

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

**FORM S-1  
 REGISTRATION STATEMENT**  
 UNDER  
 THE SECURITIES ACT OF 1933

**SUTROVAX, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**  
 (State or other jurisdiction of  
 incorporation or organization)

2836  
 (Primary Standard Industrial  
 Classification Code Number)  
 SutroVax, Inc.  
 353 Hatch Drive  
 Foster City, California 94404  
 (650) 837-0111

46-4233385  
 (I.R.S. Employer  
 Identification Number)

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

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 President and Chief Executive Officer  
 SutroVax, Inc.  
 353 Hatch Drive  
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 (650) 837-0111

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement is declared 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, 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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer   
 Non-accelerated filer

Accelerated filer   
 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 Securities To Be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee
Common Stock, \$0.001 par value per share	\$	\$

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

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 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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

Subject to Completion  
Preliminary Prospectus dated \_\_\_\_\_, 2020

PROSPECTUS

**Shares**



**Common Stock**

This is an initial public offering of shares of common stock of SutroVax, Inc. We are selling \_\_\_\_\_ shares of our common stock.

We expect the public offering price to be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share. Currently, no public market exists for the shares. After pricing of the offering, we expect that the shares will trade on the Nasdaq Global Market under the symbol “\_\_\_\_\_.”

We are an “emerging growth company” as defined under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

**Investing in our common stock involves risks that are described in the “[Risk Factors](#)” section beginning on page 12 of this prospectus.**

	<u>Per Share</u>	<u>Total</u>
Initial public offering price	\$ _____	\$ _____
Underwriting discounts and commissions(1)	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

(1) See the section entitled “Underwriting” for additional information regarding compensation payable to the underwriters.

To the extent the underwriters sell more than \_\_\_\_\_ shares of common stock, the underwriters have the option to purchase up to an additional \_\_\_\_\_ shares of common stock from us at the initial public offering price less the underwriting discounts and commissions.

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

The underwriters expect to deliver the shares to purchasers on or about \_\_\_\_\_, 2020.

**BofA Securities**

**Jefferies**

**Evercore ISI**

**Cantor**

**Needham & Company**

Prospectus dated \_\_\_\_\_, 2020

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Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus 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 offering to sell, and seeking offers to buy, common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of 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 entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Our fiscal year ends on December 31. Unless the context otherwise requires, all references in this prospectus to “we,” “us,” “our,” “our company” and “SutroVax” refer to SutroVax, Inc.*

### Overview

We are a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent or treat some of the most common and deadly infectious diseases worldwide. Our cell-free protein synthesis platform enables us to design and produce protein carriers and antigens, the critical building blocks of vaccines, in ways that we believe conventional vaccine technologies currently cannot. Our lead vaccine candidate, SVX-24, is a 24-valent investigational broad-spectrum pneumococcal conjugate vaccine, or PCV, that we believe, if approved, has the potential to become the most broad-spectrum pneumococcal conjugate vaccine addressing the \$7 billion global pneumococcal vaccine market.

Our cell-free protein synthesis platform, which is comprised of the XpressCF platform exclusively licensed from Sutro Biopharma, Inc., or Sutro Biopharma, and our proprietary know-how, offers several advantages over conventional cell-based protein expression methods, which we believe enable us to generate potentially best-in-class, more broad-spectrum and/or more immunogenic vaccines. In the context of conjugate vaccines, we believe we can add more antigenic strains without compromising the overall immune response. In particular, our ability to specify the attachment point of antigens, including polysaccharides, on protein carriers represents a significant improvement over the random conjugation that occurs with conventional technologies. This site-specific conjugation is designed to ensure that B-cell and/or T-cell epitopes are optimally exposed, maximizing the immune response, whereas random conjugation blocks these critical immunogenic epitopes, dampening the immune response and causing a phenomenon known as carrier suppression. We believe this precise control of conjugation chemistry enables us to design broader-spectrum conjugate vaccine candidates using carrier-sparing conjugates that use less protein carrier without sacrificing immunogenicity. We are also able to design novel conjugate vaccine candidates using standard amounts of protein carrier to generate heightened immunogenicity. Beyond conjugate vaccines, we believe we can also design novel protein vaccine candidates based on well-appreciated but highly complex antigens that currently cannot be made with conventional technologies to address diseases for which there are no available vaccines.

The global vaccine market was \$36 billion in 2018 and is expected to grow at an 8% compound annual growth rate, or CAGR, to approximately \$58 billion by 2025. The global pneumococcal vaccine market has grown rapidly over the last two decades, reaching \$7 billion in sales in 2019, and is expected to grow to \$10 billion by 2025. The two leading pneumococcal vaccine franchises, Pneumovax and Prevnar, have generated over \$100 billion in combined sales and have been on the market for over 40 years and 20 years, respectively. The major types of pneumococcal disease are pneumonia (lung infection), bacteremia (bloodstream infection) and meningitis (infection of the tissue surrounding the brain and spinal cord). According to the American Thoracic Society, pneumonia is the world’s leading cause of death among children under five years of age, accounting for 16% of all deaths in the age group. Pneumonia is also the most common cause of unplanned hospitalization in the United States and affects both children and adults. There are currently more than 90 circulating strains of pneumococcus, of which approximately one-third are known to be pathogenic.

The current vaccine standard of care for pneumococcal disease includes the combination of Merck’s Pneumovax 23 and Pfizer’s Prevnar 13 for adults, and Pfizer’s Prevnar 13 for infants. Pneumovax 23 is a







polysaccharide vaccine that protects against 23 strains of pneumococcus but is not thought to protect against pneumonia and provides only transient protection against bacteremia in adults, and is not effective in children under two years of age. Prevnar 13 is a PCV that protects against only 13 strains of pneumococcus but offers significantly better immunogenicity, protects against pneumonia and is suitable for both adults and infants. Routine immunization with PCVs has been effective in dramatically lowering the incidence of invasive pneumococcal disease, or IPD, in both adults and children in the United States and other industrialized nations. However, due to a phenomenon called serotype replacement, strains that are not covered by existing vaccines are increasing in prevalence. In 2016, over 75% of IPD incidence in both children and adults was caused by strains beyond the 13 strains covered by Prevnar 13. Efforts to improve upon current standard of care vaccines center around expanding the valency of PCVs to address the strains driving residual pneumococcal disease. However, limitations due to conventional conjugation chemistry and carrier suppression have complicated those efforts, and there remains a growing need for broader-spectrum PCVs, as evidenced by the fact that despite Prevnar 13's superior immunogenicity profile, Pneumovax 23 remains universally recommended in adults, given its broader-spectrum coverage.

The U.S. Centers for Disease Control, or CDC, its Advisory Committee on Immunization Practices, or ACIP, and similar international advisory bodies develop vaccine recommendations for both children and adults. New pediatric vaccines that receive ACIP preferred recommendations are almost universally adopted, and adult vaccines that receive a preferred recommendation are widely adopted. We believe that our PCVs will be well-positioned to obtain these preferred recommendations, by virtue of their broader spectrum, which could drive rapid and significant market adoption.

Although we believe that our vaccine candidates have the potential to be widely adopted, we have not received regulatory approval for any of our vaccine candidates, and in order to obtain regulatory approval and commercialize our vaccine candidates, the U.S. Food and Drug Administration, or FDA, European Medicines Agency, or EMA, or other regulatory agencies will need to determine that our vaccine candidates are safe and effective. Obtaining such approval will require that we successfully complete additional studies and there can be no assurance that the results of such studies will be similar to our earlier studies. As such, we may not obtain regulatory approval for any of our vaccine candidates, and competing vaccines may ultimately reach the market faster or have more favorable safety and efficacy profiles than our vaccine candidates.

## Our Pipeline

We carefully select our target disease areas and vaccine candidates to address areas of significant unmet medical need based on the following criteria: well-defined commercial landscape and efficient market adoption, low biological risk and established clinical pathways. The following table summarizes our current pipeline:

Program	Profile / Type	Vaccine Description	Target Population	Disease	Status
SVX-24	Superior Conjugate Vaccine	24-valent PCV		Invasive Pneumococcal Disease	Preclinical POC vs Prevnar 13 and Polysaccharide/Alum <sup>(1)</sup> (IND-enabling stage)
				Invasive Pneumococcal Disease and Otitis Media	Preclinical POC vs Prevnar 13 (IND-enabling stage)
SVX-XP	Superior Conjugate Vaccine	Next-generation >30-valent PCV		Invasive Pneumococcal Disease	Preclinical POC vs Prevnar 13 and Polysaccharide/Alum <sup>(2)</sup>
				Invasive Pneumococcal Disease and Otitis Media	Preclinical POC vs Prevnar 13
SVX-A1	Novel Conjugate Vaccine	Monovalent conjugate / complex protein-based vaccine		Group A Strep Infections	Preclinical POC + Grant Funding
SVX-PG	Novel Protein Vaccine	Multiple complex protein-based therapeutic vaccine		Periodontitis	Preclinical POC

 = Adults     = Children     = Infants

- (1) For the Polysaccharide/Alum comparator, we used 23 polysaccharides in Pneumovax 23 at an equivalent dose with the addition of strain 6A and alum as the objective of the study was to evaluate whether SVX-24 showed a conjugate-like response in all 24 strains.
- (2) For the Polysaccharide/Alum comparator, we used 23 polysaccharides in Pneumovax 23 and 9 additional polysaccharides with alum for comparison.

