determination of Offering Price**

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

### **Listing**

We intend to apply to have our common stock approved for listing on The Nasdaq Global Market under the trading symbol "VERA".

### **Stamp Taxes**

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

### **Option to Purchase Additional Shares**

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of \_\_\_\_\_ shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

### **No Sales of Similar Securities**

We, our officers, directors and holders of all or substantially all our outstanding capital stock and other securities have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Exchange Act, or

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- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Jefferies LLC, Cowen and Company, LLC and Evercore Group L.L.C.

This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus.

Jefferies LLC, Cowen and Company, LLC and Evercore Group L.L.C. may, in their sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

### **Stabilization**

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. 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 shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on The Nasdaq Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

## **Electronic Distribution**

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

## **Other Activities and Relationships**

The underwriter and certain of its affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriter and certain of its affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriter and certain of its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

## **Disclaimers About Non-U.S. Jurisdictions**

### **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,

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- 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.

### **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.

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### **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.

**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.

## LEGAL MATTERS

The validity of the shares of our common stock being offered in this prospectus will be passed upon for us by Cooley LLP. Certain legal matters in connection with this offering will be passed upon for the underwriters by Goodwin Procter LLP.

## 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 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 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](http://www.sec.gov).

We also maintain a website at [www.veratx.com](http://www.veratx.com), at which, following the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. 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.

VERA THERAPEUTICS, INC.  
INDEX TO FINANCIAL STATEMENTS

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## 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, 2019 and 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 and in accordance with auditing standards generally accepted in the United States of America. 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

**Vera Therapeutics, Inc.**  
**Balance Sheets**  
(In thousands, except share amounts)

|   | <b>DECEMBER 31,</b> |                  |
|---|---------------------|------------------|
|   | <b>2019</b>         | <b>2020</b>      |
| <b>Assets</b>   |                     |                  |
| 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  | <u>\$ 5,381</u>     | <u>\$ 54,554</u> |
| <b>Liabilities, redeemable convertible preferred stock, and stockholders' deficit</b>   |                     |                  |
| 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   | <u>1,834</u>        | <u>4,326</u>     |
| 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              | 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; 3,731,682 and 4,117,498 shares issued and outstanding as of December 31, 2019 and 2020, respectively                      | 4                   | 4                |
| 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  | 1,482               | 2,095            |
| Accumulated deficit   | (38,034)            | (91,447)         |
| Total stockholders' deficit   | <u>(36,548)</u>     | <u>(89,348)</u>  |
| Total liabilities, redeemable convertible preferred stock, and stockholders' deficit  | <u>\$ 5,381</u>     | <u>\$ 54,554</u> |

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

**Vera Therapeutics, Inc.**  
**Statements of Operations and Comprehensive Loss**  
**(In thousands)**

|   | <b>YEAR ENDED DECEMBER 31,</b> |                    |
|---|--------------------------------|--------------------|
|   | <b>2019</b>                    | <b>2020</b>        |
| Operating expenses:   |                                |                    |
| Research and development  | \$ 7,290                       | \$ 45,206          |
| General and administrative  | 4,410                          | 4,039              |
| Restructuring costs   | 261                            | 2,996              |
| Total operating expenses  | <u>11,961</u>                  | <u>52,241</u>      |
| 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)  | <u>108</u>                     | <u>(1,171)</u>     |
| Loss before provision for income taxes                                    | <u>\$ (11,853)</u>             | <u>\$ (53,412)</u> |
| Provision for income taxes  | (1)                            | (1)                |
| Net loss and comprehensive loss   | <u>\$ (11,854)</u>             | <u>\$ (53,413)</u> |
| Net loss per share attributable to common stockholders, basic and diluted | <u>\$ (3.46)</u>               | <u>\$ (14.40)</u>  |
| Weighted-average common shares outstanding, basic and diluted             | <u>3,422,676</u>               | <u>3,708,152</u>   |

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)

|  | REDEEMABLE<br>CONVERTIBLE<br>PREFERRED STOCK |                   | COMMON STOCK     |             | ADDITIONAL<br>PAID-IN<br>CAPITAL | ACCUMULATED<br>DEFICIT | TOTAL<br>STOCKHOLDERS'<br>DEFICIT |
|--|--|-------------------|------------------|-------------|----------------------------------|------------------------|-----------------------------------|
|  | SHARES                                       | AMOUNT            | SHARES           | AMOUNT      |                                  |                        |                                   |
| <b>Balance as of December 31, 2018</b>   | 14,015,773                                   | \$ 40,095         | 3,616,562        | \$ 4        | \$ 1,168                         | \$ (26,180)            | \$ (25,008)                       |
| Issuance of Class A common stock upon exercise of options  | —  | —                 | 115,120          | —           | 51                               | —                      | 51                                |
| Stock-based compensation   | —  | —                 | —                | —           | 263                              | —                      | 263                               |
| Net loss   | —  | —                 | —                | —           | —                                | (11,854)               | (11,854)                          |
| <b>Balance as of December 31, 2019</b>   | 14,015,773                                   | 40,095            | 3,731,682        | 4           | 1,482                            | (38,034)               | (36,548)                          |
| Issuance of Class A common stock upon exercise of options  | —  | —                 | 385,816          | —           | 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)                          |
| <b>Balance as of December 31, 2020</b>   | <u>182,772,372</u>                           | <u>\$ 139,576</u> | <u>4,117,498</u> | <u>\$ 4</u> | <u>\$ 2,095</u>                  | <u>\$ (91,447)</u>     | <u>\$ (89,348)</u>                |

The accompanying notes are an integral part of these financial statements

**Vera Therapeutics, Inc.**  
**Statements of Cash Flows**  
(In thousands)

|  | <b>YEAR ENDED DECEMBER 31,</b> |                  |
|--|--------------------------------|------------------|
|  | <b>2019</b>                    | <b>2020</b>      |
| <b>Cash flows from operating activities</b>  |                                |                  |
| 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  | <u>(10,289)</u>                | <u>(34,809)</u>  |
| <b>Cash flows from investing activities</b>  |                                |                  |
| Purchase of property and equipment   | (125)                          | (99)             |
| Proceeds from the sale of property and equipment   | —                              | 57               |
| Net cash used in investing activities  | <u>(125)</u>                   | <u>(42)</u>      |
| <b>Cash flows from financing activities</b>  |                                |                  |
| Proceeds from exercise of stock options  | 51                             | 230              |
| Proceeds from issuance of Series C redeemable convertible preferred stock                            | —                              | 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  | <u>(137)</u>                   | <u>85,290</u>    |
| Net (decrease) increase in cash and cash equivalents and restricted cash                             | (10,551)                       | 50,439           |
| Cash, cash equivalents and restricted cash, beginning of year  | 14,109                         | 3,558            |
| Cash, cash equivalents and restricted cash, end of year  | <u>\$ 3,558</u>                | <u>\$ 53,997</u> |
| <b>Reconciliation of cash and cash equivalents and restricted cash to the balance sheets</b>         |                                |                  |
| Cash and cash equivalents  | \$ 3,195                       | \$ 53,654        |
| Restricted cash  | 363                            | 343              |
| Total cash and cash equivalents and restricted cash  | <u>\$ 3,558</u>                | <u>\$ 53,997</u> |
| <b>Supplemental disclosure of cash flow information</b>  |                                |                  |
| 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.

**Vera Therapeutics, Inc.**  
**Notes to Financial Statements**  
**(Dollar amounts in thousands, except per share data)**

***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.

**Vera Therapeutics, Inc.**  
**Notes to Financial Statements**  
**(Dollar amounts in thousands, except per share data)**

***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

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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

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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 stockholders, because potentially dilutive 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.

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**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.

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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.

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**3. OTHER FINANCIAL STATEMENT INFORMATION****Prepaid Expense and Other Current Assets**

Prepaid expenses and other current assets consist of the following.

---

|  | <u>DECEMBER 31,</u>  |                      |
|--|----------------------|----------------------|
|  | <u>2019</u>          | <u>2020</u>          |
| Prepaid expenses                                       | \$ 332               | \$ 336               |
| Deposits   | 34                   | 86                   |
| Receivables on exercise of options                     | —                    | 52                   |
| Other  | 4                    | 83                   |
| <b>Total prepaid expenses and other current assets</b> | <b><u>\$ 370</u></b> | <b><u>\$ 557</u></b> |

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**Property and Equipment, net**

Property and equipment, net consists of the following as of December 31, 2019.

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|   |                        |
|---|------------------------|
| Equipment under capital lease             | \$ 929                 |
| Laboratory equipment                      | 734                    |
| Leasehold improvements                    | 421                    |
| Furniture and fixtures                    | 269                    |
| Office equipment                          | 61                     |
| Total property and equipment              | 2,414                  |
| Accumulated depreciation and amortization | (1,020)                |
| <b>Total property and equipment, net</b>  | <b><u>\$ 1,394</u></b> |

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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.

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**Accrued and Other Current Liabilities**

Accrued and other current liabilities consist of the following.

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|  | <u>DECEMBER 31,</u> |               |
|--|---------------------|---------------|
|  | <u>2019</u>         | <u>2020</u>   |
| Accrued expenses                                     | \$ 318              | \$ 128        |
| Accrued payroll                                      | 58                  | 405           |
| Other  | 47                  | —             |
| Total accrued expenses and other current liabilities | <u>\$ 423</u>       | <u>\$ 533</u> |

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**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                                 | <u>\$ —</u> |

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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.

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**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<br>PRICE | SHARES<br>AUTHORIZED | SHARES ISSUED AND<br>OUTSTANDING | CARRYING<br>VALUE | AGGREGATE<br>LIQUIDATION<br>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         |                | <u>182,772,372</u>   | <u>182,772,372</u>               | <u>\$ 139,576</u> | <u>\$ 139,338</u>                      |

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 atacept 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 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

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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, 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

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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 share 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 3,320,559 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 35,365,177 shares. No other changes were made to the 2017 Equity Incentive Plan. As of December 31, 2020, there were 14,486,211 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.

|  | YEAR ENDED DECEMBER 31, |               |
|--|-------------------------|---------------|
|  | 2019                    | 2020          |
| Research and development               | \$ 40                   | \$ 4          |
| General and administrative             | 223                     | 327           |
| Total stock-based compensation expense | <u>\$ 263</u>           | <u>\$ 331</u> |

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|  | YEAR ENDED DECEMBER 31, |               |
|--|-------------------------|---------------|
|  | 2019                    | 2020          |
| Employees                              | \$ 233                  | \$ 321        |
| Nonemployees                           | 30                      | 10            |
| Total stock-based compensation expense | <u>\$ 263</u>           | <u>\$ 331</u> |

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 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<br>OPTIONS | WEIGHTED-<br>AVERAGE<br>EXERCISE<br>PRICE PER<br>SHARE | WEIGHTED-<br>AVERAGE<br>REMAINING<br>CONTRACTUAL<br>LIFE (YEARS) | AGGREGATE<br>INTRINSIC<br>VALUE<br>(000S) |
|---|----------------------|--|--|---|
| Balance—December 31, 2019                         | 1,837,965            | \$ 0.68  | 8.19   | \$ 10                                     |
| Granted   | 21,610,797           | 0.26   |  |   |
| Exercised   | (385,816)            | 0.73   |  |   |
| Cancelled and forfeited                           | (1,563,243)          | 0.58   |  |   |
| Balance—December 31, 2020                         | <u>21,499,703</u>    | \$ 0.26  | 9.79   | \$ 8                                      |
| Options exercisable – December 31, 2020           | <u>1,701,374</u>     | \$ 0.33  | 8.17   | \$ 1                                      |
| Unvested and expected to vest – December 31, 2020 | <u>21,073,329</u>    | \$ 0.25  | 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 \$0.35 per share and \$0.19 per share, respectively.

**Restricted Stock Awards**

In October 2020, in conjunction with the Series C redeemable convertible preferred stock issuance, the Company restricted 575,132 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

**Vera Therapeutics, Inc.**  
**Notes to Financial Statements**  
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vesting term of restricted stock is one year. The grant date fair value of the restricted shares was \$0.55. The following table summarizes the activity for the Company's restricted stock for the year ended December 31, 2020.

|                                  | <u>NUMBER OF SHARES</u> |
|----------------------------------|-------------------------|
| Unvested as of December 31, 2019 | 119,820                 |
| Granted                          | 575,132                 |
| Vested                           | <u>(215,675)</u>        |
| Unvested as of December 31, 2020 | <u>479,277</u>          |

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 allowed the CMU License Agreement to expire in 2019 without achieving any of the development or sales milestones. Accordingly, no royalty or development milestone payments were 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

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**(Dollar amounts in thousands, except per share data)**

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 atacacept, 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.

|                                  | DECEMBER 31, |      |
|----------------------------------|--------------|------|
|                                  | 2019         | 2020 |
| Current:                         |              |      |
| Federal                          | \$ —         | \$ — |
| State                            | 1            | 1    |
| Total current provision          | 1            | 1    |
| Total deferred provision         | —            | —    |
| Total provision for income taxes | \$ 1         | \$ 1 |

**Vera Therapeutics, Inc.**  
**Notes to Financial Statements**  
(Dollar amounts in thousands, except per share data)

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                    | 2020        |
| 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                         | <u>\$ 1</u>             | <u>\$ 1</u> |

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.

|   | DECEMBER 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 | <u>\$ 66</u> | <u>\$ —</u> |
| Deferred tax liabilities:                             |              |             |
| Property and equipment                                | (66)         | —           |
| Total deferred tax liabilities                        | <u>(66)</u>  | <u>—</u>    |
| Net deferred tax assets                               | <u>\$ —</u>  | <u>\$ —</u> |

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.

**Vera Therapeutics, Inc.**  
**Notes to Financial Statements**  
**(Dollar amounts in thousands, except per share data)**

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 the 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<br>LEASES (1) | SUBLEASE<br>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           | <u>\$ 11,780</u>        | <u>\$ (8,823)</u>  |

(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.

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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.

**Vera Therapeutics, Inc.**  
**Notes to Financial Statements**  
**(Dollar amounts in thousands, except per share data)**

The activity related to the restructuring liabilities for the years ended December 31, 2019 and 2020 are as follows.

|                                 | LEASE-RELATED<br>EXIT COSTS | EMPLOYEE<br>TERMINATION | 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 | <u>\$ 2,584</u>             | <u>\$ 12</u>            | <u>\$2,596</u> |

### 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).

|   | DECEMBER 31,      |                    |
|---|-------------------|--------------------|
|   | 2019              | 2020               |
| Redeemable convertible preferred stock              | 14,015,773        | 182,772,372        |
| Class A common stock options issued and outstanding | 1,837,965         | 21,499,703         |
| Unvested restricted stock awards                    | 119,820           | 479,277            |
| Total   | <u>15,973,558</u> | <u>204,751,352</u> |

### 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.

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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.)

**15. SUBSEQUENT EVENTS**

The Company evaluated events subsequent to December 31, 2020 through March 19, 2021, the date at which the financial statements were available to be issued.

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. The consideration receivable at closing under the asset purchase agreement will be \$808 in cash and shares of Neubase common stock equal to \$2,904 divided by the average of the volume weighted average closing price per share of Neubase common stock, as reported on Nasdaq, for the 60 consecutive trading day period ending on the fifth trading day prior to the closing date. A certain number of shares of Neubase common stock to be received equal to \$1,904 divided by the average of the volume weighted average closing price per share of Neubase common stock, as reported on Nasdaq, for the 60 consecutive trading days' period ending on the fifth trading day prior to the closing date will be placed in escrow to secure certain obligations under the agreement. In addition, Neubase will be assuming certain related liabilities. The sale is subject to certain closing conditions and is pending completion.

## Shares



## Common Stock

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Preliminary Prospectus

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**Jefferies**

**Cowen**

**Evercore ISI**

, 2021

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**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 and The Nasdaq Global Market (Nasdaq) listing fee.

|   |           |          |
|---|-----------|----------|
| SEC registration fee                        | \$        | *        |
| FINRA filing fee                            |           | *        |
| Nasdaq listing fee                          |           | *        |
| Printing and engraving expenses             |           | *        |
| Legal fees and expenses                     |           | *        |
| Accounting fees and expenses                |           | *        |
| Custodian transfer agent and registrar fees |           | *        |
| Miscellaneous expenses                      |           | *        |
| <b>Total</b>                                | <b>\$</b> | <b>*</b> |

\* 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 that will be in effect immediately after the closing of this offering permits indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the DGCL, and our amended and restated bylaws that will be in effect upon the closing of this offering 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.

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The underwriters are obligated, under certain circumstances, under the underwriting agreement to be filed as Exhibit 1.1 to this Registration Statement, to indemnify us and our officers and directors against liabilities under the Securities Act.

### **Item 15. Recent Sales of Unregistered Securities.**

Set forth below is information regarding unregistered securities issued by us since January 1, 2018.

#### ***Equity Plan-Related Issuances***

1. Since January 1, 2018, we have granted to certain of our directors, employees and consultants options to purchase 23,585,892 shares of our common stock with per share exercise prices ranging from \$0.20 to \$0.91 under the 2017 Plan.
2. Since January 1, 2018, we have issued to certain of our directors, employees and consultants an aggregate of 1,987,244 shares of our common stock at per share purchase prices ranging from \$0.00213 to \$0.91 pursuant to exercises of options under the PNA Stock Plan and 2017 Plan for an aggregate purchase price of \$680,446.42.

#### ***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 15 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) and (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.

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### **Item 16. Exhibits and Financial Statement Schedules.**

(a) Exhibits.

| <u>EXHIBIT<br/>NUMBER</u> | <u>DESCRIPTION</u>  |
|---------------------------|---|
| 1.1+                      | Form of Underwriting Agreement.   |
| 3.1+                      | Fourth Amended and Restated Certificate of Incorporation, as currently in effect.   |
| 3.2+                      | Form of Fifth Amended and Restated Certificate of Incorporation, to be in effect immediately after the closing of the offering.                 |
| 3.3+                      | Second Amended and Restated Bylaws, as currently in effect.   |
| 3.4+                      | Form of Third Amended and Restated Bylaws, to be in effect upon the closing of the offering.  |
| 4.1+                      | Form of Common Stock Certificate.   |
| 4.2+                      | Second Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated October 29, 2020.   |
| 5.1+                      | Opinion of Cooley LLP.  |
| 10.1+                     | Vera Therapeutics, Inc. 2017 Equity Incentive Plan.   |
| 10.2+                     | Forms of Grant Notice, Stock Option Agreement and Notice of Exercise under the Vera Therapeutics, Inc. 2017 Equity Incentive Plan.              |
| 10.3+                     | Vera Therapeutics, Inc. 2021 Equity Incentive Plan.   |
| 10.4+                     | Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Vera Therapeutics, Inc. 2021 Equity Incentive Plan. |
| 10.5+                     | Forms of Restricted Stock Unit Grant Notice and Award Agreement under the Vera Therapeutics, Inc. 2021 Equity Incentive Plan.                   |
| 10.6+                     | Vera Therapeutics, Inc. 2021 Employee Stock Purchase Plan.  |
| 10.7+                     | Vera Therapeutics, Inc. 2021 Non-Employee Director Compensation Policy.   |
| 10.8+                     | Form of Indemnification Agreement by and between the Registrant and its directors and executive officers.                                       |
| 10.9+                     | Amended and Restated Offer Letter by and between the Registrant and Marshall Fordyce, M.D., dated December 22, 2020.                            |
| 10.10+                    | Offer Letter by and between the Registrant and Joanne Curley, Ph.D., dated February 5, 2020.  |
| 10.11+                    | Amendment to Employment Agreement by and between the Registrant and Joanne Curley, Ph.D., dated September 3, 2020                               |
| 10.12+                    | Confidential Consulting Agreement by and between the Registrant and FLG Partners, LLC, dated March 15, 2020.                                    |
| 10.13+                    | Offer Letter by and between the Registrant and Allen Ebens, Ph.D., dated July 26, 2018.   |
| 10.14+                    | Transition and Separation Agreement by and between the Registrant and Allen Ebens, Ph.D., dated August 5, 2020.                                 |
| 10.15*                    | License Agreement by and between the Registrant and Ares Trading S.A., dated as of October 29, 2020.  |
| 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).   |
| +                         | To be filed by amendment.   |

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\* Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit (indicated by asterisks) have been omitted.