Our lead vaccine candidate, SVX-24, is a preclinical, 24-valent PCV designed to provide the broad-spectrum coverage of Pneumovax 23 with an immunogenicity profile comparable to Prevnar 13. We believe SVX-24, if approved, has the potential to become most broad-spectrum pneumococcal conjugate vaccine addressing the \$7 billion global pneumococcal vaccine market. Our second PCV, known as SVX-XP, builds on the technical proof of concept established by SVX-24 and would, if approved, expand the breadth of coverage to at least 30 strains, including emerging strains responsible for IPD and antibiotics resistance, without compromising immunogenicity due to carrier suppression.

Our preclinical proof of concept studies for SVX-24 measured serotype-specific IgG antibody responses, the surrogate endpoint for pediatrics, and opsonophagocytic activity, or OPA, responses, the surrogate endpoint for adults of our vaccine candidates against Prevnar 13 and Pneumovax 23. In these studies, our vaccine candidates have shown comparable responses to the 13 common strains in Prevnar 13 and superior responses to the 23 common strains in Pneumovax 23.

We believe our PCVs could receive regulatory approval based on a demonstration of non-inferiority to the standard of care using well-defined surrogate immune endpoints rather than requiring clinical field efficacy studies, consistent with how other PCVs have obtained regulatory approval in the past. We expect to submit an investigational new drug, or IND, application for SVX-24 to the U.S. Food and Drug Administration, or FDA, in the second half of 2021.

In addition to our PCV franchise, we are developing a novel conjugate vaccine candidate for Group A Strep. Group A Strep causes 700 million cases, the majority of which are of pharyngitis, commonly known as

strep throat, worldwide each year and increases the risk for severe invasive infections, such as sepsis, necrotizing fasciitis and toxic shock syndrome. There is currently no vaccine against Group A Strep. In September 2019, we announced a grant of up to \$15.1 million, awarded by CARB-X, a global non-profit partnership dedicated to accelerating antibacterial innovation to tackle the rising global threat of drug-resistant bacteria, to develop this vaccine candidate.

We are also developing a novel protein vaccine candidate targeting the keystone pathogen responsible for periodontitis, a chronic oral inflammatory disease affecting an estimated 65 million adults in the United States. Our initial goal is to develop a therapeutic vaccine to slow or stop disease progression; however, the results from clinical trials may inform the potential adoption of prophylactic immunization.

### **Our Platform**

We are leveraging our scalable cell-free protein synthesis platform to develop potentially superior and novel conjugate and protein vaccine candidates for adult and pediatric indications by taking advantage of the following:

- *Site-Specific Conjugation.* We are able to specify the attachment point of antigens, including polysaccharides, on protein carriers to ensure optimal exposure of B-cell and/or T-cell epitopes, thereby creating protein carriers designed to have enhanced potency. We believe this precise control of conjugation chemistry enables us to create broader-spectrum conjugate vaccine candidates using carrier-sparing conjugates that use less protein carrier without sacrificing immunogenicity. We are also able to design novel conjugate vaccine candidates using standard amounts of protein carrier to generate heightened immunogenicity.
- *Production of Novel Protein Vaccines.* We can design novel protein vaccine candidates based on well-appreciated but highly complex antigens that currently cannot be made with conventional technologies to address diseases for which there are no available vaccines and we believe we may be able to leverage our platform to rapidly respond to new or emerging pathogens. We can design and produce these “tough-to-make” antigens that conform to the target pathogens, thereby increasing the likelihood that the vaccine will elicit a protective immune response.
- *Speed, Flexibility and Scalability of the Discovery Engine.* We are able to rapidly screen vaccine candidates and produce conjugates, thereby accelerating the process of making and testing vaccine candidates. Furthermore, we believe our platform can scale linearly from discovery to commercial scale.

### **Our Strategy**

The key elements of our strategy are:

- Advance SVX-24 through IND-enabling activities, clinical development and regulatory approval.
- Establish scalable production of SVX-24.
- Create a long-lasting PCV franchise by offering the broadest-spectrum PCV available.
- Advance our novel vaccine candidates and expand our pipeline.
- Continue to build a robust intellectual property portfolio.

## **Manufacturing and Supply**

We believe that an efficient and high-quality manufacturing process is critical to our long-term success. We have strategically aligned with our contract manufacturer, Lonza, a globally recognized contract development and manufacturing organization based in Switzerland, to develop a robust and scalable manufacturing process for SVX-24. We have partnered closely with Lonza to transfer technology, develop and optimize processes to produce not only clinical trial material, but also to scale up for potential commercial production of SVX-24. With this ongoing partnership, we believe we are addressing the complexity of vaccine development and production, thus establishing barriers to entry to protect our PCV franchise.

## **Management and Investors**

SutroVax was formed in 2013 through its relationship with Sutro Biopharma by our three co-founders, Grant Pickering, Jeff Fairman and Ash Khanna, with the goal of utilizing Sutro Biopharma's proprietary XpressCF platform in the field of vaccines to address infectious diseases. Since that time, we have assembled a distinguished group of executives, directors and advisors with extensive experience in vaccine development, manufacturing and commercialization. Our co-founder and Chief Executive Officer, Grant Pickering, played a prominent role in developing Provenge, the first therapeutic cancer vaccine to reach the market. Our co-founder and Vice President of Research, Jeff Fairman, our Chief Operating Officer, Jim Wassil and our Senior Vice President of Process Development and Manufacturing, Paul Sauer, have been developing and industrializing vaccines and other biologics for close to 80 years, collectively. We also benefit from directors and advisors that have previously served as heads of research and development for GlaxoSmithKline, Merck and Sanofi-Pasteur, including our board chairman, Moncef Slaoui, who served as the chairman of GlaxoSmithKline Vaccines. Together, our executives, directors and advisors have made essential contributions to the development of many widely used preventative and therapeutic vaccines, including pneumococcal vaccines such as Prevnar, Prevnar 13, Synflorix and Pneumovax 23, as well as other vaccines, including Provenge, Gardasil, Cervarix, Shingrix, Zostavax, Rotateq, Rotarix, Menveo and Bexsero, among others.

We are supported by leading investors, including TPG Growth, Abingworth LLP, Longitude Capital, Frazier Healthcare Partners, Pivotal bioVenture Partners, Medicxi, Roche Venture Fund, CTI Life Sciences Fund and Foresite Capital.

## **Risk Factors Summary**

Our business is subject to numerous risks and uncertainties, including those discussed more fully in the section entitled "Risk Factors." These risks include, but are not limited to:

- We are in the early stages of vaccine development and have a very limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant net losses since inception and anticipate that we will continue to incur substantial net losses for the foreseeable future and may never achieve or maintain profitability. Our stock is a highly speculative investment.
- Even after this offering, we will require substantial additional funding to finance our operations. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.
- Our approach to the discovery and development of our vaccine candidates is based on novel technologies that are unproven, which may expose us to unforeseen risks and makes it difficult to predict the time and cost of vaccine candidate development and time to obtain regulatory approval.



- Our vaccine candidates have never been tested in human subjects and are in early, preclinical stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we are unable to complete development of or commercialize our vaccine candidates or experience significant delays in doing so, our business would be materially harmed.
- Approvals by the FDA and EMA for existing pneumococcal vaccines, such as Prevnar 13 and Pneumovax 23, may not be indicative of what these regulators may require for approval of our vaccine candidates. For example, we expect to use OPA titers as the primary immunogenicity surrogate endpoint for the SVX-24 program in adults because Prevnar 13 was approved based on the establishment of non-inferiority of serotype-specific OPA responses relative to Pneumovax 23; however, there can be no assurance that this streamlined non-inferiority approach will be sufficient for regulatory approval or that regulators will not require field efficacy trials.
- Our business is highly dependent on the success of SVX-24, which is in the early stages of development. If we are unable to obtain approval for SVX-24 and effectively commercialize SVX-24, our business would be significantly harmed.
- Our primary competitors have significantly greater resources and experience than we do, which may make it difficult for us to successfully develop our vaccine candidates, or may result in others discovering, developing or commercializing products before or more successfully than us.
- We may not be successful in our efforts to use our cell-free protein synthesis platform to expand our pipeline of vaccine candidates and develop marketable candidates.
- We currently rely on third-party manufacturing and supply partners, including Lonza and Sutro Biopharma, to supply raw materials and components for, and manufacture, our vaccine candidates. Our inability to have sufficient quantities of our vaccine candidates manufactured, or our failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.
- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our vaccine candidates.
- If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

#### **Corporate Information**

We were incorporated under the laws of the state of Delaware in November 2013. Our principal executive offices are located at 353 Hatch Drive, Foster City, California 94404. Our telephone number is (650) 837-0111. Our website address is <https://www.sutrovax.com>. Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus.

SutroVax, the SutroVax logo and our other registered or common law trade names, trademarks or service marks appearing in this prospectus are the property of SutroVax, Inc. or exclusively licensed for SutroVax's use. Trade names, trademarks and service marks of other companies appearing in this prospectus are the property of their respective owners.

### **Implications of Being an Emerging Growth Company**

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- not being required to comply for a certain period of time with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a stockholder advisory vote on executive compensation and any golden parachute payments not previously approved.