(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) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant under the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the U.S. 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.

(c) 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 on Rule 430A and contained in a form of prospectus filed by the registrant under Rule 424(b)(1) or (4) or 497(h) under the Securities Act will 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 of 1933, as amended, each post-effective amendment that contains a form of prospectus will be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time will 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 South San Francisco, State of California on \_\_\_\_\_, 2021.

#### VERA THERAPEUTICS, INC.

By: \_\_\_\_\_  
Name: Marshall Fordyce, M.D.  
Title: Chief Executive Officer

### POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Marshall Fordyce, M.D. and Jonathan Wolter, 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.

| <u>SIGNATURE</u>                   | <u>TITLE</u>   | <u>DATE</u> |
|------------------------------------|--|-------------|
| _____<br>Marshall Fordyce, M.D.    | President, Chief Executive Officer and Director<br>(Principal Executive Officer) | , 2021      |
| _____<br>Jonathan Wolter           | Chief Financial Officer<br>(Principal Financial and Accounting Officer)          | , 2021      |
| _____<br>Kurt von Emster, C.F.A.   | Chairperson of the Board   | , 2021      |
| _____<br>Andrew Cheng, M.D., Ph.D. | Director   | , 2021      |
| _____<br>Beth Seidenberg, M.D.     | Director   | , 2021      |
| _____<br>Maha Katabi, Ph.D.        | Director   | , 2021      |
| _____<br>Patrick Enright           | Director   | , 2021      |
| _____<br>Scott Morrison            | Director   | , 2021      |

\*\*\* = Certain marked information has been omitted from this exhibit because it is both not material and is the type that the registrant treats as private or confidential.

Execution Version

**LICENSE AGREEMENT**

**dated October 29, 2020**

**by and between**

**Vera Therapeutics, Inc.**

**and**

**Ares Trading S.A.**

## LICENSE AGREEMENT

This License Agreement (“**Agreement**”) is entered into as of October 29, 2020 (the “**Effective Date**”) by and between:

- (1) **Vera Therapeutics, Inc.**, a corporation organized under the laws of Delaware, located at 170 Harbor Way, 3<sup>rd</sup> Floor, South San Francisco, CA 94080, USA (“**Company**”); and
- (2) **Ares Trading S.A.**, a corporation organized under the laws of Switzerland, located at Zone Industrielle de l’Ourietaz, CH-1170 Aubonne, Switzerland (“**ATSA**”).

Company and ATSA each may be referred to herein individually as a “**Party**” or collectively as the “**Parties**”.

## RECITALS

**WHEREAS**, ATSA is engaged, among other activities, in the development of pharmaceutical products and Controls (as defined below) several rights in the Compound (as defined below);

**WHEREAS**, ATSA wishes to license and/or sublicense to Company on an exclusive basis, the right to develop, manufacture and commercialize products comprising the Compound (as defined below) in the Field (as defined below).

**NOW, THEREFORE**, in consideration of the promises and mutual covenants contained herein, the Parties agree as follows.

## ARTICLE 1 - DEFINITIONS

For purposes of this Agreement, the following capitalized terms will have the following meanings:

- 1.1. “**Accounting Standards**” means GAAP or IFRS, as generally and consistently applied by the relevant Person.
- 1.2. “**Acquired Competing Product**” has the meaning set forth in Section 10.7(b).
- 1.3. “**Acquiring Party**” has the meaning set forth in Section 10.7(b).
- 1.4. “**Action**” has the meaning set forth in Section 6.5(b).
- 1.5. “**Additional Third Party License**” has the meaning set forth in Section 6.1(b).
- 1.6. “**Affiliate**” means a Person that controls, is controlled by or is under common control with another Person, but only for so long as such control exists. For the purposes of this Section, the word “**control**” (including, with correlative meaning, the terms “**controlled by**” or “**under the common control with**”) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person, whether by the ownership of at least fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.
- 1.7. “**Agreement**” has the meaning set forth in the preamble.
- 1.8. “**Alliance Manager**” has the meaning set forth in Section 4.2.
- 1.9. “**Applicable Laws**” means any applicable supranational, federal, state, local or foreign law, statute, ordinance or principle of common law, or any rule, regulation, standard (e.g. cGMP), judgment, order, writ, injunction, decree, arbitration award, agency guidelines or other requirement, license or permit of any Governmental Body, which may be in effect from time to time.

1.10. “**Approval Application**” means an NDA or similar application or submission for a Product filed with a Regulatory Authority in a country or group of countries to obtain marketing approval for a biological or pharmaceutical product in that country or group of countries.

1.11. “**APRIL**” means A Proliferation Inducing Ligand.

1.12. “**Atacicept**” has the meaning set forth in Section 1.34.

1.13. “**ATSA**” has the meaning set forth in the preamble.

1.14. “**ATSA Equity Consideration**” has the meaning set forth in Section 5.9.

1.15. “**ATSA Indemnitees**” has the meaning set forth in Section 9.2.

1.16. “**ATSA Know-How**” means all Compound related or Existing Product related Know-How that is owned or Controlled by ATSA or any of its Affiliates (a) as of the Effective Date, including that received from Third Parties to the extent sublicensable or otherwise permissible to provide it, but solely to the extent ATSA has an obligation to provide such Know-How by way of technology transfer or Know-How transfer pursuant to this Agreement; or (b) during the Term, solely in connection with ATSA’s manufacturing activities with respect to Product, in each case, that is necessary or reasonably useful in the Research, Development, manufacture, use, or Commercialization of the Compound or the Product in the Territory in the Field.

1.17. “**ATSA Patents**” means (a) the Patent Rights listed in **Schedule 1.17**, as well as those Compound related or Existing Product related Patent Rights according to Section 6.2(c)(i) and Section 6.2(c)(iii) that are filed by ATSA, in each case, that are necessary or reasonably useful for the Research, Development, manufacture, use, or Commercialization of the Compound or the Product in the Territory in the Field and (b) any other Patent Rights that are owned or Controlled by ATSA or any of its Affiliates as of the Effective Date or during the Term, that claim or cover (i) the composition of a Compound, (ii) the method of using a Compound or Existing Product in the prevention, treatment, diagnosis, detection or monitoring of any Indication or (iii) a method of manufacturing a Compound or Existing Product solely as used by or on behalf of ATSA or its Affiliates as of the Effective Date or during the Term in connection with ATSA’s manufacturing activities with respect to the Product; provided, that, ATSA Patents shall exclude Patent Rights that specifically cover or claim Other Components.

1.18. “**ATSA Technology**” means the ATSA Know-How and the ATSA Patents, collectively.

1.19. “**BlyS**” means B Lymphocyte Stimulator.

1.20. “**Business Day**” means a day other than Saturday or Sunday on which banking institutions in San Francisco, California, New York, New York, Vaud, Switzerland, Rome, Italy and Darmstadt, Germany are open for business.

1.21. “**Calendar Quarter**” means each three (3) month period commencing January 1, April 1, July 1 or October 1, provided, however, that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end on the date of termination or expiration of this Agreement.

1.22. “**Calendar Year**” means the period beginning on January 1 and ending on December 31 of the same year, provided, however, that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the same year and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

1.23. “**Change of Control**” means, with respect to a Person: (a) a transaction or series of related transactions that results in the sale or other disposition of all or substantially all of such Person’s assets; or (b) a merger or consolidation in which such Person is not the surviving corporation or in which, if such Person is the surviving corporation, the shareholders of such Person immediately prior to the consummation of such merger or consolidation do not, immediately after consummation of such merger or consolidation, possess, directly or indirectly through one or more intermediaries, a majority of the voting power of all of the surviving entity’s outstanding stock and other securities and the power to elect a majority of the members of such Person’s board of directors; or (c) a transaction or series of related transactions (which may include a tender offer for such Person’s stock or the issuance, sale or exchange of stock of such Person) if the shareholders of such Person immediately prior to the initial such transaction do not, immediately after consummation of such transaction or any of such related transactions, own, directly or indirectly through one or more intermediaries, stock or other securities of the entity that possess a majority of the voting power of all of such Person’s outstanding stock and other securities and the power to elect a majority of the members of such Person’s board of directors.

1.24. “**Clinical Study Report**” means the study report to be prepared with respect to the Existing Clinical Study.

1.25. “**Clinical Trial**” means a clinical trial in human subjects that has been approved by a Regulatory Authority and Institutional Review Board or Ethics Committee and is designed to measure the safety or efficacy of a pharmaceutical product. Clinical Trials shall include Phase I Trials, Phase II Trials and Phase III Trials.

1.26. “**Combination Product**” means any pharmaceutical product that comprises (a) a Product and (b) Other Components.

1.27. “**Commercialization**” or “**Commercialize**” means any and all activities undertaken before or after Marketing Approval for a particular Product and directed to the commercial exploitation of the Product, including the marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of the Product, and interacting with Regulatory Authorities regarding the foregoing.

1.28. “**Commercialization Plan**” has the meaning set forth in Section 3.2(b).

1.29. “**Commercially Reasonable Efforts**” means the exertion on a substantially continuous basis of efforts as would normally be devoted to the applicable task by commercial parties with similar resources to those of the applicable party, where such parties are highly motivated to accomplish such task to the maximum extent practicable, taking into account, without limitation, consideration of the anticipated safety and efficacy of a subject product, its likely competition, the strength of its proprietary position, regulatory factors, profit potential, and other scientific, medical, legal and commercial factors. Commercially Reasonable Efforts will not mean that a party commits that it will actually accomplish the applicable task, or that it will devote thereto efforts or resources beyond those that a prudent commercial enterprise would devote, even though remaining motivated to do so as described above.

1.30. “**Company**” shall have the meaning set forth in the preamble.

1.31. “**Company Indemnitees**” has the meaning set forth in Section 9.1.

1.32. “**Company Terminated Product Technology**” means, with respect to a Terminated Product in the form and formulation such Terminated Product exists as of the applicable effective date of termination, all Patent Rights and Know-How Controlled by Company as of the effective date of termination of this Agreement that (a) was developed or invented during the Term by or on behalf of Company, its Affiliates or Sublicensees in the Development, manufacture or Commercialization of Compounds or Products and (b) is necessary for, or was otherwise used by Company, its Affiliates or Sublicensees in, the Development, manufacture or Commercialization of such Terminated Product.

1.33. “**Competing Product**” means any dual inhibitor that inhibits both of the following two biological targets: (a) BlyS and (b) APRIL in any dosage form, formulation, presentation or package configuration which is developed or commercialized in the Field.

1.34. “**Compound**” means (a) the investigational recombinant fusion protein known as “atacept”, as set forth in **Schedule 1.34 (“Atacept”)**, (b) any TACI-Ig Fusion Molecule the composition of matter of which is covered by a claim of any of the ATSA Patents set forth in **Schedule 1.17**, and (c) any prodrug, derivative, conjugate or fusion of a compound in the preceding (a) or (b), and including any Further Linked TACI-Ig Fusion Molecule.

1.35. “**Confidential Information**” of a Party means information relating to the business, operations or products of such Party or any of its Affiliates, including this Agreement, and including any Know-How that such Party or any of its Affiliates discloses to the other Party or its respective Affiliate under this Agreement, or otherwise becomes known to the other Party or its Affiliate by virtue of this Agreement.

1.36. “**Controlled**” means, with respect to (a) Patent Rights, (b) Know-How or (c) biological, chemical or physical material, that the Party or one of its Affiliates owns or has a license or sublicense to such right, item, or material (or in the case of material, has the right to physical possession of such material) and has the ability to grant a license or sublicense to, or assign its right, title and interest in and to, such right, item or material as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party, in particular such Third Party that has assigned or licensed such Patent Rights, Know-How or material to such Party (or any Affiliate of such Party), provided, that, other than with respect to Existing Third Party Licenses, neither Party shall be deemed to Control any Patent Rights, Know-How, or biological material, or other property right of a Third Party if access under this Agreement requires or triggers a payment obligation to such Third Party, unless the other Party agrees to reimburse the first Party for or otherwise bear the fee or charge associated therewith.

1.37. “**Controlling Party**” has the meaning set forth in Section 6.6(c).

1.38. “**Data Protection Law**” means, to the extent governing the relevant Personal Data, any data protection laws, statutes, or regulations that relate to the protection of a natural person with regard to the Processing of Personal Data in connection with this Agreement such as, to the extent applicable, the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (“**General Data Protection Regulation**” or “**GDPR**”).

1.39. “**Development**” means, with respect to a Compound or Product, all non-clinical research and clinical development activities conducted after filing of an IND for such Compound or Product, including toxicology, pharmacology test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, Clinical Trials (other than post-Marketing Approval Clinical Trials), regulatory affairs, pharmacovigilance, Clinical Trial regulatory activities and obtaining and maintaining Marketing Approval. When used as a verb, “**Develop**” or “**Developing**” means to engage in Development.

1.40. “**Development Plan**” shall have the meaning set forth in Section 3.1(b).

1.41. “**Drug Product**” means the final formulation containing Drug Substance in a formulation for use in clinical trials. For the avoidance of doubts this does not mean the finished product (i.e. formulated product filled in an auto injector).

1.42. “**Drug Substance**” means the drug substance required for the manufacturing of the drug product form of the Product, which is on stock at ATSA on the Effective Date.

1.43. “**Effective Date**” has the meaning set forth in the preamble.

1.44. “**EMA**” means the European Medicines Agency, or any successor agency thereto.

1.45. “**Equity Documentation**” means collectively Company’s Series C Preferred Stock Purchase Agreement, Voting Agreement, Investor Rights Agreement, Right of Refusal and Co-Sale Agreement, and Certificate of Incorporation (the last four of which being amended and restated from those used in the Company’s Series B financing), together with all other appropriate or advisable investment documentation between, among, or relating to, inter alia, the Company, ATSA and all other investors and/or stockholders, dated as of the Effective Date, constituting their respective contractual commitments for the Initial Financing. For clarity, this includes without limitation the Company’s issue to ATSA of agreed shares of Series C Preferred Stock to ATSA as contemplated by Section 5.9, of Series C shares to cash investors of at least \$65,000,000 of cash, and of Series C to all holders of convertible debt, as referenced in the definition of Initial Financing.

1.46. “**European Commission**” means the authority within the European Union that has the legal authority to grant Marketing Approvals in the European Union based on input received from the EMA or other competent Regulatory Authorities.

1.47. “**European Union**” or “**EU**” means the European Union, as may be redefined from time to time.

1.48. “**Existing Clinical Study**” means the Clinical Trial listed in Schedule 1.48.

1.49. “**Existing Product**” means the Product as it exists as of the Effective Date.

1.50. “**Existing Third Party Licenses**” has the meaning set forth in Section 6.1(a).

1.51. “**FDA**” means the United States Food and Drug Administration, or any successor agency thereto.

1.52. “**FD&C Act**” means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.

1.53. “**Field**” means any and all uses, including the prevention, treatment, diagnosis, detection, and monitoring of any disease, disorder or condition in humans and animals.

1.54. “**First Commercial Sale**” means, with respect to a country in the Territory, the first sale or commercial transfer or disposition for value of the Product to a Third Party by Company, its Affiliates or Sublicensees in such country after receipt of Marketing Approval in such country for such Product. Only sales under the definition of “Net Sales” are considered to determine First Commercial Sales.

1.55. “**Further Linked TACI-Ig Fusion Molecule**” means any TACI-Ig Fusion Molecule in which TACI-Ig is further linked to another protein or protein domain with immune-modulating activity.

1.56. “**Generic Competition**” has the meaning set forth in Section 5.2(c)(iii).

1.57. “**Good Manufacturing Practices**” or “**cGMP**” shall mean the then current Good Manufacturing Practices as such term is defined from time to time by the FDA or analogous set of regulations, guidelines or standards as defined by other relevant Regulatory Authority having jurisdiction over the Development, manufacture or sale of Product in a particular jurisdiction of the Territory, if and to the extent the Development, manufacture or sale of Product takes place in such jurisdiction.

1.58. “**Governmental Body**” means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

1.59. “**IFRS**” or “**International Financial Reporting Standards**” means the set of accounting standards and interpretations and the framework in force on the Effective Date and adopted by the European Union as issued by the International Accounting Standards Board (“**IASB**”) and the International Financial Reporting Interpretations Committee (“**IFRIC**”), as such accounting standards may be amended from time to time.

1.60. “**Improper Conduct**” has the meaning set forth in Section 12.1.

1.61. “**IND**” means an investigational new drug application filed with the FDA or the equivalent application or filing filed with any equivalent agency or Governmental Body outside the United States (including any supra-national entity such as in the European Union) for approval to commence Clinical Trials in such jurisdiction, and including all regulations at 21 U.S. CFR § 312 et seq. and equivalent foreign regulations.

1.62. “**Indemnified Party**” has the meaning set forth in Section 9.3.

1.63. “**Indemnifying Party**” has the meaning set forth in Section 9.3.

1.64. “**Indication**” means any generally acknowledged disease or condition, a significant manifestation of a disease or condition, or symptoms associated with a disease or condition, or a risk for a disease or condition for which an NDA may be obtained. For clarity, (a) moving from one line of therapy to another within an Indication will not be considered to be a new Indication, a non-limiting example of which is moving from second line therapy to first line therapy, (b) a single Indication would include the primary disease and all variants or sub-divisions or sub-classifications within such primary disease (a non-limiting example of which is that breast cancer would be a single Indication, regardless of type of breast cancer), and regardless of prophylactic or therapeutic use, pediatric or adult use and irrespective of different formulation(s), dosage forms, dosage strengths, or delivery system(s) used, and (c) obtaining a label expansion for use of the Product in combination with another pharmaceutical product will not be considered to be a new Indication.

1.65. “**Initial Financing**” means the execution of the Equity Documentation by all applicable parties thereto on the Effective Date of this Agreement, and the issue and sale at the “Initial Closing” portion and at any “Additional Closing” portion of such Initial Financing of the Company’s Series C Preferred Stock as referenced in the Equity Documentation’s Stock Purchase Agreement, where the Initial *Financing*’s Initial *Closing* involves (a) the Company’s receipt of gross cash proceeds of at least USD \$65,000,000 (not counting any shares paid for with convertible debt) in exchange for Series C Shares, and with a commitment by the Company to use the funds primarily to finance the Research, Development and Commercialization of the Compound or Product under the Agreement, (b) the issue to ATSA of the ATSA Equity Consideration with respect to this Agreement, and (c) the conversion of all convertible debt in exchange for Series C Shares.

1.66. “**Initial Indication**” means any of the following Indications: systemic lupus erythematosus, lupus nephritis, and cutaneous lupus.

1.67. “**Initiation**” means the notification from ATSA to Company after the effective date of the Manufacturing Quality Agreement that the first tranche of the Inventory is ready for delivery.

1.68. “**Inventory**” means the inventory of Compound and placebo listed in **Schedule 1.68** as at the Effective Date to be delivered to Company which is not required by ATSA to meet its obligation regarding the Existing Clinical Study.