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 30<sup>th</sup>; 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.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. 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 some accounting standards until those standards would otherwise apply to private companies. 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 we are no longer an emerging growth company or we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. However, as described in Note 3 to our financial statements included elsewhere in this prospectus, we early adopted certain accounting standards, as the JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies to the extent early adoption is permitted. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

**The Offering**

Common stock offered by us	shares
Option to purchase additional shares	shares
Common stock to be outstanding immediately after this offering	shares ( additional shares in full) shares if the underwriters exercise their option to purchase

Use of proceeds We estimate that the net proceeds from the sale of our common stock in this offering will be approximately \$ million (or approximately \$ million if the underwriters exercise their option to purchase additional shares in full), based on the assumed initial public offering price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our capitalization and financial flexibility, create a public market for our common stock, facilitate future access to the public equity markets by us, our employees and our stockholders and increase our visibility in the marketplace. We currently intend to use the net proceeds we receive from this offering to fund completion of IND-enabling activities and our clinical development of SVX-24, ongoing preclinical development of our other vaccine candidates and general corporate purposes, including working capital, operating expenses and capital expenditures. See the section entitled "Use of Proceeds" for additional information.

Risk factors See the section entitled "Risk Factors" for additional information.

Proposed trading symbol on the Nasdaq Global Market " "

The number of shares of our common stock that will be outstanding after this offering is based on shares of our common stock (including (i) 34,398,138 shares of our redeemable convertible preferred stock on an as-converted basis, (ii) the issuance of shares of our common stock as a result of the expected net exercise of an outstanding warrant to purchase 100,000 shares of our redeemable convertible preferred stock and (iii) the issuance of shares of our common stock as a result of the expected net exercise of an outstanding warrant to purchase 53,744 shares of our common stock) outstanding as of December 31, 2019, and excludes:

- 5,676,107 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of December 31, 2019, with a weighted-average exercise price of \$1.13 per share;
- 268,000 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted after December 31, 2019, with a weighted-average exercise price of \$2.21 per share;

- shares of our common stock reserved for future issuance under our 2020 Equity Incentive Plan, or 2020 Plan, (including up to shares of our common stock comprised of (i) the shares reserved and remaining available for issuance under our 2014 Equity Incentive Plan, or 2014 Plan, that will be added to our 2020 Plan reserve upon its effectiveness plus (ii) the number of shares subject to stock options or other stock awards granted under our 2014 Plan that would have otherwise returned to our 2014 Plan, which will be added as they become available (e.g., due to forfeiture of the underlying 2014 Plan award)), which includes an annual evergreen increase and will become effective in connection with this offering; and
- shares of our common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, or ESPP, which includes an annual evergreen increase and will become effective in connection with this offering.

Unless otherwise indicated, the information in this prospectus assumes:

- an initial public offering price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus;
- the conversion of all outstanding shares of our redeemable convertible preferred stock into 34,398,138 shares of our common stock upon the closing of this offering;
- no exercise of the outstanding options described above;
- the net exercise of (i) the outstanding warrant to purchase 100,000 shares of our redeemable convertible preferred stock with an exercise price of \$6.8296 per share, resulting in the issuance of shares of our common stock and (ii) the outstanding warrant to purchase 53,744 shares of our common stock with an exercise price of \$0.47 per share, resulting in the issuance of shares of our common stock, in each case, assuming an initial public offer price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, both of which will terminate if not exercised prior to the completion of this offering;
- no exercise of the underwriters' option to purchase up to an additional shares of our common stock; and
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur upon the closing of this offering.

### Summary Financial Data

The following tables set forth our summary statements of operations data for the years ended December 31, 2018 and 2019, and our summary balance sheet data as of December 31, 2019, which have been derived 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 sections entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Selected Financial Data” 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 December 31,	
	2018	2019
	(in thousands, except share and per share data)	
<b>Statements of Operations Data:</b>		
Operating expenses:		
Research and development	\$ 30,145	\$ 45,607
General and administrative	5,388	8,546
Total operating expenses	<u>35,533</u>	<u>54,153</u>
Loss from operations	<u>(35,533)</u>	<u>(54,153)</u>
Other income (expense), net:		
Interest expense	(75)	(40)
Interest income	903	632
Grant income	—	237
Foreign currency transaction gain (loss)	42	(135)
Change in fair value of the redeemable convertible preferred stock tranche liability	5,178	3,185
Total other income (expense), net	<u>6,048</u>	<u>3,879</u>
Net loss and comprehensive loss	<u>\$ (29,485)</u>	<u>\$ (50,274)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (4.80)</u>	<u>\$ (7.85)</u>
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted <sup>(1)</sup>	<u>6,142,274</u>	<u>6,402,359</u>
Pro forma net loss per share, basic and diluted (unaudited) <sup>(1)</sup>		
Weighted-average shares outstanding used in computing pro forma net loss per share, basic and diluted (unaudited) <sup>(1)</sup>		

(1) See Notes 2 and 13 to our financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share, basic and diluted pro forma net loss per share and the weighted-average number of shares used in the computation of the per share amounts.

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	As of December 31, 2019		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)(3)
	(in thousands)		
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 58,976	\$ —	\$ —
Working capital(4)	50,671		
Total assets	65,698		
Redeemable convertible preferred stock warrant liability	450		
Redeemable convertible preferred stock tranche liability	—		
Series A redeemable convertible preferred stock	24,967		
Series B redeemable convertible preferred stock	55,151		
Series C redeemable convertible preferred stock	80,192		
Total stockholders' (deficit) equity	(106,373)		
(1)	<p>The pro forma balance sheet data gives effect to (i) the conversion of all of our outstanding shares of redeemable convertible preferred stock as of December 31, 2019 into 34,398,138 shares of our common stock immediately prior to the closing of this offering; (ii) the issuance of _____ shares of our common stock as a result of the expected net exercise of an outstanding warrant to purchase 100,000 shares of our redeemable convertible preferred stock and the related reclassification of the redeemable convertible warrant liability to common stock and additional paid-in capital, assuming an initial public offering price of \$ _____ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus; (iii) the issuance of _____ shares of our common stock as a result of the expected net exercise of an outstanding warrant to purchase 53,744 shares of our common stock, assuming an initial public offering price of \$ _____ per share; and (iv) the removal of gains or losses resulting from the re-measurement of the redeemable convertible preferred stock warrant liability as the warrant will be exercised for shares of common stock immediately prior to our IPO.</p>		
(2)	<p>The pro forma as adjusted column gives effect to: (i) the pro forma adjustments set forth in footnote (1) above and (ii) the sale of _____ shares of our common stock in this offering at the assumed initial public offering price of \$ _____ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p>		
(3)	<p>Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) each of our pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by approximately \$ _____ million, 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 estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares of common stock offered by us would increase (decrease) each of our pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by approximately \$ _____ million, assuming the assumed initial public offering price of \$ _____ per share remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma and pro forma as adjusted information discussed above is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing.</p>		
(4)	<p>Working capital is defined as total current assets less total current liabilities. See our financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.</p>		

## 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 of this prospectus entitled “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 Capital Needs**

***We are in the early stages of vaccine development and have a very limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

To date, we have devoted substantially all of our resources to performing research and development, undertaking preclinical studies and enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology and vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities. As an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful commercialization or arrange for a third party to conduct these activities on our behalf. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Our current vaccine candidate pipeline includes four preclinical programs. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives, including with respect to our vaccine candidates. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

***We have incurred significant net losses since inception and anticipate that we will continue to incur substantial net losses for the foreseeable future and may never achieve profitability. Our stock is a highly speculative investment.***

We are a preclinical stage biotechnology vaccine company that was incorporated in November 2013. Investment in preclinical stage companies and vaccine development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential vaccine candidate will not gain regulatory approval or become commercially viable. We do not have any products approved for sale and have not generated any revenue from product sales. As a result, we are not profitable and have incurred losses in each year since inception. Our net losses were \$29.5 million and \$50.3 million for the years ended December 31, 2018 and 2019, respectively. As of December 31, 2019, we had an accumulated deficit of \$109.3 million.

We expect to continue to spend significant resources to fund research and development of, and seek regulatory approvals for, our vaccine candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, manufacturing, preclinical testing and clinical trial activities increase. As a result, our accumulated deficit will also increase significantly. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. 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. However, we do not expect to generate any revenue from commercial product

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sales unless and until we successfully complete development and obtain regulatory approval for one or more of our vaccine candidates, which we expect will take a number of years. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Even if we eventually generate revenue, we may never be profitable and, if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

***Even after this offering, we will require substantial additional funding to finance our operations. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.***

As of December 31, 2019, we had cash and cash equivalents of \$59.0 million. We believe that the net proceeds from this offering will be approximately \$      million, based on an assumed public offering price of \$      per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We believe that such proceeds, together with our existing cash and cash equivalents as of the date of this prospectus, will fund our current operating plans through at least the next      months from the date of this offering. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. We will need to raise additional capital before we can progress any of our vaccine candidates into a pivotal clinical trial. We expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements or any combination of these approaches. Our future capital requirements will depend on many factors, including:

- the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical development and clinical trials;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the U.S. Food and Drug Administration, or FDA, and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies for our pneumococcal conjugate vaccine, or PCV, candidates, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the cost of building a sales force in anticipation of any product commercialization;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our vaccine candidates for which we receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the revenue, if any, received from commercial sales, or sales to foreign governments, of our vaccine candidates for which we may receive marketing approval;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we



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may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing of any patents or other intellectual property rights;

- the expenses needed to attract, hire and retain skilled personnel; and
- the costs of operating as a public company.

Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our vaccine candidates or other research and development initiatives. Our license agreements may also be terminated if we are unable to meet the payment obligations or milestones under the agreements. We could be required to seek collaborators for our vaccine candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, or relinquish or license on unfavorable terms our rights to our vaccine candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

***Due to the significant resources required for the development of our vaccine candidates, and depending on our ability to access capital, we must prioritize development of certain vaccine candidates. Moreover, we may expend our limited resources on vaccine candidates that do not yield a successful vaccine and fail to capitalize on vaccine candidates that may be more profitable or for which there is a greater likelihood of success.***

Due to the significant resources required for the development of our vaccine candidates, we must decide which vaccine candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, management and financial resources toward particular vaccine candidates may not lead to the development of any viable commercial vaccines and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate, license or collaborate with third parties in respect of certain vaccine candidates may subsequently also prove to be less than optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our vaccine candidates or misread trends in the biopharmaceutical industry, in particular for vaccines, our business could be seriously harmed. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other vaccine candidates that may later prove to have greater commercial potential than those we choose to pursue or relinquish valuable rights to such vaccine candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

***Our 2019 financial statements contain disclosures regarding the substantial doubt about our ability to continue as a going concern. We will need additional financing to execute our business plan, to fund our operations and to continue as a going concern.***

The report of our independent registered public accounting firm on our financial statements as of and for the year ended December 31, 2019 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. If we are unable to raise sufficient capital when needed, our business, financial condition and results of operations will be materially and adversely affected, and we will need to significantly modify our operational plans to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The inclusion of a going concern explanatory paragraph by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

***Raising additional capital may cause dilution to our stockholders, including investors in this offering, restrict our operations or require us to relinquish rights to our technologies or vaccine candidates.***

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or vaccine candidates, or grant licenses on terms unfavorable to us.

### **Risks Related to Our Business and Industry**

***Our approach to the discovery and development of our vaccine candidates is based on novel technologies that are unproven, which may expose us to unforeseen risks and makes it difficult to predict the time and cost of vaccine candidate development and obtain regulatory approval.***

We are developing a pipeline of vaccine candidates utilizing our cell-free protein synthesis platform, which is comprised of the XpressCF platform exclusively licensed from Sutro Biopharma, Inc., or Sutro Biopharma, and our proprietary know-how for vaccine applications against infectious disease, and our future success depends on the successful application of this approach to vaccine development. We are in the early stages of developing our vaccine candidates and there can be no assurance that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be overcome. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to manufacturing partners, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all. In addition, since we have not yet entered clinical development, we do not know the specific doses that may be effective in the clinic or, if approved, commercially. Finding a suitable dose may delay our anticipated clinical development timelines.

Furthermore, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our vaccine candidates and understand these critical factors. Conjugate vaccine development is highly complex, and development of broad-valency PCVs is further complicated by the number of components, analytical assays, and potential for adjustments, including but not limited to changes in raw materials, composition, formulation, manufacturing methods and dosing, which could result in drug substances and/or drug product that may vary between preclinical and clinical studies over time.

In addition, the preclinical and clinical trial requirements of the FDA, European Medicines Agency, or EMA, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a vaccine candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. Approvals by the FDA and EMA for existing pneumococcal vaccines, such as Prevnar 13 and Pneumovax 23, may not be indicative of what these regulators may require for approval of our vaccine candidates. For example, we expect to use opsonophagocytic activity, or OPA, titers as the primary immunogenicity surrogate endpoint for the SVX-24 program in adults because Prevnar 13 was approved based on the establishment of non-inferiority of serotype-specific OPA responses relative to Pneumovax 23; however, there can be no assurance that this streamlined non-inferiority approach will be sufficient for regulatory approval or that regulators will not require field efficacy trials. Furthermore, while there have been approvals granted for both pneumococcal conjugate vaccines and meningococcal conjugate vaccines based on surrogate immune endpoints rather than field efficacy studies, we will not be able to confirm this approach's applicability for our vaccines until we complete our Phase 2

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clinical development program. Additionally, novel aspects of our vaccine candidates and manufacturing processes may create further challenges in obtaining regulatory approval. The regulatory approval process for our novel vaccine candidates can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other vaccine candidates. More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new vaccine candidates. Moreover, our vaccine candidates may not perform successfully in clinical trials.

***Our vaccine candidates have never been tested in human subjects and are in early, preclinical stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we are unable to complete development of or commercialize our vaccine candidates or experience significant delays in doing so, our business would be materially harmed.***

We have no products that have entered clinical trials or that are on the market, and all of our vaccine candidates are in early discovery and preclinical stages of development. Vaccine development generally takes many years. In particular, our most advanced vaccine candidate, SVX-24, showed positive results in a preclinical proof of concept study in 2017, and we expect to submit an investigational new drug, or IND, application to the FDA in the second half of 2021. Our other vaccine candidates are in earlier stages of discovery and preclinical development and may never advance to clinical-stage development. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing our vaccine candidates, either alone or with third parties, and we cannot guarantee that we will ever obtain regulatory approval for any of our vaccine candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. Before obtaining regulatory approval for the commercial distribution of our vaccine candidates, we must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy of our vaccine candidates.

We may not have the financial resources to continue development of, or to enter into new collaborations for, a vaccine candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, vaccine candidates, including:

- negative or inconclusive results from our preclinical or clinical trials, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related adverse effects experienced by patients in our clinical trials;
- difficulty achieving successful development of our manufacturing processes, including process development and scale-up activities to supply products for preclinical studies, clinical trials and commercial sale, if approved;
- timely completion of our preclinical studies and clinical trials, including any field efficacy studies that may be required, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- inability of us or any third-party contract manufacturer to scale up manufacturing of our vaccine candidates to supply the needs of preclinical studies, clinical trials and commercial sales, and to manufacture such products in conformity with regulatory requirements;
- delays in submitting INDs or compatible foreign applications or delays or failures in obtaining necessary approvals from regulators to commence a clinical trial, or suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or similar foreign authorities regarding the scope or design of our clinical trials, including any requirements to perform field efficacy studies;

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- delays in enrolling patients in our clinical trials;
- inadequate supply or quality of vaccine candidate components or materials or other supplies necessary for conducting clinical trials;
- inability to obtain alternative sources of supply for which we have a single source for vaccine candidate components;
- the availability of coverage and adequate reimbursement and pricing from third-party payors, including government authorities, pertaining to the vaccine candidate, once approved, and patients' willingness to pay out-of-pocket if third-party payor reimbursement is limited or not available;
- greater than anticipated costs of our clinical trials, including chemistry, manufacturing and controls, or CMC, activities related to our clinical trials;
- harmful side effects or inability of our vaccine candidates to meet efficacy endpoints;
- unfavorable FDA or other regulatory agency inspection and review of one or more of our clinical trial sites or our contract manufacturers' facilities;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology or vaccine candidates in particular; or
- varying interpretations of our data by the FDA and comparable foreign regulatory authorities.

In particular, while we believe our PCVs could receive regulatory approval based on well-defined surrogate immune endpoints rather than requiring clinical field efficacy studies, which is consistent with how other PCVs have obtained regulatory approval in the past, there can be no assurance that the FDA or comparable foreign regulatory authorities will provide approvals on such basis. In addition, changes to the standard of care or the approval of new vaccines could change the threshold for achievement of non-inferiority using the established surrogate immune endpoints that our PCVs will need to meet in our clinical trials.

Our inability to complete development of or commercialize our vaccine candidates, or significant delays in doing so due to one or more of these factors, could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our vaccine candidates.

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***Our business is highly dependent on the success of SVX-24, which is in the early stages of development. If we are unable to obtain approval for SVX-24 and effectively commercialize SVX-24, our business would be significantly harmed.***

Our business and future success depends on our ability to obtain regulatory approval of, and then successfully commercialize, our most advanced vaccine candidate, SVX-24. SVX-24 is in the early stages of development, and to date has only completed preclinical proof of concept studies as compared to Prevnar 13 and polysaccharide/alum in rabbits. Although SVX-24 has produced successful results in animal studies, it may not demonstrate the same properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. SVX-24 will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient preclinical, clinical and commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We cannot provide any assurance that we will be able to successfully advance SVX-24 through the development process.

The clinical and commercial success of SVX-24 and future vaccine candidates will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete IND-enabling studies and successfully submit IND or comparable applications;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials, including field efficacy studies, or other studies beyond those planned to support the approval and commercialization of our vaccine candidates or any future vaccine candidates;
- acceptance of our proposed indications and primary surrogate endpoint assessments for our PCV candidates by the FDA and similar foreign regulatory authorities;
- any changes to the required threshold for the achievement of non-inferiority using established surrogate immune endpoints that our PCVs will need to meet in our clinical trials;
- our ability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of SVX-24 or any future vaccine candidates;
- the pace and prevalence of serotype replacement following the introduction of SVX-24 or SVX-XP or other vaccines targeting pneumococcal disease;
- any vaccine-vaccine interference studies that may be required, particularly with the standard of care pediatric vaccine regimen;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our vaccine candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA or comparable foreign regulatory authorities;

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- achieving, maintaining and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to our lead vaccine candidates or any future vaccine candidates or approved products, if any;
- obtaining and maintaining an Advisory Committee on Immunization Practices, or ACIP, preferred recommendation or comparable foreign regulatory authority's recommendation of our vaccine candidates and the willingness of physicians, operators of clinics and patients to utilize or adopt any of our future vaccine candidates to prevent or treat age-associated diseases;
- the ability of third parties with whom we contract to manufacture adequate clinical study and commercial supplies of our lead vaccine candidates or any future vaccine candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our vaccine candidates or any future vaccine candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- the convenience of our treatment or dosing regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our vaccine candidates or any future vaccine candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our vaccine candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our vaccine candidates or any future vaccine candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our vaccine candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our vaccine candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our vaccine candidates or any future vaccine candidates to continue our business or achieve profitability.