1.69. “**Know-How**” means any: (a) scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including discoveries, inventions, trade secrets, devices, databases, practices, protocols, regulatory filings, methods, processes (including manufacturing processes, specification and techniques), techniques, concepts, ideas, specifications, formulations, formulae, data (including pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), case reports forms, medical records, data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), summaries and information contained in submissions to and information from ethical committees, or Regulatory Authorities, and manufacturing process and development information, results and data, whether or not patentable, all to the extent not claimed or disclosed in a patent or patent application; and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material, including drug substance samples, intermediates of drug substance samples, drug product samples and intermediates of drug product samples. “**Know-How**” includes any rights including copyright, database or design rights protecting such Know-How. “**Know-How**” excludes Patent Rights.

1.70. “**Knowledge**” means the knowledge of the following ATSA executives, after diligent inquiry of [\*\*\*] immediately prior to the Effective Date: [\*\*\*].

1.71. “**Licensee Patents**” has the meaning set forth in Section 6.3(a).

1.72. “**Losses**” has the meaning set forth in Section 9.1.

1.73. “**Major European Countries**” means any of [\*\*\*].

1.74. “**Major Market**” means any of the [\*\*\*].

1.75. “**Manufacturing Quality Agreement**” means the quality assurance agreement, which shall outline Parties’ respective responsibilities on quality matters, being entered into by the Parties in conjunction herewith prior to the delivery of the Inventory, covering all quality assurance agreements being entered into by the Parties in conjunction with manufacturing needs of the -Drug Product.

1.76. “**Marketing Approval**” or “**MA**” means, with respect to a Product in a particular jurisdiction, all approvals, licenses, registrations or authorizations by Regulatory Authorities necessary for the Commercialization of such Product in such jurisdiction, including, with respect to the United States, approval of an Approval Application for such Product by the FDA, with respect to the European Union, approval of an Approval Application for such Product by the European Commission, and with respect to Japan, approval of an Approval Application for such Product by the Pharmaceuticals and Medical Devices Agency, or the applicable Regulatory Authority in any particular country in the EU. For clarity, Marketing Approval does not include Price Approval.

1.77. “**Milestone Event**” means each of the milestone events listed in **Schedule 1.77**.

1.78. “**Milestone Payment**” means the milestone payment regarding a respective Milestone Event listed in **Schedule 1.77**.

1.79. “**NDA**” means a New Drug Application filed pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 314.3 et seq., a Biologics License Application filed pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 601, and any equivalent application submitted in any country in the Territory, including all additions, deletions or supplements thereto, and as any and all such requirements may be amended, or supplanted, at any time.

1.80. “**Net Sales**” means the gross invoiced price for Products sold by Company, its Affiliates or Sublicensees (the “**Selling Party**”) to independent or unaffiliated Third Party purchasers (excluding sales deferred for IFRS accounting purposes until such sales are recognized), less the following deductions with respect to such sales that are either included in the billing as a line item as part of the gross amount invoiced, or otherwise documented as a deduction in accordance with applicable Accounting Standards to be specifically attributable to actual sales of such Products:

(a) credits or allowances on account of price adjustments, recalls, claims, damaged goods, rejections or returns of items previously sold (including Product returned in connection with recalls or withdrawals);

(b) insurance, customs charges, freight, shipping and other transportation costs incurred in shipping Products to such non-related parties, to the extent [\*\*\*];

(c) sales, excise and use taxes and any other governmental charges (including value added tax) actually paid in connection with the distribution, use or sale of such Product;

(d) discounts (including trade, quantity, and cash discounts), cash and non-cash coupons, retroactive price reductions, and charge back payments and rebates granted to any non-related party (including to governmental entities or agencies, purchasers, reimbursers, customers, distributors, wholesalers, and group purchasing organizations and managed care organizations (and other similar entities and institutions)); and

(e) rebates (or their equivalent), chargebacks and retroactive price adjustments and any other similar allowances granted to non-related parties (including to governmental entities or agencies, purchasers, reimbursers, customers, Distributors, wholesalers, and managed care organizations (and other similar entities and institutions)) that [\*\*\*].

Only items that are deducted from the Selling Party’s gross sales of Product(s), as included in the Selling Party’s published financial statements or other audited financial statements and that are in accordance with applicable Accounting Standards will be deducted from such gross sales for purposes of the calculation of Net Sales.

A qualifying amount may be deducted only once regardless of the number of the preceding categories that describe such amount. If a Selling Party makes any adjustment to such deductions after the associated Net Sales have been reported pursuant to this Agreement, the adjustments and payment of any royalties due will be reported with the next quarterly report. Sales between or among Company, its Affiliates and Sublicensees will be excluded from the computation of Net Sales if such sales are not intended for end use, but Net Sales will include the subsequent final sales to Third Parties by Company or any such Affiliates or Sublicensees.

Notwithstanding the foregoing, Net Sales will not include transfers of Product for the performance of Clinical Trials or sales such as so-called "treatment IND sales," "name patient sales," "compassionate use sales" and sales in early access programs, including French ATU.

Net Sales for a Combination Product in a country shall be calculated as follows:

(i) Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination Product by the fraction  $A/C$ , where A is the average sale price of an equivalent quantity of the Product incorporated into such Combination Product when sold separately in finished form in the same geographical market, and C is the average sales price of the Combination Product.

(ii) If the Product incorporated into such Combination Product is not sold separately in finished form in the same geographical market, the Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination Product by the fraction  $(C - B)/C$ , where B is the average sale price of an equivalent quantity of the Other Component(s) when sold separately in finished form in the same geographical market and C is the average sale price of the Combination Product.

(iii) If neither the Product nor the other component(s) is sold independently in such country a market price for the Product and the other component(s) shall be negotiated by the Parties in good faith based upon [\*\*\*]. In case of disagreement, an independent expert agreed upon by both Parties or, failing such agreement, designated by the International Chamber of Commerce, shall determine such relative value contributions and such determination shall be final and binding upon the Parties.

The average sale price of a Product, Other Component(s) or Combination Product shall be calculated using data from sales made during the entire immediately preceding calendar year.

1.81. "**Other Component**" means any other pharmacologically active compound or value-added delivery system that is: (a) included in any Combination Product; and (b) not a Compound or a Product.

1.82. "**Partnering Notice**" shall have the meaning set forth in Section 3.2(b).

1.83. "**Party**" or "**Parties**" shall have the meaning set forth in preamble.

1.84. "**Patent Right(s)**" means (a) all national, regional and international patent applications, including provisional patent applications, (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, 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, renewals, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b), and (c)).

1.85. “**Person**” means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.

1.86. “**Personal Data**” as used in this Agreement shall mean any information or data that constitutes “personal information”, “personal data” or similar term governed by applicable Data Protection Laws and does not include information pertaining to a Party’s business contacts such as its employees, agents or representatives or those of their respective Affiliates.

1.87. “**Phase I Trial**” means a Clinical Trial in which the Product is administered to human subjects at multiple dose levels with the primary purpose of determining safety, metabolism, and pharmacokinetic and pharmacodynamic properties of the Product, and consistent with 21 U.S. CFR § 312.21(a).

1.88. “**Phase II Trial**” means a Clinical Trial of the Product in human patients, the principal purposes of which are to make a preliminary determination that the Product is safe for its intended use, to determine its optimal dose, and to obtain sufficient information about the Product’s efficacy to permit the design of Phase III Trials, and consistent with 21 U.S. CFR 312.21(b).

1.89. “**Phase III Trial**” means a human Clinical Trial of the Product, which trial is designed (a) to establish that the Product is safe and efficacious for its intended use; (b) to define warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed; and (c) consistent with 21 U.S. CFR § 312.21(c).

1.90. “**Phase IIIb Trial**” means a pivotal Clinical Trial of the Product that is initiated following submission of a marketing application but prior to receipt of Marketing Approval for the Indication(s) being studied.

1.91. “**Pivotal Clinical Trial**” means any Clinical Trial of the Product designed to fulfill the requirements for Marketing Approval, including Phase III Trials and Phase IIIb Trials.

1.92. “**Price Approval**” means, in any country where a Governmental Body authorizes reimbursements for, or approves or determines pricing for, pharmaceutical products, receipt or publication (if required to make such authorization, approval or determination effective) of such reimbursement authorization or pricing approval or determination.

1.93. “**Processing**” has the meaning given to such term or similar term in applicable Data Protection Law and shall include any operation or set of operations that is performed on Personal Data or sets of Personal Data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction. “Process” and “Processed” shall be construed accordingly.

1.94. “**Product**” means, with respect to the Field, any pharmaceutical product, including any dosage form or formulation thereof, that contains or comprises, in whole or in part, the Compound.

1.95. “**Regulatory Approval**” means any and all approvals, licenses, registrations, or authorizations of the relevant Regulatory Authority necessary for the Development, manufacture or Commercialization of a Product in a particular country or jurisdiction.

1.96. “**Regulatory Authority**” means (a) in the US, the FDA, (b) in the EU, the EMA or the European Commission, or (c) any Governmental Body with similar regulatory authority over pharmaceutical or biotechnology products in any other jurisdiction anywhere in the world.

1.97. “**Regulatory Milestone Event**” means any of the Milestone Events listed as numbers 3. through 14. in **Schedule 1.77**.

1.98. “**Research**” means conducting research activities to discover, design, optimize, deliver and advance Compound and Products, including pre-clinical studies and optimization, but specifically excluding Development, manufacture and Commercialization.

1.99. “**ROFN Period**” shall have the meaning set forth in Section 3.2(b).

1.100. “**Royalty Term**” has the meaning set forth in Section 5.2(d).

1.101. “**Sales-Based Milestone Event**” means any of the Milestone Events listed as numbers 15. through 19. in **Schedule 1.77**.

1.102. “**Selling Party**” has the meaning set forth in Section 1.80.

1.103. “**Senior Officer**” means a member of senior management of a Party who is designated by such Party to resolve disputes under this Agreement.

1.104. “**Sublicense Income**” means any consideration received by Company from a Third Party Sublicensee that is not a royalty based on Net Sales of a Product, in each case, to the extent attributable to a sublicense by Company to a Third Party of the rights granted by ATSA to Company under this Agreement. Notwithstanding the foregoing, Sublicense Income shall exclude payments received by Company from Sublicensee that are (i) made in advance of or to reimburse bona fide costs and expenses incurred by Company, including research, pre-clinical and clinical costs and expenses, manufacturing costs and expenses included as part of a research program budget, and patent expense reimbursements, on or after the effective date of such sublicense, (ii) payments for the cost of supply of Products or Compound provided by Company to Sublicensee, (iii) the attributed (non-monetary) value of any sublicense granted by Company to a Third Party as part of a cross-license arrangement in connection with the settlement of any claims of infringement relating to the Compound, (iv) as loans to Company or its Affiliate, in an arms’ length, full recourse debt financing of Company or its Affiliate; and (v) amounts received by Company as the purchase price, at fair market value, for equity securities.

1.105. “**Sublicensee**” means a Person, including an Affiliate of Company to which Company or another Sublicensee has, pursuant to Section 2.2, granted sublicense rights under any of the license rights granted under Section 2.1.

1.106. “**TACI-Ig Fusion Molecule**” means a molecule comprising: (a) the TACI (transmembrane activator and calcium modulator and cyclophilin ligand-interactor) extracellular domain or a fragment or a variant thereof which binds to either BlyS or APRIL (or both BlyS and APRIL); and (b) an immunoglobulin-constant domain.

1.107. “**TC**” shall have the meaning set forth in Section 4.1(a).

1.108. “**Technology Transfer Plan**” has the meaning set forth in Section 2.4.

1.109. “**Term**” shall have the meaning set forth in Section 10.1.

1.110. “**Terminated Product**” means any Product with respect to which this Agreement is terminated.

1.111. “**Territory**” means all the countries in the world.

1.112. “**Third Party**” means any Person other than Company, ATSA or their respective Affiliates.

1.113. “**Third Party Action**” has the meaning set forth in Section 6.6(a).

1.114. “**United States**” or “**US**” means the United States of America.

1.115. “**USD**” or “**\$**” means the lawful currency of the United States.

1.116. “**Valid Claim**” means a claim of an issued and unexpired patent which has not lapsed or been revoked, abandoned or held unenforceable or invalid by a final decision of a court or Governmental Body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, reexamination or disclaimer or otherwise.

1.117. “**VAT**” means value added tax.

1.118. “**Zymo License**” means that certain First Amended and Restated Development and Marketing Agreement between ATSA and ZymoGenetics, Inc., dated August 28, 2008, pursuant to which ATSA has licensed from ZymoGenetics, Inc. certain of the intellectual property relating to the Compound, together with any and all amendments thereto, but with the exception of the Zymo Side Letter and any amendments directly related to the Zymo Side Letter.

1.119. “**Zymo Side Letter**” has the meaning set forth in Section 8.3(a)(xiv).

## ARTICLE 2 - GRANT OF LICENSE

2.1. **Grant of License.** Subject to the terms and conditions of this Agreement, ATSA hereby grants to Company an exclusive, milestone- and royalty-bearing right and license, or, to the extent intellectual property is concerned which has been licensed to ATSA, sublicense, (in each case, with the right to sublicense in accordance with the provisions of Section 2.2) under the ATSA Technology to Research, Develop, have Developed, manufacture, make, have made, use, sell, offer for sale, have sold, export, import and Commercialize Compounds and Products in the Field in the Territory.

2.2. **Grant of Sublicense by Company.** Company shall have the right to grant sublicenses, in whole or in part, through multiple tiers under the licenses granted in Section 2.1. Each such sublicense will be consistent with the terms of this Agreement and will require such Sublicensee to comply with all applicable terms of this Agreement. Company will remain responsible for each Sublicensee’s compliance with the applicable terms of this Agreement. Within thirty (30) days after the grant of a sublicense, Company will provide a true copy of such sublicense to ATSA.

2.3. **Grant Back License.** Company hereby grants to ATSA a non-exclusive, royalty-free, fully-paid up, sublicensable, transferable, worldwide grant back license under the ATSA Technology, solely as necessary to enable ATSA to (a) complete the specific activities required to complete the Existing Clinical Study in accordance with Section 3.1(d) and (b) perform any of its obligations pursuant to Section 3.4.

**2.4. Manufacturing Technology Transfer.** Promptly after the Effective Date, ATSA shall commence a technology transfer to Company, or its designated Third Party contract manufacturer, of the ATSA Know-How that specifically relates to the manufacture of the Drug Substance and Drug Product (as manufactured as of the Effective Date) in accordance with the technology transfer plan attached to this Agreement as **Schedule 2.4** (the “**Technology Transfer Plan**”). For clarity, ATSA will not be responsible for any delay in performing activities in accordance with the Technology Transfer Plan, to the extent such delay is caused by Company or its designated Third Party contract manufacturer. ATSA will transfer the respective data and documents as is. ATSA shall provide Company [\*\*\*], with [\*\*\*] working hours of assistance to affect such technology transfer. For any technology transfer assistance beyond [\*\*\*] working hours up to and including [\*\*\*] working hours, Company will compensate ATSA at [\*\*\*] per hour. For any technology transfer assistance beyond the [\*\*\*], Company will compensate ATSA at [\*\*\*] per hour. ATSA will submit quarterly invoices to Company for such costs. The technology transfer shall not exceed [\*\*\*] after Effective Date; provided, that, such [\*\*\*] period shall automatically be extended to account for any force majeure described in Section 12.7 or any delay caused by ATSA, its Affiliates or Third Party contractors or vendors.

**2.5. ATSA Know-How Transfer.** ATSA shall transfer to Company within the timelines outlined in **Schedule 2.5** at Company’s cost and expense in accordance with Section 2.4, the ATSA Know-How described in **Schedule 2.5** (except for ATSA Know-How relating to the manufacture of the Compound and the Product, which are subject of Section 2.4). For clarity, ATSA will not be responsible for any delay in performing activities outlined in **Schedule 2.5**, to the extent such delay is caused by Company. In the event either Party identifies any Know-How owned or Controlled by ATSA or its Affiliates as of the Effective Date, including those received from Third Parties to the extent sublicenseable or otherwise permissible to provide it, that (a) is (i) necessary for the Research, Development, manufacture, use or Commercialization of the Compound or the Existing Product in the Territory in the Field or (ii) is as of the Effective Date used by or on behalf of ATSA or its Affiliates in the Development, manufacture, use or Commercialization of the Existing Product in the Territory in the Field, and (b) was not disclosed to Company prior to the Effective Date but Company reasonably would have asked to include such Know-How on **Schedule 2.5** if Company and had been aware of such Know-How prior to the Effective Date, then such Party shall promptly notify the other Party thereof and upon the request of Company, **Schedule 2.5** shall be automatically amended to include such Know-How and ATSA shall promptly provide Company with such Know-How, in each case, at no additional cost to Company. Notwithstanding anything to the contrary in this Agreement, in particular in the foregoing or **Schedule 2.5**, ATSA shall not have an obligation to transfer to Company: (A) any Know-How generated by or on behalf of ATSA or any of its Affiliates using certain particular Further Linked TACI-Ig Fusion Molecules prior to the Effective Date; (B) the identity of the other protein(s) or protein domain(s) with immune-modulating activity within such Further Linked TACI-Ig Fusion Molecule; or (C) the composition of the linker used to link the TACI-Ig Fusion Molecule to such other protein or protein domain with immune-modulating activity, provided that ATSA shall not, after the Effective Date and during the Term, either alone, through, on behalf of or with any Affiliate or Third Party, clinically develop, manufacture, have manufactured, sell, offer for sale, import or export any Further Linked TACI-Ig Fusion Protein in the Territory.

### ARTICLE 3 - RESEARCH, DEVELOPMENT, MANUFACTURING AND COMMERCIALIZATION

#### 3.1. Research and Development of Product by Company.

(a) Generally. Subject to the exception under Section 3.1(d), Company shall have the exclusive right and responsibility to Research and Develop Compounds and Products and to conduct (either itself or through its Affiliates, agents or Sublicensees) all Clinical Trials and non-clinical studies Company believes appropriate to obtain Marketing Approval for the Product in the Field in the Territory.

(b) **Development Plans.** The Development of each Product shall be governed by a development plan which is attached to this Agreement as **Schedule 3.1**, that describes the proposed overall program of Development, the Development assumptions, Development steps and personnel commitment of Company and which shall in particular include, in each case with estimated timelines and milestones to be achieved by Company, (i) a pre-clinical/non-clinical development plan that outlines any significant non-clinical studies to be undertaken by Company, (ii) a clinical development plan that outlines any Clinical Trial to be undertaken by Company to obtain Regulatory Approval in the US, the Major European Countries and Japan and (iii) a plan regarding any other Development activities to be performed by Company as required to obtain such Regulatory Approval (the "**Development Plan**"). The Company shall create and submit a Development Plan to ATSA for review (but not approval) within [\*\*\*] after the Effective Date. The Development Plan shall be based on the initial abbreviated Development Plan attached hereto as **Schedule 3.1**.

(c) No later than [\*\*\*] and [\*\*\*] of each Calendar Year, Company shall provide ATSA with [\*\*\*] updates to the Development Plan, whereas such updates shall take into account the progress and status of Development in any Indication, in particular the completion or cessation of Development activities or commencement of new Development activities.

(d) **Existing Clinical Study.**

(i) Notwithstanding the foregoing, ATSA shall have the right and shall be solely responsible, at its own cost, to complete the specific activities required to complete the Existing Clinical Study in accordance with the existing protocols approved by the Regulatory Authorities; provided, that from the Effective Date any changes to the protocols for the Existing Clinical Study shall be approved by Company. Any additional costs being incurred by ATSA or its Affiliates related to such changes to the protocols of the Existing Clinical Study shall be exclusively born by Company. ATSA shall provide to Company the Clinical Study Report upon finalization of the Existing Clinical Study, but in any event not before [\*\*\*]. ATSA shall timely provide any additional information requested by Company related to the Existing Clinical Study and timely answer any reasonable questions regarding the Clinical Study Report, in each case, to the extent requested or asked by Company within [\*\*\*] of receipt of the Clinical Study Report.