***Our primary competitors have significantly greater resources and experience than we do, which may make it difficult for us to successfully develop our vaccine candidates, or may result in others discovering, developing or commercializing products before or more successfully than us.***

The vaccine market is intensely competitive and is dominated by a small number of multinational, globally established pharmaceutical corporations with significant resources; Pfizer, Merck, GlaxoSmithKline, and Sanofi together control approximately 75% of the global vaccine market. We may also face competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Vaccine candidates that we successfully develop and commercialize may compete with existing vaccines and new vaccines that may become available in the future. Many of our competitors have substantially greater financial, lobbying, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior

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vaccines, including the potential that our competitors may develop chemical processes or utilize novel technologies for developing vaccines that may be superior to those we employ. In addition, many of these competitors have significantly greater experience than we have in undertaking preclinical testing and clinical trials of new products and in obtaining regulatory approvals, including for many vaccine franchises. Accordingly, our competitors may succeed in obtaining FDA approval or a preferred recommendation for their products. For example, Prevnar 13 obtained FDA approval for the prevention of invasive pneumococcal disease, or IPD, in infants based on non-inferior IgG antibody responses relative to Prevnar, using the surrogate immune endpoints established by the prior Prevnar field efficacy study. Pfizer is currently implementing a similar approach to development of its 20-valent PCV vaccine candidate, and may have a more efficient path to regulatory approval given Pfizer's and the FDA's previous experience with Prevnar 13. For more information, see the section entitled "Business—Competition."

Many of our competitors have established distribution channels for the commercialization of their vaccine products, whereas we have no such established channels or capabilities. In addition, many competitors have greater name recognition, more extensive collaborative relationships or the ability to leverage a broader vaccine portfolio. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize vaccines that are safer, more effective, more convenient, less expensive or with a more favorable label than any vaccine candidates that we may develop.

As a result of these factors, our competitors may obtain regulatory approval of their products before we are able to, which may limit our ability to develop or commercialize our vaccine candidates. Our competitors may also develop vaccines that are safer, more effective, more widely accepted or less expensive than ours, and may also be more successful than we are in manufacturing and marketing their products. These advantages could render our vaccine candidates obsolete or non-competitive before we can recover the costs of such vaccine candidates' development and commercialization.

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 and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

For additional information regarding our competition for each of our vaccine candidates, see the section entitled "Business—Competition."

***We and our contract manufacturers may face difficulty satisfying chemistry, manufacturing and controls requirements imposed by the FDA and comparable foreign regulatory authorities. To date, no product developed using a cell-free manufacturing platform has received approval from the FDA or been commercialized.***

While we are designing and developing a manufacturing process that we believe can scale to address clinical and commercial vaccine supply, we do not own or operate any manufacturing facilities. We rely on contract manufacturing organizations, or CMOs, including our strategic partnership with our contract manufacturer, Lonza, to access resources to facilitate the development and, if approved, commercialization of SVX-24 and our other vaccine candidates. Advancing our vaccine candidates may create significant challenges, including:

- manufacturing our vaccine candidates to our specifications, including process development, analytical development and quality control testing, and in a timely manner to support our preclinical and clinical trials and, if approved, commercialization;

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- sourcing the raw materials used to manufacture our vaccine candidates for preclinical, clinical and, if approved, commercial supplies; and
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of our vaccines.

Before we can initiate a clinical trial or commercialize any of our vaccine candidates, we must demonstrate to the FDA that the CMC for our vaccine candidates meet applicable requirements, and in the EU, a manufacturing authorization must be obtained from the appropriate EU regulatory authorities. Because no product manufactured on a cell-free manufacturing platform has been approved in the United States, there is no manufacturing facility that has demonstrated the ability to comply with FDA requirements, and, therefore, the timeframe for demonstrating compliance to the FDA's satisfaction is uncertain. Delays in establishing that our manufacturing process and the facilities we utilize for manufacturing comply with cGMP or disruptions in our manufacturing processes, implementation of novel technologies or scale-up activities, may delay or disrupt our development efforts.

***Even if we obtain regulatory approval of our vaccine candidates, the products may not gain market acceptance among regulators, advisory boards, physicians, patients, third-party payors and others in the medical community.***

Even if any of our vaccine candidates receive marketing approval, they may fail to receive recommendations for use by regulators or advisory boards that recommend vaccines, or gain market acceptance by physicians, patients, third-party payors and others in the medical community. If such vaccine candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of any vaccine candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- receiving CDC and ACIP recommendations for use, as well as recommendations of comparable foreign regulatory and advisory bodies;
- prevalence and severity of the disease targets for which our vaccine candidates are approved;
- physicians, hospitals, third-party payors and patients considering our vaccine candidates as safe and effective;
- the potential and perceived advantages of our vaccine candidates over existing vaccines, including with respect to spectrum coverage or immunogenicity;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory and advisory bodies;
- limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory and advisory bodies;
- the timing of market introduction of our vaccine candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors, including government authorities;



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- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors, including government authorities;
- relative convenience and ease of administration, including as compared to competitive vaccines and alternative treatments; and
- the effectiveness of our sales and marketing efforts.

In the United States, the CDC and ACIP develop vaccine recommendations for both children and adults, as do similar agencies around the world. To develop its recommendations, ACIP forms working groups that gather, analyze and prepare scientific information. The ACIP also considers many of the factors above, as well as myriad additional factors such as the value of vaccination for the target population regarding the outcomes, health economic data and implementation issues. ACIP recommendations are also made within categories, such as in an age group or a specified risk group. For example, the ACIP may determine that a preferred recommendation in a smaller child population may be more economical than recommending vaccinations for a larger adult population, which could adversely impact our market opportunity.

New pediatric vaccines that receive an ACIP preferred recommendation are almost universally adopted, and adult vaccines that receive a preferred recommendations are widely adopted. For example, in 2014, the ACIP voted to recommend Prevnar 13 for routine use to help protect adults aged 65 years and older against pneumococcal disease, which caused Prevnar 13 to become the standard of care along with continued use of Pneumovax 23. ACIP can also modify its preferred recommendation. For instance, in June 2019, the ACIP voted to revise the pneumococcal vaccination guidelines and recommend Prevnar 13 for adults 65 and older based on the shared clinical decision making of the provider and patient, rather than a preferred use recommendation, which means the decision to vaccinate should be made at the individual level between health care providers and their patients. Pfizer recently noted that this revised recommendation is expected to have a negative effect on Prevnar 13 revenue for future periods.

If our vaccine candidates are approved but fail to receive CDC and ACIP recommendations, or recommendations of other comparable foreign regulatory and advisory bodies, or achieve market acceptance among physicians, healthcare providers, patients, third-party payors or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

***We may not be successful in our efforts to use our cell-free protein synthesis platform to expand our pipeline of vaccine candidates and develop marketable products.***

The success of our business depends in large part upon our ability to identify, develop and commercialize products based on our cell-free protein synthesis platform. We intend to pursue clinical development of additional vaccine candidates beyond SVX-24, including SVX-XP for PCV, SVX-A1 for Group A Strep and SVX-PG for periodontitis. Our research programs may fail to identify potential vaccine candidates for clinical development for a number of reasons or we may focus our efforts and resources on potential programs or vaccine candidates that ultimately prove to be unsuccessful. In addition, we cannot provide any assurance that we will be able to successfully advance any of our existing or future vaccine candidates through the development process.

Our potential vaccine candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for a program or for multiple programs, which would materially harm our business and could potentially cause us to cease operations.

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Even if we receive FDA approval to market additional vaccine candidates, we cannot provide assurance that any such vaccine candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. In addition, current PCVs do not address the majority of circulating strains causing pneumococcal disease. There has been a decrease in the incidence of disease attributable to the strains covered by existing vaccines but an increase in incidence attributable to non-covered strains that now cause most residual disease. Such change is driven by the void created when strains are taken out of circulation after widespread vaccination, which is a phenomenon known as serotype replacement. As a result of such change, broader spectrum PCVs are required to maintain protection against historically pathogenic strains while expanding coverage to current circulating and emerging strains. There can be no assurance that we will be able to develop higher valent vaccines to address serotype replacement.

In addition, because SVX-24 is our most advanced vaccine candidate, and because our other vaccine candidates are also based on our cell-free protein synthesis platform, if SVX-24 encounters safety or efficacy problems, manufacturing problems, developmental delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

***We currently rely on third-party manufacturing and supply partners, including Lonza and Sutro Biopharma, to supply raw materials and components for, and manufacture, our vaccine candidates. Our inability to have sufficient quantities of our vaccine candidates manufactured, or our failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.***

Efficient and scalable manufacturing and supply is a vital component of our business strategy. We currently do not own or operate any manufacturing facilities. We are designing and developing a manufacturing process that we believe can scale to address clinical and commercial vaccine supply. However, our assumptions as to our ability and our CMOs' ability to produce vaccines at the scale needed for clinical development and commercial demand, in particular for our PCVs, may prove to be wrong. If we encounter problems in our manufacturing processes or in our ability to scale to address commercial vaccine supply, our business would be materially adversely affected.

We rely on third-party contract manufacturers to manufacture preclinical and clinical trial product materials and supplies for our needs. There can be no assurance that our preclinical and clinical development product supplies will not be limited or interrupted or be of satisfactory quality or continue to be available on acceptable terms.

The manufacturing process for a vaccine candidate is subject to FDA or comparable foreign regulatory authority review. Our suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our vaccine candidates. Moreover, we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills, raw materials or technology required to manufacture our vaccine candidates may be unique or proprietary to the original manufacturer or supplier, and we may have difficulty applying such skills or technology or sourcing such raw materials ourselves, or in transferring such skills, technology or raw materials to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our vaccine

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candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines, and we may be required to repeat some of the development program. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop vaccine candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers and suppliers, including Lonza and Sutro Biopharma, if we receive regulatory approval for any PCV or any other vaccine candidates. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for vaccine candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our vaccine candidates successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMPs could adversely affect our business in a number of ways, including:

- an inability to initiate or complete clinical trials of vaccine candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for our vaccine candidates;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our vaccine candidates; and
- in the event of approval to market and commercialize a vaccine candidate, an inability to meet commercial demands for our products.

In addition, because SVX-24 is our most advanced vaccine candidate, and because our other vaccine candidates are also based on our cell-free protein synthesis platform, if SVX-24 encounters safety or efficacy problems, manufacturing problems, developmental delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

Additionally, we and our contract manufacturers may experience manufacturing difficulties due to limited vaccine manufacturing experience, resource constraints or as a result of labor disputes or unstable political environments. If we or our contract manufacturers were to encounter any of these difficulties, our ability to manufacture sufficient vaccine supply for our preclinical studies and clinical trials, or to provide product for patients once approved, would be jeopardized.

***Our vaccine candidates may cause undesirable side effects or have other properties, including interactions with existing vaccine regimens, that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.***

Adverse effects or other undesirable or unacceptable side effects caused by our vaccine candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. We have not yet initiated any clinical trials of our vaccine candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In such an event, our clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our vaccine candidates. Such side effects could also affect trial recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. The data safety monitoring board may also suspend or terminate a clinical trial at any time on

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various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, any vaccine to be approved in pediatric populations may need to undergo extensive vaccine-vaccine interference studies with the standard of care pediatric vaccine regimen. Further, to the extent field efficacy studies are required, prophylactic vaccines typically require clinical testing in thousands to tens of thousands of healthy volunteers to define an approvable benefit-risk profile. The need to show a high degree of safety and tolerability when dosing healthy individuals could result in rare and even spurious safety findings, negatively impacting a program prior to or after commercial launch. Any of these occurrences may harm our business, financial condition and prospects significantly.

***Negative developments and negative public opinion of new technologies on which we rely may damage public perception of our vaccine candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our vaccine candidates.***

Negative developments and negative public opinion of new or existing technologies on which we rely may damage public perception of our vaccine candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our vaccine candidates. Public perception may be influenced by claims that vaccines are unsafe, and products incorporating new vaccine technology may not gain the acceptance of the public or the medical community. Adverse public attitudes may negatively impact our ability to enroll patients in clinical trials. Moreover, our success will depend upon physicians specializing in our targeted diseases prescribing, and their patients being willing to receive, our vaccine candidates in lieu of, or in addition to, existing, more familiar vaccines or treatments for which greater clinical data may be available. Any increase in negative perceptions of the technologies that we rely on may result in fewer physicians prescribing our products or may reduce the willingness of patients to utilize our products or participate in clinical trials for our vaccine candidates.

***We may not be able to file INDs to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.***

We plan to submit an IND to the FDA to initiate a clinical trial of SVX-24 in the second half of 2021. However, our timing of filing on SVX-24 is dependent on further preclinical and manufacturing success. We cannot be sure that submission of an IND or IND amendment will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

***We may encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect.***

Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. Even if these trials begin as planned, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;

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- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required institutional review board, or IRB, approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly; or if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in adding a sufficient number of trial sites and recruiting suitable patients to participate in our clinical trials;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's good clinical practice, or GCP, requirements or applicable regulatory guidelines in other jurisdictions;
- transfer of manufacturing processes to any new CMO or our own manufacturing facilities or any other development or commercialization partner for the manufacture of vaccine candidates;
- delays in having patients complete participation in a study or return for post-injection follow-up;
- patients dropping out of a study;
- occurrence of side effects associated with our vaccine candidates that are viewed to outweigh their potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our vaccine candidates being greater than we anticipate;
- clinical studies of our vaccine candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs;
- delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary raw materials; and
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our vaccine candidates for use in clinical studies or the inability to do any of the foregoing.

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Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our vaccine candidates, we may be required to or we may elect to conduct additional studies to bridge our modified vaccine candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our vaccine candidates and may harm our business and results of operations.

***If we encounter difficulties enrolling patients in any clinical trials we may conduct, including any field efficacy trials that may be required, our clinical development activities could be delayed or otherwise adversely affected.***

We may experience difficulties in patient enrollment in any clinical trials we may conduct for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the severity and difficulty of diagnosing the disease under investigation;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the risk that patients enrolled in clinical trials will drop out of the trials before the injection of our vaccine candidates or trial completion.

To the extent we are required to conduct any field efficacy studies, enrollment of a sufficient number of patients may require additional time and resources given widespread vaccination rates in the United States, particularly in the pediatric population. As a result, we may be required to conduct any such trials outside the United States, which could cause additional complexity and delay. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of any clinical trials we may conduct, which could prevent completion of these trials and adversely affect our ability to advance the development of our vaccine candidates.

***Interim "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 publish interim "top line" or preliminary data from our preclinical or clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We

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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 when we publish such data. As a result, the “top line” 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. Preliminary or “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 may publish. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

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 the particular program, the approvability or commercialization of the particular vaccine candidate 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 the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular vaccine candidate or our business. If the “top line” data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, vaccine candidates may be harmed, which could significantly harm our business prospects.

***We currently have no marketing and sales organization, and as an organization have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our vaccine candidates, we may not be able to generate product revenue.***

We currently have no sales, marketing or distribution capabilities and as an organization have no experience in marketing products. If we develop an in-house marketing organization and sales force, we will require significant capital expenditures, management resources and time, and we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products; however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our vaccine candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our vaccine candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product that receives regulatory approval in the United States or overseas. If we are unable to develop in-house sales and distribution capabilities or enter into relationships with third-party collaborators on acceptable terms or at all, we may not be able to successfully commercialize our products. If we are not successful in commercializing our products or any future products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

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*A variety of risks associated with potentially conducting research and clinical trials abroad and marketing our vaccine candidates internationally could materially adversely affect our business.*

As we pursue approval and commercialization for our vaccine candidates overseas and conduct CMC and other operations overseas, we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping vaccine candidates abroad;
- import and export requirements and restrictions;
- 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;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended, 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 and our collaborations with Lonza, based in Switzerland, may materially adversely affect our ability to attain or maintain profitable operations.



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***We are highly dependent on our key personnel, and if we are not able to retain these members of our management team or recruit and retain highly qualified personnel, we may not be able to successfully implement our business strategy.***

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our President, Chief Executive Officer and co-founder and Vice President of Research and co-founder. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct substantially all of our operations at our facilities in the San Francisco Bay Area. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management and scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key person” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

***We have grown rapidly and will need to continue to grow the size of our organization, and we may experience difficulties in managing this growth.***

As our discovery, development and commercialization plans and strategies develop, and as we continue to transition into operating as a public company, we have rapidly expanded our employee base and expect to continue to add managerial, operational, sales, research and development, marketing, financial and other personnel. Current and future growth imposes 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 and FDA review process for our vaccine candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our vaccine candidates will depend, in part, on our ability to effectively manage our growth. 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.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our vaccine candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

Obtaining and maintaining regulatory approval of our vaccine candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a vaccine candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the vaccine candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a vaccine 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 products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of vaccine candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our vaccine candidates will be harmed.

***We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.***

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our discovery, development and commercialization efforts with respect to our vaccine candidates and any future vaccine candidates that we may seek to develop. 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. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our vaccine 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 our vaccine candidates as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new strategic partnership agreements related to our vaccine candidates could delay the development and commercialization of our vaccine candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

***Revenue from any “catch up” opportunity may decline over time as more of the patient population is vaccinated.***

We intend to initially seek approval of our SVX-24 vaccine candidate in adults. If approved, we believe it may have the potential to serve as a “catch up” or booster to those adults who have previously received Pneumovax 23 or a lower valent PCV. Previous vaccines with a “catch up” opportunity have seen a high initial capture rate, but sales may decline over time as the number of individuals who remain unvaccinated with the new

vaccine, and eligible for “catch up” opportunities, declines. Such decline could adversely affect our revenue over time.

***Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.***

Despite the implementation of security measures, our internal computer systems and the systems of our CROs, contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our vaccine candidates could be delayed.

***Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.***

Our operations, and those of our CMOs, CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our ability to manufacture our vaccine candidates could be disrupted if our operations or those of our suppliers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

***Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 outbreak, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations. The COVID-19 pandemic could materially affect our operations, including at our headquarters in the San Francisco Bay Area, as well as the business or operations of our contract manufacturer or other third parties with whom we conduct business.***

Our business could be adversely affected by health epidemics in regions where we have concentrations of potential clinical trial sites or other business operations, and could cause significant disruption in the operations of our contract manufacturer and other third parties upon whom we rely. For example, in December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread to multiple countries, including the United States and several European countries. Our headquarters is located in the San Francisco Bay Area, and our contract manufacturer, Lonza, is located in Switzerland. In March 2020, the State of California declared a state of emergency related to the spread of COVID-19, and the San Francisco Department of Public Health announced aggressive recommendations to reduce the spread of the disease, including recommendations to suspend nonessential travel, encourage telecommuting and cancel or postpone large gatherings. On March 10, 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government suspended all travel from Europe for a 30-day period. We continue to monitor our operations and government recommendations and may elect to temporarily close our office space to protect our employees. There is a risk that other countries or regions may be less effective at containing COVID-19, or it may be more difficult to contain if the outbreak reaches a larger population or broader geography, in which case the risks described herein could be elevated significantly.