(ii) ATSA shall conduct the Existing Clinical Study in good scientific manner and in compliance with all Applicable Laws and, as applicable, GLP, GCP and/or cGMP. Without limiting the foregoing, ATSA will not engage directly or indirectly, in any capacity in connection with the Existing Clinical Study any Person who either has been debarred by the FDA, is the subject of a conviction described in section 306 of the FD&C Act or subject to any such similar sanction.

### 3.2. Commercialization.

(a) Subject to the terms and conditions of this Agreement, Company shall have the exclusive right to Commercialize Products in the Field in the Territory itself or through one or more Third Parties selected by Company.

(b) The Commercialization of each Product shall be governed by a commercialization plan that describes the proposed overall program of Commercialization, including (i) information on marketing strategy and sales targets, (ii) overview on economic and regulatory conditions, (iii) timelines and activities prior to and after the First Commercial Sale of a Product in a given country in the Territory and (iv) personnel resources required to fulfill such activities in due time, in either such scope of detail as the commercialization plans that ATSA prepares for its own therapeutic products in commercialization or such other scope of detail as otherwise agreed by the Parties (the “**Commercialization Plan**”). The Company shall prepare and provide to ATSA the Commercialization Plan at the latest [\*\*\*] prior to the expected date of Commercialization of the Product and thereafter [\*\*\*] in case of any update.

(c) The first time that the Company determines that it will seek a partner for Commercialization of a Product (except as by way of a Change of Control transaction), the Company shall notify ATSA in writing without delay (the “**Partnering Notice**”). For clarity, an agreement with a contractor, vendor or other Third Party, under which such Third Party performs contract services on behalf of Company or its Affiliates, shall not be subject to this Section 3.2(b). If ATSA provides written notice to Company within [\*\*\*] after receipt of the Partnering Notice by ATSA, then ATSA shall have a one-time right of first negotiation to obtain from the Company such Commercialization rights for a period of up to [\*\*\*] after receipt of the Partnering Notice by ATSA (the “**ROFN Period**”). During the ROFN Period, the Parties shall negotiate in good faith on the terms and conditions under which ATSA may obtain such Commercialization rights, whereby the Parties shall not be obligated to enter into any agreement with regard to such Commercialization rights. During the ROFN Period, the Company may not enter into an agreement with a Third Party in relation to such Commercialization rights or solicit new interest from any Third Party regarding such Commercialization rights; provided, however, that the Company will not be restricted from negotiation with a Third Party that has expressed or subsequently expresses interest in obtaining such Commercialization rights without solicitation from the Company. In the event that (i) ATSA does not provide written notice to Company within such [\*\*\*] period or (ii) the Parties do not execute an agreement within the ROFN Period (or any mutually agreed upon extension), then Company shall be free to enter into an agreement with a Third Party regarding such Commercialization rights.

**3.3. Company Diligence.** Company shall use Commercially Reasonable Efforts to:

(a) Develop at least one (1) Product in accordance with the Development Plan;

(b) Launch at least one (1) Product in at least [\*\*\*] in a Major Market [\*\*\*] after receiving Marketing Approval and, if applicable, Price Approval therefor; and

(c) have and maintain, either directly or through Third Party contractors or vendors, adequate and available manufacturing, storage and shipping facilities, supplies, qualified personnel, regulatory approvals and registrations, and all other resources required to manufacture and supply sufficient quantities of Compound or Product to meet the then current and reasonably anticipated marketplace demands for such Compound or Product in all countries of the Territory in which such Compound or Product has received Regulatory Approval.

**3.4. Manufacturing and Supply.**

(a) Subject to ATSA’s retained right to manufacture Compound and Product itself or through one or more Third Parties on behalf of Company pursuant to this Section 3.4, Company shall have the exclusive right to manufacture the Compound and the Product itself or through one or more Third Parties selected by Company.

(b) ATSA herewith agrees to deliver [\*\*\*] (Incoterms 2020) to Company the Inventory within a period of [\*\*\*] after the effective date of the Manufacturing Quality Agreement. For the avoidance of doubt, Company shall bear all costs related to the transportation/shipment of such Inventory.

(c) From [\*\*\*] until [\*\*\*], in the event Company requests ATSA to provide additional supply of Drug Product before Company is able to manufacture Drug Product, ATSA shall supply Drug Product to Company in accordance with this Section 3.4(c) [\*\*\*] (Incoterms 2010) at [\*\*\*] costs (i.e. [\*\*\*]) for clinical supply, and with [\*\*\*]. Invoice will be provided at the ATSA's release of the Drug Product. In the event that Company requests such additional supply of Drug Product in accordance with the foregoing, such additional supply shall also be governed by the terms and conditions of the Manufacturing Quality Agreement. To the extent that there is any conflict between the terms and conditions of this Agreement and the Manufacturing Quality Agreement, the terms and conditions of this Agreement shall govern and control. Company shall provide ATSA with a binding forecast of the quantities of Drug Product expectedly required [\*\*\*] in advance with its requested delivery date. The quantities of Drug Product to be supplied by ATSA to Company this Section 3.4(c) shall in no case exceed the equivalent amount of Drug Substance in inventory taking into consideration yield and batch size. The Parties agree that ATSA shall be obliged only to manufacture Drug Product as provided for under this Section 3.4(c), not exceeding the amount of Drug Substance on stock with ATSA taking into account the respective yield and batch size. In the event any Drug Product manufactured pursuant to this Section 3.4(c) does not conform to the warranty provided pursuant to Section 8.2(a)(xiii), Company's sole remedy shall be that [\*\*\*].

(d) Upon the request of Company, ATSA shall store any Drug Product manufactured in accordance with Section 3.4(c) or up to a period of [\*\*\*] from the completion of the manufacture of such batch of Drug Product at the cost to Company of [\*\*\*] per [\*\*\*].

(e) Other than as provided in this Section 3.4, ATSA shall have no further obligation regarding the manufacturing and supply of Drug Substance or Drug Product.

For the avoidance of doubt the manufacture of Drug Product does not include assembly of drug product into an autoinjector.

**3.5. Reporting Obligation and Information Right.** Company shall, within [\*\*\*] after the end of each [\*\*\*] period of a Calendar Year, i.e. [\*\*\*] after [\*\*\*] of each Calendar Year, provide ATSA with a written report summarizing in reasonable detail, as applicable, its Development and Commercialization activities conducted during the preceding [\*\*\*] period, including development status, results achieved, problems encountered and other pertinent material information relating to the Development and Commercialization of Compound or any Products hereunder.

**3.6. Trademarks.** Company shall have the sole authority to select trademarks in connection with the Commercialization of any Product in the Field in the Territory and shall own all such trademarks. Company will not use nor seek to register, anywhere in the Territory, any trademark that is confusingly similar to any trademark used by or on behalf of ATSA, its Affiliates or Sublicensees in connection with any Product.

### **3.7. Regulatory Matters.**

(a) Regulatory Filings. Subject to Section 3.7(c), Company or its designated Affiliates and Sublicensees will have the exclusive right to (a) prepare and file regulatory filings, each in its own name, and applications for Marketing Approval and Price Approval for the Compound and Products in the Field in the Territory, and (b) communicate with Regulatory Authorities with respect to the Compound and Products in the Field in the Territory, both prior to and following Marketing Approval and Price Approval.

(b) **Ownership.** Ownership of all rights in and to all regulatory filings, Marketing Approvals and Price Approvals directed to any Compound or Product in the Field in each country of the Territory will be held in the name of Company, its Affiliate, designee or Sublicensee.

(c) **Assignment of Existing Regulatory Filings.** Within [\*\*\*] of the Effective Date, ATSA shall assign and transfer to Company in electronic format (i) all regulatory filings set forth on, **Schedule 2.5**, (ii) one (1) copy of all material documents and records that have been generated by or on behalf of ATSA with respect to any such regulatory filings set forth on **Schedule 2.5**, (iii) one (1) copy of all material correspondence between ATSA and any Regulatory Authority related to Compounds or Products in electronic format. All costs related to the assignment and transfer of the regulatory filings shall be regarded as costs in accordance with Section 2.4. For clarity, ATSA will not be responsible for any delay in transferring documents pursuant to this Section 3.7(c), to the extent such delay is caused by Company or Regulatory Authority.

(d) **Global Safety Database.** Promptly after the Effective Date, the safety teams of the Parties will set up a meeting to agree on the transfer of the safety data of the global safety database for the Product (the “**GSD**”) from ATSA to Company. Notwithstanding the foregoing, ATSA shall transfer the GSD to Company no later than [\*\*\*] after the Effective Date; provided, that, such time period shall be automatically extended to the extent Company is unable to receive the transfer of the GSD. The transfer of the GSD shall be completed prior first patient in of a Company sponsored study with the Compound. After completion of the transfer of the GSD, Company will be solely responsible for all safety aspects of the Product in compliance with all Applicable Law pertaining to safety reporting of the Product and related activities. For clarity, ATSA will not be responsible for any delay in transferring safety data pursuant to this Section 3.7(c), to the extent such delay is caused by Company.

**3.8. Applicable Laws.** Company will, and will require its Affiliates and Sublicensees to comply with all Applicable Laws in its and their Research, Development, manufacture and Commercialization of Compound and Product, including where appropriate cGMP, GCP and GLP (or similar standards). Without limiting the foregoing, Company will not engage directly or indirectly, in any capacity in connection with this Agreement any Person who either has been debarred by the FDA, is the subject of a conviction described in section 306 of the FD&C Act or subject to any such similar sanction.

## ARTICLE 4 - GOVERNANCE

### 4.1. Transition Committee.

(a) **Formation.** Within [\*\*\*] after the Effective Date, the Parties will establish a transition committee (the “**TC**”) to oversee and coordinate activities related to the transfer set forth in Section 2.4, Section 2.5, Section 3.4(b) and Section 3.7. The TC will be comprised of two (2) representatives from each Party. In addition, each Party may invite a reasonable number of additional representatives to participate in discussions and meetings of the TC. Each Party’s representatives on the TC and all other individuals participating in discussions and meetings of the TC on behalf of a Party will be subject to confidentiality and non-use obligations with respect to information disclosed at such meeting that are no less restrictive than the provision of Article 7. The Alliance Managers will be responsible for setting the agenda for meetings of the TC with input from the other members. The TC will conduct its responsibilities hereunder in good faith and with reasonable care and diligence.

(b) Responsibilities. The TC will:

(i) review, discuss and oversee the transfer from ATSA to Company with respect to (A) the ATSA Know-How in accordance with Section 2.4 and Section 2.5; and (B) the regulatory filings and materials in accordance with Section 3.7(c); and

(ii) perform such other duties as are specifically assigned to the TC under this Agreement.

(c) Meetings; Minutes.

(i) The TC will meet in person at least twice each Calendar Year on such dates and at such times and places as agreed to by the members of the TC. Each Party will be responsible for its own expenses relating to attendance at, or participation in, TC meetings.

(ii) The Alliance Managers will provide the members of the TC with draft written minutes for approval from each meeting within [\*\*\*] after each such meeting. The responsibility for preparing the minutes will alternate between the Alliance Managers on a meeting-by-meeting basis. If the minutes of any meeting of the TC are not approved by the TC (with each Party's representatives on the TC collectively having one vote) within [\*\*\*] after the meeting, the objecting Party will append a notice of objection with the specific details of the objection to the proposed minutes.

(d) Decision-Making. The TC will provide a forum for the Parties to plan, oversee and monitor the Parties' activities under this Agreement. If the TC is unable to reach consensus with respect to a particular matter within the scope of its planning, oversight and monitoring function for more than [\*\*\*], Section 12.16 shall apply.

(e) Discontinuation of the TC. The TC will continue to exist until the last to occur of (a) completion of the technology transfer set forth in Section 2.4, (b) completion of the transfer set forth in Section 2.5, Section 3.4(b) and Section 3.7(c), or (c) completion of the Existing Clinical Study conducted by ATSA and delivery of the Clinical Study Report.

(f) Other Committees. The Parties may, by mutual agreement, form such other committees or working groups as may be necessary or desirable to facilitate activities under this Agreement. Each such committee or working group will have no decision-making authority under this Agreement.

**4.2. Alliance Managers Appointment.** Each Party will appoint a representative of such Party with sufficient experience to act as its alliance manager under this Agreement (each, an "**Alliance Manager**"). Each Party may replace its Alliance Manager at any time upon notice to the other Party. The initial Alliance Managers will be:

For Company: [\*\*\*]

For ATSA: [\*\*\*]

**4.3. Specific Responsibilities.** The Alliance Managers shall attend meetings of the TC but shall not be members of the TC. The Alliance Managers will serve as the primary contact point between the Parties for the purpose of providing each Party with information regarding the other Party's activities pursuant to this Agreement and will have the following responsibilities:

(a) schedule meetings of the TC, set the agenda for meetings of the TC and circulate draft written minutes;

(b) facilitate the flow of information and otherwise promote communication, coordination and collaboration between the Parties;

(c) provide a single point of communication for seeking consensus both internally within the respective Party’s organization and between the Parties regarding key strategy and planning issues; and

(d) perform such other functions as requested by the TC.

**ARTICLE 5 - FINANCIAL TERMS**

**5.1. Milestone Payments.**

(a) As consideration for the grant of the rights and licenses hereunder, Company shall pay to ATSA the respective non-refundable Milestone Payments.

(b) Company shall notify ATSA in writing within [\*\*\*] after a Milestone Event occurred.

(c) Subject to Section 5.4(c), Company shall deliver the corresponding Milestone Payments to ATSA within [\*\*\*] upon receipt of a corresponding invoice from ATSA for the Milestone Payment set forth in the aforementioned written notice.

(d) The Milestone Payments relating to the occurrence of a Milestone Event [\*\*\*] in **Schedule 1.77** shall be paid at the first instance such a Milestone Event is achieved.

(e) The Milestone Payments relating to the occurrence of Regulatory Milestone Events shall be paid at the first instance a Regulatory Milestone Event is achieved by a Product and shall be paid only once, regardless of which Product achieves such Regulatory Milestone Event. If Company terminates Development of a Product, subsequent Milestone Payments relating to Regulatory Milestone Events shall only be paid when another Product advances beyond the last Milestone Event in relation to which Company has made a Milestone Payment to ATSA.

(f) The Milestone Payments relating to Sales-Based Milestone Events shall be paid only once under this Agreement, in the Calendar Year during which the respective sales threshold for a Product is first achieved. The achievement of a higher Sales-Based Milestone Event shall also trigger the payment of a lower Sales-Based Milestone Event in the event such lower Sales-Based Milestone Event had not been triggered under this Agreement prior to achievement of the higher Sales-Based Milestone Event.

**5.2. Royalty.**

(a) Royalty Rate. Subject to the rest of this Section 5.2, as further consideration for ATSA’s grant of the rights and licenses to Company hereunder, Company shall pay to ATSA a royalty on worldwide aggregate annual Net Sales of a Product in the Territory for each Calendar Year during the Royalty Term, on a Product-by-Product and country-by-country basis at the rates set forth below (whereby the below royalty rates shall be applicable for the portion of annual Net Sales achieved per Product).

| <u>Worldwide aggregate annual Net Sales of a Product in the Territory</u> | <u>Royalty Rate</u> |
|---|---------------------|
| [***]   | [***]               |
| [***]   | [***]               |

(b) Prohibition to Offset. Except as expressly set forth in this Agreement, the royalty shall not be subject to offset or reduction for any reason, including any royalties, milestone payments or other consideration that Company pays under any Third Party licenses.

(c) Royalty Adjustments. Provided that royalties on Net Sales due under Section 5.2(a) may not be reduced by more than [\*\*\*], the Company may adjust or offset, as the case may be, as follows:

(i) Nothing herein contained shall obligate Company or its Sublicensees to pay or cause to be paid to ATSA more than one royalty on any unit of a Product. In the event that during the Royalty Term for a Product in a particular country such Product is not covered by a Valid Claim in such country before the [\*\*\*] after the First Commercial Sale in such country, then the royalties on Net Sales of a Product in such country due under Section 5.2(a) shall be reduced by [\*\*\*] until the expiration of the aforementioned fifteen (15) years.

(ii) Up to [\*\*\*] of any royalties, and any upfront and milestones actually paid by the Company under Additional Third Party Licenses will be credited towards the royalties on Net Sales of a Product in such country due under Section 5.2(a), but not to more than [\*\*\*] of the royalty amounts otherwise due and payable by Company to ATSA in relation to the Compound or Product for which the Additional Third Party Licenses were obtained by the Company. For clarity, this credit will not apply with respect to Third Party Patent Rights covering the formulation, medical use or a method of manufacture of Compound or Product or the other active ingredient of a combination product. No offset for payments for Additional Third Party Licenses shall be allowed where royalties on Net Sales of a Product in a country are [\*\*\*].

(iii) In the event that in any country in the Territory during the Royalty Term for a Product there is generic competition (“**Generic Competition**” as defined hereinafter) in such country, then for the remainder of the Royalty Term for such Product in such country the royalties on Net Sales of a Product in such country due under Section 5.2(a) shall be reduced by [\*\*\*]. For purposes herein, Generic Competition means, on a country and Product basis, the unit volume of a generic product(s) sold in such country or other jurisdiction by one (1) or more Third Party(ies) in a Calendar Year is at least [\*\*\*] of the sum of unit volume of such Product sold by Company, its Affiliates and Sublicensees and all generic products unit volume of Products sold in that country or other jurisdiction by Third Parties. Unless otherwise agreed by the Parties, the unit volumes of each generic product sold during a Calendar Year shall be as reported by IQVIA or any other independent sales auditing firm reasonably agreed upon by the Parties.

(iv) Company shall have the right to carry forward any reductions permitted under Section 5.2(c)(i), Section 5.2(c)(ii) and Section 5.2(c)(iii) that are incurred or accrued in a Calendar Quarter but are not applied against royalties due to ATSA in such Calendar Quarter as result of the restriction set forth in the first sentence of Section 5.2(c) and apply such amounts against royalties due to ATSA in any subsequent Calendar Quarter (subject to the restriction set forth in the first sentence of Section 5.2(c)) until the amount of such reduction has been fully applied against royalties due to ATSA.

(d) Royalty Term. Royalties shall be payable on a Product-by-Product and country-by-country basis from the date of First Commercial Sale of a Product in a country until the later of (i) the expiration of fifteen (15) years after the First Commercial Sale of such Product in such country; (ii) the expiration of the last Valid Claim of a Patent Right included in the ATSA Technology (or the expiration of the last Supplementary Protection Certificate or corresponding right that is based on a Patent Right included in the ATSA Technology, including pediatric extensions) that covers such 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 (“**Royalty Term**”).

(e) Payment of Royalties. Simultaneously with the delivery of the report described in Section 5.3(a) hereof, Company shall pay, or cause to be paid, to ATSA at such place as ATSA may from time to time designate in writing, all royalties earned pursuant to this Section 5.2 in the preceding Calendar Quarter. All such payments shall be made in U.S. Dollars. In the event that, by reason of Applicable Laws in any country, it becomes impossible or illegal for Company to transfer, or have transferred on its behalf, royalties or other payments in either USD or EUR out of such country, Company shall promptly notify ATSA and, thereafter, such royalties or other payments shall be deposited in local currency of such country to the credit of ATSA in a banking institution designated by ATSA in writing (or, failing prompt designation by ATSA, a banking institution reasonably selected by Company).

(f) Blended Royalty. Company acknowledges that (a) the ATSA Know-How licensed to Company regarding the Indications is proprietary and valuable and that without such Know-How, Company would not be able to obtain and maintain Marketing Approvals with respect to the Products, (b) access to the ATSA Know-How and the rights with respect to the Patent Rights Controlled by ATSA have provided Company with a competitive advantage in the marketplace beyond the exclusivity afforded by the ATSA Patents, and (c) the royalties set forth in Section 5.2 are, in part, intended to compensate ATSA for such competitive advantage. The Parties agree that the royalty rates set forth in Section 5.2(a) reflect an efficient and reasonable blended allocation of the value provided by ATSA to Company.

### **5.3. Royalty Reports; Currency Conversion; Disputes regarding Reports.**

(a) Commencing with the Calendar Quarter in which the First Commercial Sale of a Product is made by Company or its Affiliate or Sublicensee, Company shall submit to ATSA with each royalty payment a detailed, written report detailing its computation of royalties due on Net Sales in each country during each Calendar Quarter within [\*\*\*] after the end of each Calendar Quarter (and Company shall cause its Sublicensees to submit royalty reports containing the same level of detail), whereas the report shall indicate: (i) the amount of Net Sales of the Product sold by Company, its Affiliates and Sublicensees during the reporting period; (ii) the royalties due thereon; (iii) the exchange rates used in determining the amount of U.S. Dollars; (iv) the number of units and average selling price for the Product included in Net Sales for such Calendar Quarter, and (v) any other information reasonably requested by ATSA to assess the calculation of the royalty payments.

(b) All payments to ATSA hereunder shall be made by deposit of U.S. Dollars in the requisite amount to such bank account as ATSA may from time to time designate by written notice to Company. If any amounts that are relevant to the determination of amounts to be paid under this Agreement or any calculations to be performed under this Agreement are denoted in a currency other than U.S. Dollars, such amounts will be converted to their U.S. Dollar equivalent using the average rate of exchange for the [\*\*\*] preceding the date of payment for the conversion of local currency to U.S. Dollars as published by the Wall Street Journal (or if it ceases to be published, a comparable publication to be agreed upon by the Parties) or, for those countries for which such average exchange rate is not published by the Wall Street Journal, the exchange rate used by the Company in line with its standard procedures and methodology for the translation of foreign currency expenses into U.S. Dollars. Calculation of Net Sales will exclude hedging and foreign exchange gain or loss realized through a hedging program.

(c) In the event of a dispute regarding the royalty reports, the Parties shall work in good faith to resolve the dispute in good faith. If the Parties are unable to resolve the dispute within [\*\*\*] following a Party's notification of dispute, the dispute shall be submitted for decision to a certified public accounting firm mutually selected by each Party's certified public accountants or to such other Third Party as the Parties shall mutually agree. The decision of such expert shall be final, and the costs of such decision shall be borne between the Parties in such manner as such expert shall determine. Not later than [\*\*\*] after such decision and in accordance with such decision, Company shall make any additional payments to ATSA. Any overpayment shall be credited against future amounts due by Company to ATSA.

#### 5.4. Sublicense Income.

(a) If Company sublicenses the licenses herein in any country in accordance with Section 2.2, Company shall, in addition to the payments owed to ATSA pursuant to Sections 5.1 to 5.2, pay to ATSA the following amounts:

- (i) [\*\*\*];
- (ii) [\*\*\*]; and
- (iii) [\*\*\*].

(b) Payments owed by Company pursuant to this Section 5.4 shall be made by Company to ATSA within [\*\*\*] of the event that triggered the obligation for the Sublicensee to pay the Sublicense Income.

(c) Any payment made by the Company to ATSA on Sublicense Income that is directly derived from the achievement by Sublicensee of a milestone event under such sublicense agreement that is the same as a Milestone Event under this Agreement shall be creditable towards the applicable Milestone Payment owed by Company to ATSA pursuant to Section 5.1. For example, a milestone event that is triggered by [\*\*\*] will be deemed substantially equivalent to [\*\*\*] on Schedule 1.77.

**5.5. Record Retention, Inspection.** Company shall keep or cause its Affiliates and Sublicensee to keep complete and accurate records in sufficient detail to enable Net Sales and royalties payable under Section 5.2 to be established for a period of [\*\*\*] after the date that such royalties were payable. Such records shall be consistent with Company's normal accounting principles. At the request of ATSA (but not more frequently than once each Calendar Year) an independent certified public accountant chosen by ATSA but approved by Company (which approval shall not be unreasonably withheld or delayed) shall be allowed access during ordinary business hours and with reasonable advance notice to such records pertaining to the preceding [\*\*\*] solely to verify the accuracy of any payments made to ATSA under Section 5.2. The accountant shall not disclose to ATSA any information other than that which should properly be contained in a report of matters relevant to Net Sales and royalty calculation and payment arising under Section 5.2 above. Any such accounting firm shall sign a confidentiality agreement (in form and substance reasonably acceptable to Company) as to any of Company's, its Affiliate's or Sublicensee's confidential information that such accounting firm is provided, or to which they have access, while conducting any audit pursuant to this Section 5.5. In the case of Sublicensees, Company shall make such Sublicensees' records available for audit by ATSA in accordance with the terms of this Section 5.5. Any inspection conducted under this Section 5.5 shall be at the expense of ATSA, unless such inspection reveals any underpayment of the payments due hereunder for the audited period by at least [\*\*\*], in which case the full costs of such inspection for such period shall be borne by Company. Any underpayment shall be paid by Company to ATSA within [\*\*\*] of written notice with interest on the underpayment at the rate specified in Section 5.8 from the date such payment was originally due. Any overpayment shall be credited against future amounts due by Company to ATSA; provided, that, if no future amounts are due by Company to ATSA, ATSA shall timely reimburse such overpayment to Company.

5.6. **Withholding Tax.** Where any sum due to be paid to ATSA hereunder is subject to any withholding or similar tax, Company will pay such withholding or similar tax to the appropriate Government Body and deduct the amount paid from the amount then due to ATSA and within [\*\*\*] transmit to ATSA an official tax certificate or other evidence of such withholding sufficient to enable ATSA to claim such payment of taxes. The Parties will cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties and other payments made by Company to ATSA under this Agreement. ATSA will provide Company any tax forms that may be reasonably necessary in order for Company not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax. ATSA shall timely provide a properly completed IRS Form W-8BEN-E.

5.7. **Indirect Tax.**

(a) All payments under this Agreement shall be understood as inclusive of any transfer, documentary, sales, use, stamp, registration, goods and services Tax or other similar tax, but exclusive of VAT (each an “**Indirect Tax**”).

(b) Except as set forth in Section 5.7(c), if the transactions, payments or the related transfer of rights or other property pursuant to the terms of this Agreement would be subject to Indirect Tax, ATSA shall timely pay and be responsible for (and shall indemnify Company for) any such Indirect Tax and ATSA shall file all applicable tax returns. ATSA shall remit such indirect taxes to the competent tax authorities and Company shall cooperate with ATSA in any way reasonably requested to obtain legally permitted reductions, credits or refunds of any invoiced Indirect Tax amount. ATSA shall indemnify Company for any such Indirect Taxes imposed on Company under this Agreement and if Company directly pays any such Indirect Taxes, ATSA shall promptly reimburse Company for such Indirect Taxes including all reasonable related costs.

(c) If the transactions, payments or the related transfer of rights or other property pursuant to the terms of this Agreement become subject to Indirect Tax that arises as a result of any action by Company (other than the making of such payment itself), including any assignment of this Agreement, that has the effect of modifying the tax treatment of the Parties hereto with respect to such Indirect Tax, then ATSA shall timely invoice Company for the applicable tax amounts in addition to the net amounts and be paid by Company to ATSA and Company shall pay and be responsible for (and shall indemnify ATSA for) any such Indirect Tax. ATSA shall remit such indirect taxes to the competent tax authorities and ATSA shall cooperate with Company in any way reasonably requested to obtain legally permitted reductions, credits or refunds of any invoiced Indirect Tax amount. Company is entitled to receive an invoice from ATSA issued in accordance with applicable tax law.

5.8. **Late Payments.** All payments under this Agreement that are not paid within the applicable time period set forth herein shall earn interest from the date due until paid at a per annum rate equal to the lesser of (a) the maximum rate permissible under Applicable Laws and (b) [\*\*\*]. Interest will be calculated on an actual/360 basis.

5.9. **ATSA Equity Consideration.** As further consideration for the grant of the rights and licenses hereunder, on the Effective Date, the Company shall issue to ATSA at the Initial Financing's Initial Closing (referenced in the definition of "**Initial Financing**"), without any obligation of ATSA to pay up for those shares in cash, such number of Company's Series C Preferred Stock representing 10% of Company's equity on a fully diluted basis calculated after taking into account the shares authorized both for the Initial Financing's Initial Closing and for its Additional Closing(s), as referenced in the associated Stock Purchase Agreement and including any authorized shares as if they have been issued or (where applicable) vested (the "**ATSA Equity Consideration**"). For these purposes, the shares authorized for possible issue at any portion of the Initial Financing (including Initial and Additional Closing(s)) shall be included in the calculation of "fully diluted" when computing the ATSA Equity Consideration to be issued at the Initial Closing, as shall all other authorized shares and equity securities of any class or series. In this context, the Parties shall, together with other investors, sign the Equity Documentation at the Effective Date. The ATSA Equity Consideration shall be issued to ATSA by Company in accordance with the terms of the Equity Documentation.

## **ARTICLE 6 - THIRD PARTY LICENSES, IP OWNERSHIP, INVENTIONS AND PATENT PROSECUTION AND MAINTENANCE**

### **6.1. Third Party Licenses.**

(a) As between the Parties, ATSA shall be solely responsible for all liabilities and payments owed to Third Parties pursuant to any agreements between ATSA and such Third Parties related to the Compound and/or Products which are in existence as of the Effective Date of this Agreement (collectively, "**Existing Third Party Licenses**").

(b) In the event the Company determines that it will be necessary or reasonably useful to obtain additional licenses to Patent Rights of a Third Party (any such license a "**Additional Third Party License**") that cover the applicable Compound in such Product as a composition of matter or method of use in order to Commercialize the Compound or Products, the Company shall have the sole right to negotiate and obtain such Additional Third Party License but will not be obligated to do so.

### **6.2. Intellectual Property Ownership.**

(a) Subject to the licenses granted in this Agreement, ATSA shall own or Control and retain all right, title and interest in the ATSA Technology and in any and all other Patent Rights, Know-How and other intellectual property rights that are (i) in existence and Controlled by ATSA as of the Effective Date; or (ii) developed by, for or on behalf of ATSA after the Effective Date other than in performance of this Agreement.

(b) Subject to the licenses granted in this Agreement, Company shall own or Control and retain all right, title and interest in any and all Patent Rights, Know-How and other intellectual property rights that are (i) in existence and Controlled by Company as of the Effective Date; or (ii) developed by, for or on behalf of Company after the Effective Date other than in performance of this Agreement.

(c) All right, title and interest in any and all Patent Rights, Know-How and intellectual property rights that are developed in performance of this Agreement shall be owned (i) solely by ATSA, if developed solely by employees, agents or independent contractors of ATSA (collectively, “**ATSA Sole Inventions**”); or (ii) solely by Company, if developed solely by employees, agents or independent contractors of Company (collectively, the “**Company Sole Inventions**”) and (iii) jointly and equally by both Parties, if developed jointly by employees, agents or independent contractors of both Parties (collectively, “**Joint Inventions**”). All Patent Rights claiming patentable Company Sole Inventions shall be referred to herein as “**Company Patents**” and all Patent Rights claiming Joint Inventions shall be referred to herein as “**Joint Patents**”. Determination of ‘joint’ or ‘sole’ inventorship will be made in accordance with US patent laws. All of ATSA’s right, title and interest in and to the ATSA Sole Inventions and Joint Inventions (including the Joint Patents) shall be included within the ATSA Technology licensed to Company pursuant to Section 2.1. Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice, license (through multiple tiers), assign and otherwise exploit the Joint Inventions and Joint Patents in all countries and jurisdictions without the duty of accounting or seeking consent from the other Party.

### 6.3. Patent Prosecution and Maintenance of Licensee Patents.

(a) Company shall have the sole right to file, prosecute and maintain the Company Patents and the first right to file, prosecute and maintain the Joint Patents (such Company Patents and Joint Patents collectively, the “**Licensee Patents**”). To the extent that a Company Patent relates to the subject matter of this Agreement and with respect to any Joint Patent, Company shall keep ATSA informed of the course of the filing and prosecution of such Licensee Patents or related proceedings (e.g. interferences, oppositions, re-examinations, reissues, revocations or nullifications) in the Major Markets in a timely manner, and shall take into consideration the advice and recommendations of ATSA in that respect.

(b) Company shall bear all costs and expenses of its filing, prosecuting and maintaining the Licensee Patents in the Territory.

(c) If Company elects not to file, prosecute or maintain a Joint Patent in a country in the Territory, then it shall notify ATSA in writing at least [\*\*\*] before any deadline applicable to the filing, prosecution or maintenance of such Joint Patent, as the case may be, or any other date by which an action must be taken to establish or preserve such Joint Patent in such country or possession. In such case, by no later than [\*\*\*] before any deadline applicable to the filing, prosecution or maintenance of such Joint Patent, or any other date by which an action must be taken to establish or preserve such Joint Patent in such country or possession, ATSA shall have the right, but not the obligation, to pursue the filing or support the continued prosecution or maintenance of such Joint Patent. If ATSA does not revert to Company or elects not to take such action in a country in the Territory, Company shall be free to terminate the prosecution or maintenance of such Joint Patent. If ATSA does elect to take such action in a country in the Territory, then it shall notify Company of such election, and ATSA shall have the right at its discretion and expense, to continue prosecution or maintenance of such Joint Patent in such country and Company shall reasonably cooperate with ATSA in this regard.

### 6.4. Patent Prosecution and Maintenance of ATSA Patents.

(a) US Drug Product Listing. Company shall have the sole right to determine which of the ATSA Patents, if any, shall be listed for inclusion in the Approved Drug Products with Therapeutic Equivalence Evaluations pursuant to 21 U.S.C.F.R § 355, or any successor law in the United States, together with any comparable laws or regulations in any other country in the Territory.

(b) Responsibility and Costs. Company shall have the first right to file Patent Rights according to Section 6.2(c)(i) and (iii), and the obligation, to prosecute and maintain ATSA Patents. Company shall bear all costs and expenses of filing, prosecuting and maintaining Patent Rights according to Section 6.2(c)(i) and (iii) and all costs and expenses of prosecuting and maintaining ATSA Patents in the Territory. Company shall keep ATSA informed of the course of the prosecution of ATSA Patents or related proceedings (e.g. interferences, oppositions, re-examinations, reissues, revocations or nullifications) in the Major Markets in a timely manner, and shall [\*\*\*]. At Company's request, ATSA will provide Company with reasonable assistance in prosecuting ATSA Patents and in filing Patent Rights according to Section 6.2(c)(i) and (iii) to the extent possible, including providing such data in ATSA's control that is, in reasonable judgment, needed to support the prosecution of an ATSA Patent and the filing of Patent Rights according to Section 6.2(c)(i) and (iii); provided, however, that Company shall reimburse ATSA for ATSA's out-of-pocket expenses incurred in providing such assistance with regard to ATSA Patents and Patent Rights referred to in 6.2(c)(i).

(c) Election not to File and Prosecute ATSA Patents.

(i) If Company elects not to prosecute or maintain an ATSA Patent owned or co-owned by ATSA or one of its affiliates in a country or possession in the Territory, then it shall notify ATSA in writing at least [\*\*\*] before any deadline applicable to the prosecution or maintenance of such ATSA Patent, as the case may be, or any other date by which an action must be taken to establish or preserve such ATSA Patent in such country or possession. In such case, by no later than [\*\*\*] before any deadline applicable to the prosecution or maintenance of such ATSA Patent, or any other date by which an action must be taken to establish or preserve such ATSA Patent in such country or possession, ATSA shall have the right, but not the obligation, to support the continued prosecution or maintenance of such ATSA Patent. If ATSA does elect to take such action in a country in the Territory, then it shall notify Company of such election, and Company shall reasonably cooperate with ATSA in this regard.

(ii) Notwithstanding Section 6.4(c)(i), if Company elects not to prosecute or maintain an ATSA Patent owned by Bristol-Myers Squibb Company or one of its Affiliates (e.g. ZymoGenetics, Inc.) in a country or possession in the Territory, or co-owned by Bristol-Myers Squibb Company or one of its Affiliates together with another owner which is not ATSA or one of its Affiliates in a country or possession in the Territory (as identified on Schedule 1.17), then it shall notify Bristol-Myers Squibb Company in writing (in accordance with the contact information ATSA may provide to Company in writing) at least [\*\*\*] before any deadline applicable to the prosecution or maintenance of such ATSA Patent, as the case may be, or any other date by which an action must be taken to establish or preserve such ATSA Patent in such country or possession. In such case, by no later than [\*\*\*] before any deadline applicable to the prosecution or maintenance of such ATSA Patent, or any other date by which an action must be taken to establish or preserve such ATSA Patent in such country or possession, Bristol-Myers Squibb Company shall have the right, but not the obligation, to support the continued prosecution or maintenance of such ATSA Patent. If Bristol-Myers Squibb Company does elect to take such action in a country in the Territory, then it shall notify Company of such election, and Company shall reasonably cooperate with Bristol-Myers Squibb Company in this regard.

## 6.5. Enforcement of Patent Rights.

(a) Notice. If either Party believes that an ATSA Patent is being infringed by a Third Party or if a Third Party claims that any ATSA Patent is invalid or unenforceable, the Party possessing such knowledge or belief shall promptly notify the other Party and provide it with details of such infringement or claim that are known by such Party.

(b) Right to Bring an Action. Company shall have the first right, but not the obligation, to attempt to resolve such infringement or claim, including by filing an infringement suit, defending against such claim or taking other similar action (each, an “**Action**”) and to compromise or settle such infringement or claim. If Company does not intend to prosecute or defend an Action, Company shall promptly inform ATSA and ATSA then shall have the right, but not the obligation, to attempt to resolve such infringement or claim, including by filing an Action and to compromise or settle any such infringement or claim. The Party initiating such Action shall have the sole and exclusive right to select counsel for any suit initiated by it pursuant to this Section 6.5. Each Party shall have the right to join an Action relating to an ATSA Patent, taken by the other Party at its own expense.

(c) Costs of an Action. Subject to the respective indemnity obligations of the Parties set forth in Article 9, the Party taking an Action under Section 6.5(b) shall pay all costs associated with such Action, other than (subject to Section 6.5(e)) the expenses of the other Party if the other Party elects to join such Action.

(d) Settlement. Neither Party shall settle or otherwise compromise any Action by admitting that any ATSA Patent is not infringed, invalid or unenforceable without the other Party’s prior written consent, and, in the case of Company, Company may not settle or otherwise compromise an Action in a way that adversely affects or would be reasonably expected to adversely affect the other Party’s rights or benefits hereunder with respect to the Product, without the other Party’s prior written consent. The settlement will be treated in accordance with the Applicable Laws of the country to which the settlement relates.

(e) Reasonable Assistance. The Party not enforcing or defending ATSA Patents shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence and making its employees available, subject to the other Party’s reimbursement of any out-of-pocket expenses incurred by the non-enforcing or non-defending Party in providing such assistance.

(f) Distribution of Amounts Recovered. Any amounts recovered by the Party taking an Action pursuant to this Section 6.5, whether by settlement or judgment, shall be allocated in the following order: (i) to reimburse the Party taking such Action for any costs incurred, (ii) to reimburse the Party not taking such Action for its costs incurred in such Action, if it joins such Action; and (iii) the remaining amount of such recovery shall be (A) allocated to Company if Company is the Party taking such Action, provided that such remainder shall be subject to royalty payments to ATSA as if such remainder constituted Net Sales under this Agreement to the extent that any such infringement resulted in lost sales of Product and (B) [\*\*\*] allocated to ATSA if ATSA is the Party taking such Action and [\*\*\*] to Company.