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In addition, our planned clinical trials may be affected by the COVID-19 outbreak. Site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 outbreak. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our planned clinical trial operations.

The global outbreak of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our planned clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our vaccine candidates.***

We face an inherent risk of product liability as a result of the clinical testing of our vaccine candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our vaccine candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our vaccine candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our vaccine candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any vaccine candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or

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with corporate collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Assuming we obtain clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

### ***Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.***

The global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

### ***Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures, reckless and/or negligent conduct or unauthorized activities that violates (i) the laws and regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (iv) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

***The Tax Cuts and Jobs Act, or the Tax Act, could adversely affect our business and financial condition.***

In December 2017, the Tax Act was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (ii) limitation of the tax deduction for interest expense to 30% of adjusted earnings (with certain exceptions, including for certain small businesses), (iii) limitation of the deduction for post-2017 net operating losses, or NOLs, to 80% of current-year taxable income and elimination of net operating loss carrybacks for post-2017 NOLs, (iv) immediate deductions for certain new investments instead of deductions for depreciation expense over time and (v) modifying or repealing many business deductions and credits (including reducing 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 the Tax Act may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business, financial condition, results of operations and prospects could be adversely affected. We urge our stockholders, including purchasers of common stock in this offering, to consult with their legal and tax advisors with respect to the Tax Act and the tax consequences of investing in our common stock.

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

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. As of December 31, 2019, we had federal and state net operating loss carryforwards of \$110.9 million and \$28.0 million, respectively. The federal and state loss carryforwards, except the federal loss carryforward arising in tax years beginning after December 31, 2017, begin to expire in 2034 unless previously utilized. Federal NOLs arising in tax years beginning after December 31, 2017 have an indefinite carryforward period and do not expire. As of December 31, 2019, we also had federal and state research credit carryforwards of \$0.1 million and \$1.1 million, respectively. The federal research and development tax credit carryforwards expire beginning in 2034 unless previously utilized, and the state research and development tax credits can be carried forward indefinitely. In general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, a corporation that undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We have experienced ownership changes in the past. As a result of the ownership changes, we have determined that approximately \$1.3 million of our federal research credits will expire unutilized, and such amounts are excluded from our research carryforwards as of December 31, 2019. We may have experienced additional ownership changes in the past and may experience ownership changes in the future. As a result, if, and to the extent that we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations.

The Tax Act, among other things, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards. For federal NOLs arising in tax years beginning after December 31, 2017, the Tax Act limits a taxpayer’s ability to utilize NOL carryforwards to 80% of taxable income. In addition, federal NOLs arising in tax years beginning after December 31, 2017 can be carried forward indefinitely, but carryback is generally prohibited. Deferred tax assets for NOLs will need to be measured at the applicable tax rate in effect when the NOL is expected to be utilized. The new limitation on use of NOLs may significantly impact our ability to utilize our NOLs to offset taxable income in the future.

***Our insurance policies may be inadequate and potentially expose us to unrecoverable risks.***

Although we intend to maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any vaccine candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to

obtain appropriate insurance coverage for insurable risks that we identify; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Conditions in the insurance markets relating to nearly all areas of traditional corporate insurance change rapidly and may result in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

### **Risks Related to Our Reliance on Third Parties**

***We rely and will continue to rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our vaccine candidates.***

We currently do not have the ability to independently conduct preclinical or clinical studies that comply with the regulatory requirements known as good laboratory practices and GCP. The FDA and regulatory authorities in other jurisdictions require us to comply with GCP requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners to conduct our preclinical and clinical trials under agreements with us.

We will need to negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol and legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for vaccine candidates 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 fail to comply with applicable GCP regulations, 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. There can be no assurance that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated 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.

Any third parties conducting our preclinical studies and clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our programs. 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 drug development activities, which could affect their performance on our behalf. If these third parties 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 or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our vaccine candidates. As a result, our financial results and the commercial prospects for our vaccine candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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If any of our relationships with trial sites or any CRO that we may use in the future terminates, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

***We rely on third parties, including Sutro Biopharma and Lonza, to supply raw materials and manufacture our preclinical and clinical product supplies of our vaccine candidates, and expect to rely on third parties to supply raw materials and produce and process our vaccine candidates, if approved. The loss of these suppliers or their failure to comply with applicable regulatory requirements or provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.***

We do not have nor do we plan to build or acquire the infrastructure or capability internally to manufacture supplies for our vaccine candidates or the materials necessary to produce our vaccine candidates for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our vaccine candidates on a preclinical, clinical or commercial scale. We have entered into an agreement with Sutro Biopharma to supply us with extract and custom reagents for use in manufacturing non-clinical and certain clinical supply of vaccine compositions. We have engaged Lonza to perform manufacturing process development and clinical manufacture and supply of components for SVX-24, including the manufacture of polysaccharide antigens, our proprietary eCRM protein carrier and conjugated drug substances. We also engaged Lonza to perform manufacturing process development and clinical manufacture and supply of SVX-24 finished drug product. Our agreements with Lonza are denominated in Swiss Francs. Fluctuations in the exchange rate for Swiss Francs may increase our costs and affect our operating results.

We intend to engage with Lonza and other outside vendors to manufacture supplies for our vaccine candidates. We have not yet caused our vaccine candidates to be manufactured on a clinical or commercial scale and may not be able to achieve commercial scale manufacturing and may be unable to create an inventory of mass-produced product to satisfy demands for any of our vaccine candidates.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our vaccine candidates, and the actual cost to manufacture and process our vaccine candidates could materially and adversely affect the commercial viability of our vaccine candidates. As a result, we may never be able to develop a commercially viable product.

In addition, our anticipated reliance on a limited number of third-party suppliers and manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any.
- Our third-party suppliers and manufacturers might be unable to timely formulate and manufacture or supply raw materials for our vaccine candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.



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- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.
- Our third-party suppliers and manufacturers could breach or terminate their agreement with us.

Each of these risks could delay our clinical trials, the approval, if any, of our vaccine candidates by the FDA or the commercialization of our vaccine candidates, or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our vaccine candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

***If we or our third-party suppliers use hazardous, non-hazardous, biological or other materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We and our suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that we and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we and our suppliers cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business prospects, financial condition or results of operations.

### **Risks Related to Government Regulation**

***The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our vaccine candidates.***

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products, including biologics such as conjugate vaccines, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We expect that our vaccine candidates will be regulated by the FDA as biologics. We are not permitted to market any biological drug product in the United States until we receive approval of a Biologics License Application, or BLA, from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the vaccine candidate's safety and effectiveness for each desired indication. Further, because our vaccine candidates that are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure and potent for use in their target indications. The BLA must also include significant information regarding the CMC for the product, including with respect to chain of identity and chain of custody of the product.

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 preclinical studies of our vaccine candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of

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early clinical trials of our vaccine candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same vaccine candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Vaccine candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most vaccine candidates that begin clinical trials are never approved by regulatory authorities for commercialization. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit a BLA or other marketing application.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- obtaining regulatory authorization to begin a trial, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective 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 at each clinical trial site by an independent IRB;
- recruiting suitable patients to participate in and complete a trial;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a patient by patient basis for use in clinical trials.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our vaccine candidates in lieu of using existing vaccines that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities 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 other 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 vaccine candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial or based on a recommendation by the data safety monitoring board. If we experience termination of, or delays in the completion of, any clinical trial of our vaccine candidates, the commercial prospects for our vaccine candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

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Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our vaccine candidates.

***The FDA may disagree with our regulatory plan, and we may fail to obtain regulatory approval of our vaccine candidates.***

The general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from two Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and are time consuming. While we have not had any discussions with the FDA regarding our regulatory plan, as a prerequisite for FDA approval, we believe that any new PCV, such as SVX-24, will have to be compared to the current standard of care, Prevnar 13 in infants and Prevnar 13 and Pneumovax 23 in adults. We believe that a successful comparison would be based on demonstrating clinical non-inferiority of the immune response to Prevnar 13 for common serotypes and to Pneumovax 23 for the incremental 11 serotypes. In addition, we expect to use OPA titers as the primary immunogenicity surrogate endpoint for the SVX-24 program in adults because Prevnar 13 was approved based on the establishment of non-inferiority of OPA responses relative to Pneumovax 23, on a strain-by-strain basis, but there can be no assurance that this approach will be sufficient for regulatory approval or that regulators will not require field efficacy trials. If the results are sufficiently compelling, we intend to discuss with the FDA submission of a BLA for SVX-24. However, we do not have any agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a BLA for SVX-24.

We may seek accelerated approval from the FDA for our vaccine candidates and, if granted, the FDA may require us to perform post-marketing studies as a condition of approval to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint. If the results from such post-marketing studies are not positive or otherwise fail to show the predicted effect, the drug or biologic may be subject to expedited withdrawal procedures by the FDA. In addition, the standard of care may change with the approval of new products in the same disease areas that we are studying. This may result in the FDA or other regulatory agencies requesting additional studies to show that our vaccine candidate is non-inferior or superior to the new products.