## 6.6. Third Party Actions Claiming Infringement.

(a) Notice. If a Party becomes aware of any claim or action by a Third Party against either Party that claims that the Product, or its use, Development, manufacture or Commercialization infringes such Third Party’s intellectual property rights (each, a “**Third Party Action**”), such Party shall promptly notify the other Party of all details regarding such claim or action that is reasonably available to such Party.

(b) Right to Defend. Company shall have the sole right, at its sole expense, but not the obligation, to defend against a Third Party Action resulting from activities conducted by or on behalf of Company through counsel of its choosing. ATSA shall have the first right, at its sole expense, but not the obligation, to defend against a Third Party Action resulting from activities conducted by or on behalf of ATSA in conducting the Existing Clinical Study through counsel of its choosing. If ATSA declines or fails to assert its intention to defend against such Third Party Action within [\*\*\*] of receipt/sending of notice under Section 6.6(a), then Company shall have the right to defend against such Third Party Action. The Party defending against such Third Party Action shall have the sole and exclusive right to select counsel for defending against such Third Party Action.

(c) Consultation. The Party defending against a Third Party Action pursuant to Section 6.6(b) shall be the “**Controlling Party**”. The Controlling Party shall consult with the non-Controlling Party on all material aspects of the defence. The non-Controlling Party shall have a reasonable opportunity for meaningful participation in decision-making and formulation of the defence strategy. The Parties shall reasonably cooperate with each other in all such actions or proceedings. The non-Controlling Party will be entitled to be represented by independent counsel of its own choice at its own expense.

(d) Costs of an Action. Subject to the respective indemnity obligations of the Parties set forth in Article 9, the Controlling Party shall pay all costs associated with such Third Party Action other than the expenses of the other Party if the other Party elects to join such Action. Each Party shall have the right to join a Third Party Action defended by the other Party, at its own expense.

(e) No Settlement Without Consent. No Controlling Party shall settle or otherwise compromise any Third Party Action, e.g. by admitting that a third party patent right is valid and/or infringed, without the non-Controlling Party’s prior written consent.

**6.7. Patent Term Extensions**. Company shall have the exclusive right, but not the obligation, to seek, in ATSA’s name (in the case of an ATSA Patent owned by ATSA), in the name of Bristol-Myers Squibb Company (in the case of an ATSA Patent owned by Bristol-Myers Squibb Company) or in the name of ZymoGenetics, Inc. (in the case of an ATSA Patent owned by ZymoGenetics, Inc.), if so required, patent term extensions (including any pediatric exclusivity extensions as may be available), patent term restorations and supplemental protection certificates or the like available under Applicable Law, including 35 U.S.C § 156 and applicable foreign counterparts, in any country in the Territory in relation to the ATSA Patents (including Joint Patents). Company and ATSA shall cooperate in connection with all such activities. Company, its agents and attorneys shall give due consideration to all suggestions and comments of ATSA regarding any such activities, but in the event of a disagreement between the Parties, Company shall have the final decision making authority; *provided*, that Company shall seek to extend any ATSA Patent at ATSA’s request, including through the use of supplemental protection certificates and the like, unless in Company’s reasonable legal determination such ATSA Patent may not be extended under Applicable Law without limiting Company’s right to extend any other Patent Right.

**6.8. Certification Under Drug Price Competition and Patent Restoration Act**. Each Party shall immediately give written notice to the other Party of any certification of which they become aware filed pursuant to 21 U.S. CFR § 355(b)(2)(A) (or any amendment or successor statute thereto) or corresponding Applicable Laws in other countries claiming that any ATSA Patents covering a Compound or a Product, or the manufacture or use of each of the foregoing, are invalid or unenforceable, or that infringement will not arise from the manufacture, use or sale of a product by a Third Party.

**ARTICLE 7 - CONFIDENTIALITY**

**7.1. Confidentiality Obligations.** Each Party agrees that, for the Term and for [\*\*\*] thereafter, such Party shall, and shall ensure that its Affiliates, Sublicensees, and their respective officers, directors, equity-investors, employees and agents shall keep completely confidential and not publish or otherwise disclose and not use for any purpose except as expressly permitted hereunder any Confidential Information disclosed to it by the other Party pursuant to this Agreement. Notwithstanding the foregoing, the confidentiality obligations under this Agreement shall remain in full force and effect without timely limitation as to any Confidential Information which meets the definition of a trade secret according to Applicable Laws and which the receiving Party is aware or should be aware as a reasonable person (taking into account its content and nature, the circumstances and purpose of the disclosure) constitutes a trade secret. The foregoing obligations shall not apply to any Confidential Information disclosed by a Party hereunder to the extent that the receiving Party can demonstrate that such Confidential Information:

(a) was already known to the receiving Party or its Affiliates, other than under an obligation of confidentiality, at the time of disclosure;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was subsequently lawfully disclosed to the receiving Party or its Affiliates without an obligation of confidentiality by a Third Party who has the right to make such disclosure; or

(e) was independently developed or discovered by employees or agents of the receiving Party or its Affiliates who had no access to the Confidential Information of the disclosing Party.

Each Party (or its Affiliates) may disclose or grant access to the other Party's (or its Affiliates) Confidential Information without the prior written permission of the other Party to only those Affiliates, employees, Sublicensees, advisors/consultants (e.g. attorneys, tax advisors etc.) which are bound by either a confidentiality agreement containing reasonable obligations of confidentiality and non-use (which, in the event any trade secrets of the disclosing Party will be disclosed, shall include an obligation to maintain any trade secrets disclosed in a manner at least as protective as the provisions of this Agreement) or by statutory and/or professional obligations of secrecy. The receiving Party shall be fully liable to the disclosing Party for any non-compliance of its Affiliates, employees, Sublicensees, consultants/advisors with the terms and conditions of such contractual or statutory/professional obligation to the same extent as the receiving Party is liable for any non-compliance on its own part under this Agreement.

Notwithstanding the above obligations of confidentiality and non-use, a Party may disclose information to the extent that such disclosure is reasonably necessary in connection with:

(i) filing or prosecuting patent applications, subject to the terms of Section 6.3 or Section 6.4;

(ii) prosecuting or defending litigation;

(iii) conducting pre-clinical studies or Clinical Trials;

(iv) seeking or maintaining Marketing Approval of the Product;

(v) ATSA's compliance with its obligations (in particular notice obligations) under the Zymo License or reasonable information requests by the licensor under the Zymo License. It is hereby confirmed by Company that ATSA was and is entitled to provide a final draft of this Agreement or the executed version of this Agreement to ZymoGenetics, Inc.; or

(vi) complying with Applicable Laws, including securities law and the rules of any securities exchange or market on which a Party's securities are listed or traded.

In addition, in connection with any permitted filing by either Party of this Agreement with any Governmental Body, including the U.S. Securities and Exchange Commission, the filing Party shall endeavour to obtain confidential treatment of economic, trade secret information and such other Confidential Information, and shall provide the other Party with the proposed confidential treatment request with reasonable time for such other Party to provide comments, and shall include in such confidential treatment request all reasonable comments of the other Party. The disclosing Party shall, where reasonably practicable, give such advance notice to the other Party of such disclosure requirement as is reasonable under the circumstances and will use its reasonable efforts to cooperate with the other Party in order to secure confidential treatment of such Confidential Information required to be disclosed.

For clarity, Company shall not use any portion of the manufacturing process for Compound or Existing Product within the ATSA Know-How that constitutes a trade secret under applicable law (and has been designated as such by ATSA) to manufacture any compound other than a Compound or any product other than a Product and Company shall not independently or with or through a Third Party, reverse engineer such trade secret portion of the manufacturing process within the ATSA Know-How without ATSA's prior written consent.

**7.2. Publications.** ATSA shall not publish any information relating to the Product without the written consent of Company. Company shall submit to ATSA for ATSA's review and comment any publication or presentation (including in any seminars, symposia or otherwise) of information related directly or indirectly to the Product at least [\*\*\*] prior to submission for the proposed date of publication or presentation.

**7.3. Press Releases and Disclosure.** After the Effective Date, each Party shall be entitled to issue a press release regarding the signing of this Agreement. The content of such press release shall be mutually aligned between both Parties and no Party shall issue such a press release without the prior written consent of the other Party regarding the content of such press release, such consent not unreasonably withheld or delayed. The Parties shall align on such content and on the date and time of the press release as soon as practicable after the Effective Date, but in any event within [\*\*\*] following the Effective Date. Except (a) as set forth in the preceding sentence, or (b) as required to comply with Applicable Laws (including the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent Governmental Body in any country in the Territory), neither Party will make any public announcement regarding this Agreement or any matter governed by this Agreement without the prior written approval of the other Party. Any disclosure that is required by Applicable Laws or applicable securities exchange regulation, as reasonably advised by the disclosing Party's counsel of a reputable law firm, may be made without prior written consent of the other Party; however, such other Party shall be given prompt notice of any such legally required disclosure and the disclosing Party shall provide such other Party with a reasonable opportunity to comment on the proposed disclosure, which comments will be given due consideration by the disclosing Party. Such disclosure shall contain the minimum amount of information required to meet the legal requirement to disclose, as reasonably advised by the disclosing Party's counsel of a reputable law firm.

**ARTICLE 8 - REPRESENTATIONS, WARRANTIES and Covenants****8.1. Mutual Representations and Warranties.**

(a) Each Party represents and warrants to the other Party as of the Effective Date that:

- (i) it is a corporation, duly organized, validly existing and in good standing under the laws of the state or other jurisdiction of its organization.
- (ii) it has the full power, authority and right to enter into this Agreement and to perform its obligations hereunder in accordance with the terms and conditions hereof, and all requisite corporate action has been taken to authorize its execution, delivery and performance of this Agreement;
- (iii) the execution, delivery and performance of this Agreement by such Party does not breach, violate, contravene or constitute a default under any contract, arrangement or commitment to which such Party is a party or by which it is bound, or violate any statute, law or regulation or any court or Governmental Body having jurisdiction over such Party;
- (iv) except for the governmental and Marketing Approvals required to Commercialize Product in the Territory, all consents, approvals and authorizations from all Governmental Bodies or other Third Parties required to be obtained by such Party in connection with the execution, delivery and performance of this Agreement have been obtained; and
- (v) this Agreement has been duly authorized, executed and delivered and constitutes such Party's legal, valid and binding obligation enforceable against it in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to or affecting creditors' rights and to the availability of particular remedies under general equity principles.

**8.2. Additional Representations and Warranties of ATSA.**

(a) ATSA represents and warrants to Company as of the Effective Date that:

- (i) the Patent Rights set forth in **Schedule 1.17** constitute all Patent Rights owned or Controlled by ATSA or any of its Affiliates as of the Effective Date that claim Compounds as a composition of matter or that claim a method of using the Compounds in the Field (with the exception of [\*\*\*]);
- (ii) the ATSA Technology includes all the currently alive Patent Rights (with the exception of [\*\*\*]) and all the Know-How licensed to ATSA from ZymoGenetics, Inc. pursuant to the Zymo License and the Zymo Side Letter that relate to Compounds or Products;
- (iii) it does not own any Patent Rights that are not ATSA Patents that claim Compounds as a composition of matter or that claim the method of using the Compounds in medical treatment that, in the absence of a license, would prevent Company to further Develop, manufacture or Commercialize Compounds or Products;
- (iv) neither ATSA nor its Affiliates has received any Know-How or any Patent Rights from a Third Party that is necessary for Company to research, develop, manufacture, use, commercialize or otherwise exploit Compounds or Products (in the form such Products exist as of the Effective Date) that ATSA cannot sublicense and provide to Company pursuant to the terms of this Agreement;

(v) to ATSA's Knowledge, all Know-How Controlled by ATSA or any of its Affiliates that is necessary for Company to research, develop, manufacture, use, commercialize or otherwise exploit Compounds or Products (in the form such Products exist as of the Effective Date) is either included on **Schedule 2.5** or subject to transfer to Company pursuant to the Technology Transfer Plan;

(vi) it is the sole owner (or, to the extent identified on **Schedule 1.17** co-owner), or exclusive licensee, of the entire right, title and interest in and to the ATSA Patents listed on **Schedule 1.17**;

(vii) it is not restricted or prohibited by any contractual obligation from having the right to license to Company the ATSA Patents or, to its Knowledge, the ATSA Know-How, and it has not previously transferred, assigned, conveyed or otherwise encumbered its right, title and interest in and to the Compounds or Products to any Third Party;

(viii) to ATSA's Knowledge, (A) no Third Party has any right, title or interest in or to, or any license under, any ATSA Technology that conflicts with the rights granted to Company pursuant to this Agreement with respect to Atacicept and (B) no Third Party has any right, title or interest in or to, or any license under, any ATSA Technology that conflicts with any other rights granted to Company pursuant to this Agreement, except that no representation or warranty is made by ATSA with respect to this subsection (B) in regard of [\*\*\*];

(ix) no claims have been asserted, or to ATSA's Knowledge threatened to be asserted by any Person, nor is ATSA aware of any valid grounds for any claim challenging the inventorship, validity (whereby Company is aware of [\*\*\*]), enforceability, effectiveness, or ownership of ATSA Technology,

(x) (A) ATSA is not aware that the use, reproduction, modification, manufacturing, distribution, licensing, sublicensing or sale of Atacicept infringes any intellectual property right of any Person, and (B) ATSA is not aware that the use, reproduction, modification, manufacturing, distribution, licensing, sublicensing, sale or any other exercise of any other rights in any of ATSA Technology infringes any intellectual property right of any Person, except that no representation or warranty is made by ATSA with respect to this subsection (B) in regard of [\*\*\*];

(xi) (A) to ATSA's Knowledge, no Third Party is practicing the ATSA Technology to research, develop, manufacture or commercialize Atacicept or products containing Atacicept and (B) to ATSA's Knowledge, no Third Party is practicing the ATSA Technology to research, develop, manufacture or commercialize compounds or products, except that no representation or warranty is made by ATSA with respect to this subsection (B) in regard of [\*\*\*];

(xii) to ATSA's Knowledge, all fees required to be paid in order to maintain any of the ATSA Patents listed in **Schedule 1.17** have been timely paid;

(xiii) all Inventory and Drug Product supplied by ATSA to Company pursuant to Section 3.4 have been and will be manufactured in accordance with Applicable Law (including cGMP) and shall, at the time of delivery, conform to the specifications set forth on **Schedule 8.2(a)(xiii)** and shall be free and clear of all encumbrances;

(xiv) ATSA has provided Company with a copy of the [\*\*\*] and, to ATSA's Knowledge, there is no act or omission by ATSA or its Affiliates that would provide a right to terminate the Zymo License or Zymo Side Letter; and

(xv) the [\*\*\*] in a manner that would adversely affect Company's rights hereunder; and

(xvi) to ATSA's Knowledge, other than [\*\*\*], Company's sublicense to and exploitation of materials, Know-How and Patent Rights (sub)licensed or provided to Company by ATSA pursuant to this Agreement will not trigger a payment obligation owed under any agreement between ATSA or its Affiliates and any Third Party.

### 8.3. Additional Representations and Warranties of Company.

(a) The Company represents and warrants to ATSA as of the Effective Date that:

(i) All declarations made by Company to ATSA related to Company's qualification, ability and competence to Develop and Commercialize the Product in the Territory are true and correct in all material respects;

(ii) Company has secured, or will timely secure, availability of funds sufficient to cover its Development and Commercialization expenses under this Agreement as they become due as anticipated as of the Effective Date;

(iii) (A) Company is its own ultimate parent entity; (B) Company's assets, as reflected on its most recent regularly prepared balance sheet, are less than [\*\*\*]; (C) Company's sales, as reflected on its last regularly prepared annual statement of income and expense, were less than [\*\*\*]; and (D) Company's board of directors or its designee, has reasonably and good faith determined, that the fair market value of the assets to be acquired pursuant to this Agreement, in particular the ATSA Technology and the Compound is less than [\*\*\*];

(iv) as of the Effective Date and at any time during the Term, Company (aa) performs and will perform its obligations hereunder with reasonable due care, and (bb) procures and will procure that its management establishes and maintains appropriate quality assurance, quality controls and review procedures to secure good standard performance of its obligations hereunder; and

(v) as of the Effective Date and at any time during the Term, Company has reasonably sufficient security systems and intellectual property protection guidelines within its organization to attempt to avoid any unauthorized disclosure of intellectual property rights, including Know-How, to any Third Party;

(vi) as of the Effective Date and at any time during the Term, Company will procure that all data related to human samples and other Personal Data provided to or otherwise made available to Company (including, without limitation, that which is obtained in course of the research, Development, manufacturing or Commercialization of a Compound or a Product), as applicable, was or will be obtained, stored and otherwise Processed in compliance with all Applicable Laws, in particular with Data Protection Law, and in accordance with all medical, administrative and ethical aspects related to the collection, storage and other Procession of human samples, related data and other Personal Data in research activities sufficient in scope for the Parties to exercise their rights and fulfill their obligations under this Agreement (including the transfer of all applicable Personal Data in accordance with all Applicable Laws); in particular, the signature of the informed consent from the donor will be obtained, the confidentiality and anonymization of the human samples will be procured and the personnel involved in such activities will be authorized and will have the capacity to perform such activities; and

(vii) as of the Effective Date and at any time during the Term, Company complies and will comply with all Applicable Laws for the care, welfare and ethical treatment of animals in the country where the research and Development is being performed

Notwithstanding the forgoing in this Section 8.3, the representations and warranties of ATSA in this Section 8.3 shall not apply to any Further Linked TACI-Ig Fusion Molecule.

**8.4. ATSA Covenants.** ATSA hereby covenants to Company:

(a) that during the Term, ATSA will not grant to any Third Party the right to Research, Develop or Commercialize under the ATSA Technology or any other intellectual property rights owned or controlled by ATSA, the Compounds or the Products in the Field; and

(b) that during the Term, ATSA will not amend, modify or terminate the Zymo License or Zymo Side Letter in a manner that would adversely affect Company's rights hereunder without first obtaining Company's prior written consent; and

(c) that during the Term, ATSA will promptly provide Company with any notice of a material breach submitted or received under the Zymo License or Zymo Side Letter and ATSA will try to cure any breach by ATSA of the Zymo License or Zymo Side Letter.

**8.5. Company Covenants.** Company hereby covenants to ATSA:

(a) that Company will, and will require its Affiliates to comply with all Applicable Laws in its and their Research and Development of Compound and Products;

(b) that Company will only use ATSA Technology to Research, Develop, manufacture or Commercialize the Compound or Product in the Field;

(c) that Company will not, and will cause its Affiliates not to (i) sell, assign or otherwise transfer to any Person any ATSA Technology (or agree to do any of the foregoing) other than as permitted under this Agreement, in a manner that conflicts with the rights granted to Company hereunder, or (ii) incur or permit to exist, with respect to any ATSA Technology, any lien, encumbrance, charge, security interest, mortgage, liability, grant of license to Third Parties or other restrictions, in each case, which conflicts with the rights granted to Company hereunder;

(d) that Company will not engage directly or indirectly, in any capacity in connection with this Agreement any Person who either has been debarred by the FDA, is the subject of a conviction described in section 306 of the FD&C Act or is subject to any similar sanction;

(e) that Company will inform ATSA promptly in writing if it or any Person engaged by Company or any of its Affiliates who is performing services under this Agreement or any ancillary agreements is debarred or is the subject of a conviction described in section 306 of the FD&C Act, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to Company's knowledge, is threatened, relating to the debarment or conviction of Company, any of its Affiliates or any such Person performing services hereunder or thereunder; and

(f) to ensure that in the event of a Change of Control over Company, the acquirer will assume, or accede to, as the case may be, all the obligations of Company pursuant to this Agreement.

**8.6 No Other Warranties.** EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 8, EACH PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES EXPRESS OR IMPLIED; INCLUDING WARRANTIES TO TITLE OR NON-INFRINGEMENT; TO FREEDOM TO OPERATE, OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS OF COMPOUND/PRODUCT FOR A PARTICULAR PURPOSE. COMPANY AND ATSA UNDERSTAND THAT COMPOUND OR PRODUCT ARE THE SUBJECT OF ONGOING RESEARCH AND DEVELOPMENT AND THAT NEITHER PARTY CAN ASSURE THE SAFETY, USEFULNESS OR COMMERCIAL OR TECHNICAL VIABILITY OF ANY PRODUCT. IN NO EVENT SHALL EITHER PARTY BE LIABLE TOWARDS THE OTHER PARTY FOR ANY DAMAGES OR LOSSES BASED ON FACTS OR CIRCUMSTANCES OF WHICH SUCH OTHER PARTY WAS ACTUALLY AWARE OF ON THE EFFECTIVE DATE.

#### ARTICLE 9 - INDEMNIFICATION and Insurance

**9.1. Indemnification by ATSA.** ATSA shall defend, indemnify and hold harmless Company, its Affiliates and each of its and their respective directors, officers, employees and agents (the “**Company Indemnitees**”) from and against any and all liability, damage, loss, cost or expense (including reasonable attorney’s fees and expenses of litigation) (collectively, “**Losses**”) to the extent arising or resulting from any claims made or suits brought by Third Parties (collectively, “**Claims**”) arising out of (a) the negligence or willful misconduct of any ATSA Indemnitee; (b) a breach of any of ATSA’s representations, warranties or covenants under this Agreement; and (c) the Research, Development, manufacture or Commercialization of any Compound or Product by or on behalf of ATSA, its Affiliates or (sub)licensees prior to (i) the Effective Date, (ii) with respect to the manufacturing of Drug Product only during the Term or (iii) after termination of this Agreement; except, in each case, to the extent such Claims fall within the scope of Company’s indemnification obligations under Section 9.2.

**9.2. Indemnification by Company.** Company shall defend, indemnify and hold harmless ATSA, its Affiliates, and its and their respective directors, officers employees and agents (the “**ATSA Indemnitees**”) from and against any and all Losses to the extent arising or resulting from any Claims made brought by Third Parties arising out of (a) the negligence or willful misconduct of any Company Indemnitee in connection with the performance of Company’s obligations or exercise of Company’s rights under this Agreement; (b) a breach of any of Company representations, warranties or covenants under this Agreement; (c) the activities that are actually conducted by or on behalf of Company, its Affiliates or its Sublicensees, in particular the handling and storage by or on behalf of Company, its Affiliates or its Sublicensees of any chemical agents or other compounds for the purpose of conducting Research or Development by or on behalf of Company, its Affiliates or its Sublicensees, including any product liability, personal injury, property damage or other damage caused thereby; or (d) any infringement of Patent Rights of any Third Party by Company, its Affiliates or its Sublicensees with respect to any Research, Development or Commercialization on any Product anywhere in the world; except, in each case, to the extent such Claims fall within the scope of ATSA’s indemnification obligations under Section 9.1.

9.3. **Procedure.** A Party seeking indemnification under this Article 9 (“**Indemnified Party**”) shall give prompt written notification to the other Party (“**Indemnifying Party**”) of the claim for which indemnification may be sought (it being understood and agreed, however, that the failure by a Party to give notice of such claim as provided in this Section 9.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give notice). Within [\*\*\*] after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the other Party, assume control of the defense of such claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense and, without limiting the Indemnifying Party’s indemnification obligations, the Indemnifying Party shall reimburse the Indemnified Party for all costs and expenses, including reasonable attorneys’ fees and disbursements, incurred by the Indemnified Party in defending itself within [\*\*\*] after receipt of any invoice therefor from the Indemnified Party. The Party not controlling such defense may participate therein at its own expense; provided that, if the Indemnifying Party assumes control of such defense and the Indemnified Party in good faith concludes, based on written advice from outside counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such claim sufficiently adverse to make unadvisable the representation by the same counsel of both Parties under Applicable Laws, ethical rules or equitable principles, the Indemnifying Party shall be responsible for the reasonable fees and expenses of a single counsel to the Indemnified Party in connection therewith. The Party controlling such defense shall keep the other Party advised of the status of such claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnifying Party shall not agree to any settlement of such claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or that acknowledges fault by the Indemnified Party, without the prior written consent of the Indemnified Party.

#### 9.4. **Insurance.**

(a) **Coverage.** During the Term, each Party shall obtain and maintain at its sole cost and expense, insurance (including any self-insured arrangements) in types and amounts, that are reasonable and customary in the US pharmaceutical and biotechnology industry for companies engaged in comparable activities. To the extent required under the Zymo License, (i) Company shall obtain and keep in force, in form and with insurers reasonable acceptable to ATSA, insurance covering its indemnification obligations hereunder in amount not less than [\*\*\*]; and (ii) from and after the first Regulatory Approval for a Product to be manufactured by or on behalf of the Company hereunder and/or otherwise to be marketed, distributed or sold by the Company or its Affiliates or Sublicensees, and until [\*\*\*] after the end of the respective Royalty Term, Company shall obtain and keep in force, in form and with insurers reasonable acceptable to ATSA, insurance covering Company’s indemnification obligation in amounts not less than [\*\*\*], provided that ATSA shall, by notice to the Company from time to time during such Royalty Term, but not more often than [\*\*\*], solely to the extent required [\*\*\*], have the right reasonably to increase the foregoing coverage levels generally maintained by entities manufacturing or marketing products for human use in the pharmaceutical industry. It is understood and agreed that this insurance shall not be construed to limit either Party’s liability with respect to its indemnification obligations hereunder. Each Party will, except to the extent self-insured, provide to the other Party upon request, a certificate evidencing the insurance such Party is required to obtain and keep in force under this Section 9.4.

(b) **Post-Termination Obligations.** Company will maintain the insurance required under Section 9.4(a) beyond the expiration or termination of this Agreement for a reasonable period after the period during which Company or its Affiliates or Sublicensees were Developing or Commercializing the Compound or Product, which in no event will be less than [\*\*\*].

(c) **Affiliates, Sublicensees and Distributors.** Company will require all of its Affiliates, Sublicensees and Distributors to comply with the provisions and obligations under this Section 9.4 as if such entity were Company.

**9.5. Consequential Damages; Limitation of Liability.** EXCEPT FOR (A) CLAIMS OF A THIRD PARTY THAT ARE SUBJECT TO INDEMNIFICATION UNDER THIS ARTICLE 9 OR DAMAGES AVAILABLE FOR BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 7, NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE OR OTHER INDIRECT DAMAGES OR LOST OR IMPUTED PROFITS OR ROYALTIES, LOST DATA OR COST OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, WARRANTY, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY, CONTRIBUTION OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE. NOTHING IN THIS AGREEMENT SHALL LIMIT EITHER PARTY FROM SEEKING OR OBTAINING ANY REMEDY AVAILABLE UNDER LAW FOR ANY BREACH OF BY THE OTHER PARTY OF ITS CONFIDENTIALITY AND NON-USE OBLIGATIONS UNDER ARTICLE 7.

## ARTICLE 10 - TERM AND TERMINATION

**10.1. Term of Agreement.** This Agreement shall become effective on the Effective Date and will, unless terminated earlier as provided in this Article 10 or Section 12.1, continue in full force and effect, (a) on a Product-by-Product and country-by-country basis, until the date on which the Royalty Term in such country with respect to such Product expires, or (b) in its entirety upon the expiration of all payment obligations under this Agreement with respect to all Products in all countries (the “**Term**”).

**10.2. Termination by ATSA due to insufficient financing.** In the event that within [\*\*\*] following the Effective Date (a) the Company has not received the Initial Closing portion of the Company’s Initial Financing via the Equity Documentation (i.e. at least [\*\*\*]) or (ii) ATSA hasn’t received the ATSA Equity Consideration, ATSA shall have the right to terminate this Agreement immediately by written notice to the other Party.

**10.3. Termination by Company for Convenience.** Upon expiry of a period of two (2) years from the Effective Date [\*\*\*], Company may terminate this Agreement in its entirety, without cause, for any or no reason, by providing written notice of termination to ATSA, in which case, such termination will be effective (a) within [\*\*\*] after ATSA’s receipt of such notice if no Product for the Indication has received Marketing Approval, or (b) [\*\*\*] after ATSA’s receipt of such notice if any Product has received Marketing Approval.

#### 10.4. Termination for Breach and Other Causes.

(a) If a Party breaches any of its material obligations under this Agreement, the Party not in default may give to the breaching Party a written notice specifying the nature of the default, requiring it to cure such breach, and stating its intention to terminate this Agreement if such breach is not cured (i) with respect to outstanding payments not paid within the respective payment dates within [\*\*\*], and (ii) with respect to all other curable events within [\*\*\*]. Subject to Section 10.4(c), if such breach is not cured within the respective cure period after receipt of such notice, the Party not in default shall be entitled to terminate this Agreement immediately by written notice to the other Party.

(b) In the event that Company breaches its diligence obligation with regard to the Development or Commercialization under Section 3.3 of this Agreement, ATSA may, in its sole discretion, exercise its termination right pursuant to Section 10.4 either (i) in whole or (ii) with view to one or more specific Products or (iii) with view to one or more specific countries in the Territory.

(c) Notwithstanding the foregoing, if the breaching Party in Section 10.4 disputes in good faith the existence or materiality of, or failure to cure, any breach, and provides written notice to the non-breaching Party of such dispute within the relevant cure period, the non-breaching Party will not have the right to terminate this Agreement in accordance with Section 10.4, unless and until the relevant dispute has been resolved in accordance with Section 12.16. During the pendency of such dispute, all the terms of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder. If as a result of such dispute resolution process, it is determined that the breaching Party committed a material breach of this Agreement and the breaching Party does not cure such material breach (i) with respect to outstanding payments not paid within the respective payment dates within [\*\*\*], and (ii) with respect to all other curable events within [\*\*\*], then such termination will be effective as of the expiration of the respective cure period. If, as a result of such dispute resolution proceeding, it is determined that the alleged breaching Party did not commit a material breach of this Agreement, then no termination will be effective, and this Agreement will continue in full force and effect.

**10.5. Termination for Insolvency.** If either Party makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within [\*\*\*] after the filing thereof, the other Party may terminate this Agreement in its entirety by providing written notice of its intent to terminate this Agreement to the insolvent Party, in which case this Agreement will terminate on the date on which the insolvent Party receives such written notice.

**10.6. No Challenge.** In the event that Company or any of its Affiliates or Sublicensees, anywhere in the world, institutes, prosecutes or otherwise participates in (or in any way knowingly aids any Third Party in instituting, prosecuting (in a court proceeding) or participating in), at law or in equity and before any administrative or regulatory body, including the U.S. Patent and Trademark Office or its foreign counterparts, any claim, demand, action or cause of action for declaratory relief, damages or any other remedy, or for an injunction, injunction or any other equitable remedy, alleging that any claim in an ATSA Patent is invalid, unenforceable or otherwise not patentable, except in the case where asserted as a defense or counterclaim to an action brought by ATSA against Company or any of its Affiliates or Sublicensees, ATSA shall have the right to terminate on [\*\*\*] notice (provided, that Company has not withdrawn such claim, demand, action or cause of action within such [\*\*\*]) (i) this Agreement or, in its sole discretion, (ii) the license granted to Company or Sublicensee under such challenged ATSA Patent, on a patent-by-patent basis, upon written notice to Company and, as the case may be, Sublicensee; provided, that, ATSA shall not have the right to terminate this Agreement if such challenge was brought by or on behalf of a Sublicensee and Company exercises its right to terminate the applicable sublicense agreement.

### 10.7. Exclusivity Obligation, Competing Product Acquisition

(a) To the extent legally permissible and [\*\*\*], neither Company nor any of its Affiliates, neither alone, through, on behalf of or with any Affiliate or Third Party, shall clinically develop, sell, offer for sale, import or export any Competing Product in the Territory, it being understood that Company's activities pursuant to this Agreement, alone or with Affiliates or Sublicensees (including Third Party subcontractors or distributors), shall not be considered a breach of this non-compete obligation. In the event that Company or any of its Affiliates or Sublicensees enters into such activities, then it shall thereupon be considered to be in material breach of this Agreement and ATSA shall have the right to terminate this Agreement pursuant to Section 10.4.

(b) If Company (or one of its Affiliates or its successor in interest) acquires (Company, such Affiliate or successor in interest, as applicable, the "**Acquiring Party**") a Competing Product from a Third Party or undergoes a Change of Control which results in the Acquiring Party being controlled by an entity with a Competing Product that (i) [\*\*\*], or (ii) is then being [\*\*\*] (both, an "**Acquired Competing Product**"), then Company shall deliver to ATSA as soon as possible (and in any event within [\*\*\*] after Company acquires such Acquired Competing Product or undergoes such Change of Control) a written notification of the Acquiring Party's election, in its sole discretion, either to (x) divest such Acquired Competing Product within [\*\*\*] after the closing of such transaction, (y) cease and terminate the Acquired Competing Product program or (z) solely in the event of such Change of Control, continue such Acquired Competing Product program and implement and enforce effective walls and screens between personnel working in the business of Company related to the transactions contemplated by this Agreement, on the one hand, and the Acquired Competing Product program, on the other hand, to ensure that no information relating to any Compounds or Products or the transactions contemplated by this Agreement is accessible by such Acquiring Party (or any of its Affiliates) in connection with the Acquired Competing Product program.

### 10.8. Effects of Termination or Expiration.

(a) Accrued Rights and Obligations. Termination or expiration of this Agreement shall not release either Party from its obligations accrued prior to the effective date of termination or expiration nor deprive either Party from any rights that this Agreement has conferred on such Party. Such obligations and rights shall survive termination or expiration of this Agreement. Termination of this Agreement by either Party shall be in addition to and not in lieu of any other remedies available to such Party, at law and in equity.

(b) Surviving Terms. Notwithstanding anything in this Agreement to the contrary, the following provisions shall expressly survive any expiration or termination of this Agreement in accordance with their terms: Articles 1 (*Definitions*), 7 (*Confidentiality Obligations*), 9 (*Indemnification and Insurance*), 12 (*Miscellaneous*) and Sections 5.1 (*Milestone Payments*) (to the extent sales milestone payment obligations are not fully fulfilled upon expiration of the Royalty Term) and Section 10.9 (*Effects of Termination or Expiration*).

(c) Consequences of Expiration. Solely if this Agreement expires pursuant to Section 10.1, as of the effective date of the expiration of the Royalty Term with respect to a given Product and country, the license from ATSA to Company under Section 2.1 shall convert to a fully paid, royalty free, irrevocable, perpetual, exclusive, and sublicensable license under the ATSA Technology to Research, Develop, manufacture, have manufactured, use, import, export, keep and Commercialize such Product in the Indications in the Field in such country.

(d) General Consequences of Termination. Upon termination of this Agreement, all licenses granted by ATSA to Company under Section 2.1 shall terminate and all licenses granted by Company to ATSA under Section 2.3 shall terminate. The recipient shall, promptly after expiry or termination of this Agreement, or upon request by the disclosing Party, promptly return, or at the recipient's option destroy and delete (in such a way that it cannot be retrieved and with written proof of such destruction or deletion), all documents, written or in electronic form, and other tangible objects containing or representing Confidential Information that have been disclosed by the disclosing Party to the recipient, and all copies, reproductions or extracts thereof that are in the possession of the recipient (including its Affiliates); provided, however, that the recipient may retain a single copy of such Confidential Information in its confidential files for purposes of determining compliance with this Agreement or if such copy is necessary to comply with legal requirements, but no further use shall be permitted. For clarity, ATSA shall not be required to destroy or return to Company pursuant to this Section 10.8(d) any Confidential Information of Company to which ATSA has licenses or other rights pursuant to this Section 10.8(e).

(e) Additional Consequences of Termination by ATSA pursuant to Sections 10.4, 10.5, or 10.6. Upon any termination of this Agreement by ATSA pursuant to Section 10.4, 10.5, or 10.6 in whole,

(i) Upon ATSA's request, Company shall provide ATSA with a reasonably detailed description of all Company Terminated Product Technology and trademarks specific to each Terminated Product (the "**Terminated Product Trademarks**"). Upon ATSA's request Company shall (i) grant and hereby does grant to ATSA, who accepts the same, an exclusive, worldwide, royalty-free license, with the right to grant sublicenses through multiple tiers, under the Company Terminated Product Technology to Develop, manufacture and Commercialize the Terminated Products in the terminated Indications in the applicable terminated Territory, and (ii) transfer all rights to the respective Terminated Product Trademarks to ATSA;

(ii) Company shall, upon written request by ATSA and subject to ATSA assuming legal responsibility for any Clinical Trials of the Products then ongoing, transfer to ATSA, at Company's cost and expense, all regulatory documentation, regulatory dossiers and Marketing Approvals prepared or obtained by or on behalf of Company relating to Terminated Products prior to the date of such termination, to the extent transferable;

(iii) Company shall, at ATSA's option, transfer to ATSA free of charge any and all chemical, biological or physical materials relating to or comprising Compound or Products, including clinical supplies of Products and commercial inventory of Product, that are Controlled by Company and ATSA shall reimburse Company for its cost of goods for such delivered inventory;

(iv) Company shall reasonably cooperate with ATSA and its designees to facilitate an orderly and prompt transition of the Development and Commercialization activities with respect to the Products and shall provide ATSA free of charge, with [\*\*\*] working hours of assistance to affect such transitional services. ATSA will compensate Company for any reasonable additional assistance requested by ATSA at a rate of [\*\*\*] per hour.

(f) Additional Consequences of Termination by Company pursuant to Section 10.3 or Section 10.4. Upon any termination of this Agreement by Company pursuant to Sections 10.3 or 10.4 in whole,

(i) Upon ATSA's request, Company shall provide ATSA with a reasonably detailed description of all Company Terminated Product Technology and Terminated Product Trademarks. Upon ATSA's request, subject to Company's rights pursuant to Section 10.8(g), Company shall (i) grant and hereby does grant to ATSA an exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses through multiple tiers, under the Company Terminated Product Technology to Develop, manufacture and Commercialize the Terminated Products in the terminated Indications in the applicable terminated Territory, and (ii) transfer all rights to the respective Terminated Product Trademarks to ATSA;

(ii) Promptly upon termination of this Agreement, the Parties shall negotiate in good faith reasonable payments that ATSA will make to Company to exercise the license granted pursuant to this Section 10.8(e)(i), based on [\*\*\*]. If the Parties cannot agree on such financial terms within a period of [\*\*\*], then such dispute shall be resolved in accordance with Section 12.16.

(iii) Company shall, upon written request by ATSA and subject to ATSA assuming legal responsibility for any Clinical Trials of the Products then ongoing, transfer to ATSA, in case of a termination pursuant to Section 10.4 at ATSA's cost and expense and in case of a termination pursuant to Section 10.3 at Company's cost and expense, all regulatory documentation, regulatory dossiers and Marketing Approvals prepared or obtained by or on behalf of Company relating to Terminated Products prior to the date of such termination, to the extent transferable;

(iv) Company shall, at ATSA's option and at ATSA's cost, transfer to ATSA any and all chemical, biological or physical materials relating to or comprising Compound or Products, including clinical supplies of Products (and excluding commercial inventory of Product), that are Controlled by Company and ATSA shall reimburse Company for its cost of goods plus [\*\*\*] for such delivered inventory;

(v) Company shall reasonably cooperate with ATSA and its designees to facilitate an orderly and prompt transition of the Development and Commercialization activities with respect to the Products and shall provide transitional services reasonably requested by ATSA for this purpose. Company shall provide ATSA, free of charge, with [\*\*\*] working hours of assistance to affect such transitional services. ATSA will compensate Company for any additional assistance at a rate of [\*\*\*] per hour.

(g) **Sell-Off Right.** Upon any termination of this Agreement, Company, its Affiliates or its Sublicensees shall cease all Commercialization of Products in the Territory in a prompt manner and in accordance with Applicable Laws, provided, however, that Company, its Affiliates or its Sublicensee shall be entitled, during the [\*\*\*] period following such termination, to sell any commercial inventory of Products which remains on hand as of the date of the termination, so long as Company pays to ATSA the royalties and, if applicable, Milestone Payments relating to Sales-Based Milestone Events applicable to said subsequent sales in accordance with the terms and conditions set forth in this Agreement. Any commercial inventory remaining following such [\*\*\*] period shall be offered for sale to ATSA, at a price to be mutually agreed upon between the Parties in good faith; and

(h) **Consequences of Termination in Part.** Upon any termination of this Agreement by Company pursuant to Section 10.3 or by ATSA pursuant to Section 10.4 not in whole, but in part with view to one or more Products or Indications or one or more countries of the Territory, Section 10.8(d) and Section 10.8(e) shall apply accordingly, but solely with view to the Terminated Product or Indication or, as the case may be, the terminated Territory.

(i) **Sublicensees.** Upon any termination of this Agreement, each sublicense agreement with a Sublicensee (other than an Affiliate of Company, who requires in any event prior written approval by ATSA for such an assignment) shall be assigned to ATSA and remain in effect as a direct license from ATSA to such Sublicensee for the scope of the license granted to such Sublicensee, on the same terms as this Agreement (provided, that such terms shall be reduced or limited, as applicable, to account for any reasonable difference in license scope, territory and duration of the sublicense grant but any such reduction or limitation shall not reduce the financial payments owed to ATSA as a result of such Sublicensee's activities), provided, however, that such Sublicensee is not then in breach of any of its material obligations under its sublicense agreement at the time of termination of this Agreement.

## **ARTICLE 11 - DATA PRIVACY**

### **11.1. Compliance with Data Protection Laws.**

#### **(a) General Compliance.**

(i) The Parties agree to Process any Personal Data in accordance with their respective obligations under Applicable Laws, including all Data Protection Laws. Each Party will Process Personal Data exclusively for the purposes of this Agreement including to comply with Applicable Laws.

(ii) The Parties shall use Commercially Reasonable Efforts to cooperate with the other Party to enable such Party to fulfill its obligations, as applicable, under Applicable Laws.

(iii) The Parties will only store Personal Data for as long as it is necessary in connection with this Agreement or otherwise required by Applicable Laws.

(iv) In the event a Party receives any correspondence from: (i) a Governmental Body in relation to Personal Data Processed under this Agreement; or (ii) a request or notice from a data subject exercising rights under applicable Data Protection Law in relation to Personal Data Processed under this Agreement, such Party shall notify the other Party promptly and provide information sufficient for the other Party to satisfy any obligations it may have to comply with applicable Data Protection Law.

#### **(b) Exchange of Personal Data between the Parties.**

(i) The Parties acknowledge and agree that where they Process Personal Data for the purposes of this Agreement, to the extent the EU GDPR governs such Personal Data, each Party will act as an independent controller in respect of such Personal Data and will be solely responsible for its own Processing activities of that Personal Data.

(ii) If and to the extent Personal Data is Processed by or on behalf of ATSA by the Company, or by or on behalf of the Company by ATSA, so that the Company or ATSA, as the case may be, is acting as a "processor" according to the EU GDPR, the Parties' shall enter into a Personal Data processing agreement in an effort to comply with the requirements under the EU GDPR and that shall apply in addition to the other provisions of this Agreement.

(iii) If and to the extent that the Parties jointly determine the purposes and means of Processing of Personal Data by acting as “Joint Controllers” according to the EU GDPR, the Parties shall enter into a Joint Controllership agreement that determines their respective responsibilities for compliance with the EU GDPR and that shall apply in addition to the other provisions of this Agreement.

(iv) ATSA shall, at all times during the Term, not act in manner that prevents or restricts it from disclosing or transferring Personal Data to the Company as the Agreement requires. If ATSA becomes aware of any circumstances which it reasonably believes may prevent or restrict it from transferring such Personal Data to the Company, it shall promptly notify the Company of the same and take Commercially Reasonable Efforts to ensure that it does not impact ATSA’s obligations under the Agreement.

**(c) Cross-Border Transfer.**

Any transfer of Personal Data governed by the EU GDPR out of the European Economic Area, United Kingdom or Switzerland to a third country outside the European Economic Area, United Kingdom or Switzerland in connection with this Agreement shall only be made in accordance with Articles 44 to 50 of the EU GDPR and other Applicable Laws. The Parties agree to implement appropriate safeguards in accordance with Article 46 of the EU GDPR where necessary or reasonably useful for the transfer of Personal Data for the purposes of the activities under this Agreement; this includes the obligation to enter into standard data protection clauses adopted by the European Commission in accordance with the examination procedure referred to in Article 93 (2) of the EU GDPR where necessary or reasonably useful.

**(d) Breach Notification.**

Where a Party is Processing Personal Data under this Agreement for the exclusive benefit of and at the direction of the other Party, such Party shall promptly notify the other Party in writing after becoming aware of any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, Personal Data subject to this Agreement in its possession, custody or control (the “**Data Breach**”). The Party that did not experience the Data Breach may then request from the other Party further reasonable information about the Data Breach, including a reasonably detailed description of the Data Breach and the categories of Personal Data affected by the Data Breach, and the Parties will use Commercially Reasonable Efforts to identify a root cause of, and to remediate such Data Breach. In furtherance of the foregoing, where (a) ATSA becomes aware of a Data Breach, ATSA will send an email to [\*\*\*] notifying the Company without undue delay, and (b) where the Company becomes aware of a Data Breach, the Company will send an email to [\*\*\*] notifying ATSA without undue delay.

**11.2. Data Privacy Audits.**

Each Party shall have the right during the Term, and for a period of [\*\*\*] following termination of this Agreement, to conduct an investigation and audit of the other Party’s activities, books and records, to the extent they relate to that other Party’s Processing of Personal Data under this Agreement, to verify compliance with the terms of this Agreement; provided, however, that such books and records may not be audited more than once per calendar year and that such investigation or audit shall be conducted during normal business hours, upon reasonable prior notice and performed at the sole and exclusive expense of the auditing Party. The other Party shall use Commercially Reasonable Efforts to cooperate with such investigation or audit, the scope, method, nature and duration of which shall be at the reasonable discretion of the auditing Party.

**ARTICLE 12 - MISCELLANEOUS**

12.1. **Compliance.** ATSA intends to conduct its business in accordance with environmental, labour and social standards and to abide by the standards set forth in the Merck Code of Conduct and the Merck Human Rights Charter (available at <http://www.merckgroup.com>). Company shall comply, and shall ensure that its Affiliates and Sublicensees comply, with reasonably comparable environmental, labour and social standards. Company further acknowledges and ensures that Company and its Affiliates and Sublicensees are familiar with the provisions of the United States Foreign Corrupt Practices Act, the UK Bribery Act and applicable local bribery and corruption laws, and shall not take or permit any action that will either constitute a violation under, or cause ATSA to be in violation of, the provisions of the United States Foreign Corrupt Practices Act, the UK Bribery Act or applicable local bribery and corruption law, environmental, labour and social standards and the Merck Code of Conduct and the Merck Human Rights Charter (collectively, "**Improper Conduct**"). In addition to any other rights ATSA may have under this Agreement, if Company notifies ATSA of, or if ATSA otherwise has a reasonable suspicion of, the occurrence of Improper Conduct, ATSA may inspect or have inspected by an independent auditor the premises, books and records of Company relevant to Improper Conduct for the purpose of ensuring compliance by Company of its obligations under this Section 12.1. Company shall promptly notify ATSA in writing of any Improper Conduct that it is or becomes aware of. In the event that Company or its Affiliates and Sublicensees are in breach of the foregoing, ATSA may terminate this Agreement immediately by written notice to Company.

12.2. **Relationship of the Parties.** Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. The Parties (and any successor, assignee, transferee, or Affiliate of a Party) shall not treat or report the relationship between the Parties arising under this Agreement as a partnership for United States tax purposes, without the prior written consent of the other Party unless required by Applicable Law.

12.3. **Assignment, Change of Control in Company.** This Agreement shall not be assignable by any Party to any Third Party without the prior written consent of the non-assigning Party. Notwithstanding the foregoing, either Party may assign this Agreement or its rights and obligations under this Agreement, without the written consent of the other Party, to an Affiliate or in connection with a Change of Control, provided that the assignee agrees in writing to be bound by the terms of this Agreement. This Agreement will be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein will be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 12.3 will be void. In case of a Change of Control in the Company, the acquirer shall agree in writing that it assumes, or accedes to, as the case may be, the terms of this Agreement.

12.4. **Performance and Exercise by Affiliates and Sublicensees.** Each Party shall have the right to have any of its obligations hereunder performed, or its rights hereunder exercised, by any of its Affiliates or Sublicensees and the performance of such obligations by any such Affiliate or Sublicensees shall be deemed to be performance by such Party; provided, however, that such Party shall be responsible for ensuring the performance of its obligations under this Agreement and that any failure of any Affiliate or Sublicensees performing obligations of such Party hereunder shall be deemed to be a failure by such Party to perform such obligations. For clarity, the foregoing means that each Party may designate an Affiliate or Sublicensees to perform its obligations hereunder or to be the recipient of the other Party's performance obligations hereunder.

12.5. **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

12.6. **Accounting Procedures.** Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with IFRS.

12.7. **Force Majeure.** Neither Party shall be liable to the other for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labour disputes, fire, flood, epidemic, pandemic, failure or delay of transportation, default by suppliers or unavailability of raw materials, governmental acts or restrictions or any other reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and shall use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as practicable.

12.8. **Representation by Legal Counsel.** Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, no presumption will exist or be implied against the Party that drafted such terms and provisions.

12.9. **No Implied License; No Trademark Rights.** No right or license is granted to Company hereunder by implication, estoppel, or otherwise to any Know-How, Patent Right or other intellectual property right owned or Controlled by ATSA or its Affiliates. No right, express or implied, is granted by this Agreement to a Party to use in any manner the name or any other trade name or trademark of the other Party in connection with the performance of this Agreement or otherwise.

12.10. **Entire Agreement; Amendments.** This Agreement together with the Equity Documentation constitutes and contains the entire understanding and agreement of the Parties respecting the subject matter hereof and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.

12.11. **Notices and Deliveries.** Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, transmitted by facsimile or email (receipt verified) or by express courier service (signature required) to the Party to which it is directed at its address, email address or facsimile number shown below or such other address, email address or facsimile number as such Party shall have last given by notice to the other Party.

If to ATSA, addressed to:

Merck KGaA Frankfurter Straße 250  
64293 Darmstadt  
Germany  
Attention: Alliance Management  
Facsimile: [\*\*\*]  
Email Address: [\*\*\*]

With a copy, which shall not constitute notice, to:

Merck KGaA  
Frankfurter Straße 250  
64293 Darmstadt Germany  
Attention: Legal Department / LE-H Facsimile: [\*\*\*]  
Email Address: [\*\*\*]

If to Company, addressed to:

Vera Therapeutics, Inc.  
170 Harbor Way, 3<sup>rd</sup> Floor  
South San Francisco, CA 94080  
USA  
Attention: Chief Executive Officer  
Email Address: [\*\*\*]

With a copy, which shall not constitute notice, to:

Cooley LLP  
3175 Hanover Street  
Palo Alto, CA 94304, USA  
Attn: [\*\*\*]  
Email: [\*\*\*]

12.12. **Language.** This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

12.13. **Waiver.** A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

12.14. **Severability.** If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same will not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement will be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement will be construed as if such clause or portion thereof had never been contained in this Agreement, and there will be deemed substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by Applicable Law.

12.15. **Governing Law.** This Agreement and all disputes arising out of or in connection with it, including its validity and/or termination, shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to any choice of law principles that would require the applicable of the laws of a different state, except that the issues of patentability, validity, enforceability and scope of any Patent Rights shall be determined according to the patent laws of the patent country of such Patent Rights. The Parties expressly agree that the application of the United Nations Convention on Contracts for the International Sale of Goods (1980) is specifically excluded and shall not apply to this Agreement.

12.16. **Dispute Resolution.**

(a) General Dispute Resolution Procedure.

(i) The Parties shall negotiate in good faith and use reasonable efforts to amicably settle any dispute, controversy or claim arising from or related to this Agreement or the breach hereof, including its formation, its validity, its interpretation, the enforcement of contractual rights or obligations and/or termination (each, a “**Legal Dispute**”).

(ii) If a Legal Dispute cannot be resolved within twenty (20) Business Days, any Legal Dispute hereunder shall first be presented to the Party’s Alliance Managers for resolution. A Legal Dispute shall be referred to such Alliance Managers upon either Party providing the other Party with written notice of such referral, and such Alliance Managers shall thereafter attempt to resolve such Legal Dispute through good faith discussions.

(iii) If a Legal Dispute cannot be resolved by the Alliance Managers within twenty (20) Business Days, the Legal Dispute shall then be presented to the Party’s Senior Officers for resolution. A Legal Dispute shall be referred to such Senior Officers upon either Party providing the other Party with written notice of such referral, and such Senior Officers shall thereafter attempt to resolve such Legal Dispute through good faith discussions.

(iv) If a Legal Dispute is not resolved by the Parties’ Senior Officers within fifteen (15) Business Days of such other Party’s receipt of such written notice, the Parties shall invoke the binding arbitration provisions of Section 12.16(b) by giving notice of arbitration.

(b) Arbitration.

(i) Any Legal Dispute not resolved under Section 12.16(a) shall be referred to and finally resolved by arbitration under the Rules of Arbitration of the International Chamber of Commerce (“**ICC Rules**”) in their respective applicable form, which are deemed to be incorporated by reference into this Section.

(ii) The tribunal shall consist of three (3) arbitrators, unless the Parties otherwise mutually agree to have a single arbitrator.

(iii) The seat of the arbitration shall be New York, USA.

(iv) The language of the arbitration shall be English.

(v) Judgment upon the award may be entered by any court having jurisdiction of the award or having jurisdiction over the relevant Party or its assets.

(c) Injunctive Relief. Nothing contained in this Section 12.16 shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed or maintained notwithstanding any ongoing discussions between the Parties.

(d) Intellectual Property Disputes. Notwithstanding this Section 12.16, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent Right covering the use, importation, offer for sale or sale of any Compound in the Field or Product in the Field 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.

12.17. **Rights in Insolvency**. The Parties agree that this Agreement constitutes an executory contract under Section 365 of Title 11 of the United States Code (“**Code**”) for the license of “intellectual property” as defined under Section 101 of the Code and constitutes a license of “intellectual property” for purposes of any similar laws in any other country in the Territory. The Parties further agree that Company, as licensee of such rights under this Agreement, will retain and may fully exercise all of its protections, rights and elections under the Code, including under Section 365(n) of the Code, and any similar laws in any other country in the Territory.

12.18. **Counterparts**. This Agreement may be executed in one or more counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages with signatures (in form of handwritten, non-certified electronic or certified electronic signatures), will be deemed an original.

**12.19. Headings; Construction; Interpretation.** Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. The terms of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms of this Agreement shall be interpreted and construed in accordance with the definitions for such terms provided herein or, if no such definitions are provided, with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of Applicable Laws to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to any Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement. All Schedules and Exhibits to this Agreement shall form an integral part of this Agreement. Except where the context otherwise requires, (a) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Applicable Laws refers to such Applicable Laws as from time to time enacted, repealed or amended, (c) the words “herein”, “hereof” and “hereunder”, and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, (d) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation” or words of similar import, (e) the word “or” is used in the inclusive sense (and/or), unless otherwise indicated by the term “either/or”, and (f) the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders. Any reference in this Agreement to “royalty” or “royalties” (whether used in capitalized letters or not) shall include royalties and other recurring or deferred payments payable by a Party to the other Party for compensation or consideration of rights granted hereunder.

[Signature Page follows]

**IN WITNESS WHEREOF**, the Parties hereto have caused this Agreement to be executed and delivered in duplicate by their duly authorized representatives with legal and binding effect as of the Effective Date.

**VERA THERAPEUTICS, INC.**

By: /s/ [\*\*\*]  
Name: [\*\*\*]  
Title: [\*\*\*]

Address:  
170 Harbor Way, 3rd Floor  
South San Francisco, CA 94080

Email: [\*\*\*]

**ARES TRADING S.A.**

By: /s/ [\*\*\*]  
Name: [\*\*\*]  
Title: Authorized Representative

By: /s/ [\*\*\*]  
Name: [\*\*\*]  
Title: Authorized Representative

Address:  
Ares Trading S.A.  
c/o Merck KGaA  
Frankfurter Straße 250  
64293 Darmstadt  
Germany  
Attention: Alliance Management  
Facsimile: [\*\*\*]  
Email Address: [\*\*\*]

*With a copy, which shall not constitute notice, to:*

Merck KGaA  
Frankfurter Straße 250  
64293 Darmstadt  
Germany  
Attention: Legal Department / LE-H  
Facsimile: [\*\*\*]  
Email Address: [\*\*\*]

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**SCHEDULE 1.17**

**ATSA Patents**

{12 pages omitted}

[\*\*\*]

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**SCHEDULE 1.34**

**Compound**

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**SCHEDULE 1.48**

**Existing Clinical Study**

Clinical Trial Protocol Number: MS700461-0035

Title: A Phase II, Randomized, Double blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Atacicept in IgA Nephropathy

**SCHEDULE 1.68**

**Inventory**

{6 pages omitted}

[\*\*\*]

**SCHEDULE 1.77**

**Milestone Event/ Milestone Payment**

| No.  | Milestone Event | Milestone Payment<br>(in USD) |
|--|-----------------|-------------------------------|
| 1.   | [***]           | [***]                         |
| 2.   | [***]           | [***]                         |
| 3.   | [***]           | [***]                         |
| 4.   | [***]           | [***]                         |
| 5.   | [***]           | [***]                         |
| 6.   | [***]           | [***]                         |
| 7.   | [***]           | [***]                         |
| 8.   | [***]           | [***]                         |
| 9.   | [***]           | [***]                         |
| 10.  | [***]           | [***]                         |
| 11.  | [***]           | [***]                         |
| 12.  | [***]           | [***]                         |
| 13.  | [***]           | [***]                         |
| 14.  | [***]           | [***]                         |
| <b>Sales-Based Milestones (worldwide aggregate annual Net Sales of a Product in the Territory reached for the first time in one Calendar Year)</b> |                 |                               |
| 15.  | [***]           | [***]                         |
| 16.  | [***]           | [***]                         |
| 17.  | [***]           | [***]                         |
| 18.  | [***]           | [***]                         |
| 19.  | [***]           | [***]                         |

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**SCHEDULE 2.4**

**Technology Transfer Plan**

{4 pages omitted}

[\*\*\*]

**SCHEDULE 2.5**

**ATSA Data Package Transfer**

{4 pages omitted}

[\*\*\*]

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**SCHEDULE 3.1**

**Development Plan**

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**SCHEDULE 8.2(a)(xiii)**

**Product Specification**

{17 pages omitted}

[\*\*\*]