Our clinical trial results may also not support approval. In addition, our vaccine candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our vaccine candidates are safe and effective for any of their proposed disease areas;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our vaccine candidates' clinical and other benefits outweigh their safety risks;
- any changes to the required threshold for the achievement of non-inferiority using established surrogate immune endpoints that our PCVs will need to meet in our clinical trials;
- any vaccine to be approved in pediatric populations may need to undergo extensive vaccine-vaccine interference studies with the standard of care pediatric vaccine regimen;
- the need to perform superiority or field efficacy trials, which can be larger, longer and more costly, if an existing vaccine is approved for a disease indication;

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- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our vaccine candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities will inspect the commercial manufacturing facilities we may utilize and may not approve such facilities; 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.

***Even if we receive regulatory approval of our vaccine candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our vaccine candidates.***

Any regulatory approvals that we receive for our vaccine candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including post-marketing clinical trials, and surveillance to monitor the safety and efficacy of the vaccine candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves our vaccine candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, conduct of post-marketing studies, storage, sampling, advertising, promotion, import, export and recordkeeping for our vaccine candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration and continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Further, we will be required to comply with FDA promotion and advertising rules, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Later discovery of previously unknown problems with our vaccine candidates, including side effects of unanticipated severity or frequency, or with our third-party suppliers or 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. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our vaccine candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of regulatory approvals;

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- product seizure or detention, or refusal to permit the import or export of our vaccine candidates; and
- injunctions or the imposition of civil or criminal penalties.

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 our vaccine candidates. We 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. For example, certain policies of the current U.S. President's administration may impact our business and industry. Namely, the current U.S. President's administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. 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 achieve or sustain profitability.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

***We expect the vaccine candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.***

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until twelve years after the reference product was approved under a BLA. 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. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the vaccine candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the twelve 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 the subject vaccine candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the 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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***Our relationships with customers, physicians and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, health information privacy and security laws and other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we could face substantial penalties.***

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any vaccine candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws.

These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our vaccine candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. 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;
- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and 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 Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA 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 and its implementing regulations, which also impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, including health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information for or on their behalf;

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- the Federal Food Drug or Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation, or GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the EU (including health data).

We may also be subject to other laws, such as the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibit, among other things, U.S. companies and their employees and agents from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office and foreign political parties or officials thereof, as well as federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock options for consulting services provided, 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 civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management

personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace. In addition, if the physicians or other providers or entities with whom we expect to do business are 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.

***Coverage and reimbursement may be limited or unavailable in certain market segments for our vaccine candidates, which could make it difficult for us to sell our vaccine candidates, if approved, profitably.***

Successful sales of our vaccine candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any vaccine candidates for which we obtain regulatory approval.

Patients who receive vaccines generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, 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 and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our vaccine candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our vaccine candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for administering the product. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from third-party payors and reduce the willingness of physicians to use our vaccine candidates. Certain ACA marketplace and other private payor plans are required to include coverage for certain preventative services, including vaccinations recommended by the ACIP without



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cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members. Children through 18 years of age without other health insurance coverage may be eligible to receive such vaccinations free-of-charge through the CDC's Vaccines For Children program. For Medicare beneficiaries, vaccines may be covered under either the Part B program or Part D depending on several criteria, including the type of vaccine and the beneficiary's coverage eligibility. If our vaccine candidates, once approved, are covered only under the Part D program, physicians may be less willing to use our products because of the claims adjudication costs and time related to the claims adjudication process and collection of co-payments associated with the Part D program.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

We intend to seek approval to market our vaccine candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our vaccine candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a vaccine candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular vaccine candidate to currently available vaccines. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any vaccine candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

### ***Healthcare legislative reform measures may have a negative impact on our business, financial condition, results of operations and prospects.***

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of vaccine candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any vaccine candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private payors in the United States. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries

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during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a 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;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a requirement that certain ACA marketplace and other private payor plans include coverage for preventative services, including vaccinations recommended by the ACIP without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as recent efforts by the current U.S. President's administration to repeal or replace certain aspects of the ACA. For example, the Tax Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." The 2020 federal spending package eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In December 2018, the CMS, published a new final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur towards the end of 2020. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA.

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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 BBA, will remain in effect through 2029 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, which was fully operational in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement.

Further, in the United States 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 and enacted federal and state legislation designed to, among other things, bring more transparency to drug and biological product pricing, reduce the cost of prescription drugs and biological products under government payor programs and review the relationship between pricing and manufacturer patient programs. At the federal level, the current U.S. President's administration's budget proposals for fiscal 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, the current U.S. President's administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of specific federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has solicited feedback on some of these measures and has implemented others under its existing authority. Although some measures may require additional authorization to become effective, the U.S. Congress and the current U.S. President's administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug and biological product costs. 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. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs, biological products and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future vaccine candidates or additional pricing pressures. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing or new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future vaccine candidates we may develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances,

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eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

We expect that these and 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, which could have an adverse effect on demand for our vaccine candidates. 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, attain profitability or commercialize our products. For additional information on healthcare reform, see the section entitled “Business—Government Regulation.”

***Changes in funding for the FDA and other government agencies could hinder our ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.***

The collection and use of personal data in the European Union are governed by the General Data Protection Regulation, or GDPR. The GDPR imposes stringent requirements for controllers and processors of personal data, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations when we contract with third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other third countries. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

The GDPR applies extraterritorially, and we may be subject to the GDPR because of our data processing activities that involve the personal data of individuals located in the European Union, such as in connection with our EU clinical trials. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. GDPR regulations may impose additional responsibility and liability in relation to the personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities and adversely affect our business, financial condition, results of operations and prospects.

## Risks Related to Our Intellectual Property

*If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.*

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our vaccine development programs and vaccine candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to SVX-24 and any future vaccine candidates, as well as methods of making our vaccine candidates and components thereof. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our development programs and vaccine candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patents and patent applications that we own or in-license may fail to result in issued patents with claims that protect SVX-24 or any future vaccine candidate in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover SVX-24 or any future vaccine candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any vaccine candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a vaccine candidate under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and vaccine candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for SVX-24 or any future vaccine candidate, it could dissuade companies from collaborating with us to develop vaccine candidates and threaten our ability to commercialize future vaccines. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been and will continue to be the subject of litigation and new legislation. 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. Publications of discoveries in 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 know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings

and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. 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 vaccine candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. 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. The scope of patent protection may also be limited. Without patent protection for our current or future vaccine candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new vaccine candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our vaccine candidates.***

We have licensed certain intellectual property rights related to the XpressCF platform and methods of making components of SVX-24 from Sutro Biopharma. We also license certain intellectual property rights related to a non-cross reactive Group A Strep carbohydrate antigen and related methods of production from the Regents of the University of California. If, for any reason, these agreements are terminated or we otherwise lose those rights, it could adversely affect our business. These agreements impose, and any future collaboration agreements or license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor(s) may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.***

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional

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stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering SVX-24 or any future vaccine candidate, or the XpressCF platform, our competitors might be able to enter the market, which would have an adverse effect on our business.

***Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent the development and commercialization of SVX-24 and any future vaccine candidate.***

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing vaccine candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our vaccine candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

Also, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our vaccine candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our vaccine candidates may infringe.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our vaccine candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such vaccine candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable vaccine candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our vaccine candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms.

Furthermore, as the vaccine patent landscape is crowded and highly competitive, even in the absence of litigation we may need to obtain licenses from third parties to advance our research or allow commercialization of our vaccine candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our vaccine candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against vaccine candidates resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

***We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future vaccine candidates. Such a loss of patent protection could harm our business.

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. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

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 during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares.

***Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.***

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection



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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 actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or 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 have licensed or that we may obtain in the future.

***Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.***

We expect to rely on trademarks as one means to distinguish any of our vaccine candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our vaccine candidates and have not yet begun the process of applying to register trademarks for our current or any future vaccine candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our current or any other vaccine candidate 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.

***We may not be able to protect our intellectual property rights throughout the world, which could impair our business.***

Filing, prosecuting and defending patents covering our current vaccine candidates and any future vaccine candidate throughout the world would be prohibitively expensive. 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 may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we expect to rely on third parties to manufacture SVX-24 and any future vaccine candidates, and we expect to collaborate with third parties on the development of SVX-24 and any future vaccine candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary

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information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.***

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. 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 patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

### **Risks Related to This Offering and Ownership of 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 there has been no public market for shares of our common stock. An active trading market for our shares may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock will be determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. 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. Further, 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 partnerships or acquire companies or products 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 could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this prospectus, these factors include:

- the commencement, enrollment or results of our planned or future preclinical studies or clinical trials of our vaccine candidates and those of our competitors;
- regulatory or legal developments in the United States and abroad;
- the success of competitive vaccines or technologies;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the level of expenses related to our vaccine candidates or preclinical and clinical development programs;
- the results of our efforts to develop additional vaccine candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations or reports by securities analysts;
- the level of expenses and capital investment related to manufacturing out vaccine candidates;
- our inability to obtain or delays in obtaining adequate supply for any approved vaccine candidate;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies perceived to be similar to us;
- changes in the structure of healthcare payment systems, including coverage and adequate reimbursement for any approved vaccine;
- general economic, political and market conditions and overall fluctuations in the financial markets in the United States and abroad; and
- investors’ general perception of us and our business.

In addition, the stock market in general, and the Nasdaq Global Market and biopharmaceutical 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 the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management’s attention and resources, which would harm our business, operating results or financial condition.

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***Our financial condition and results of operations may fluctuate from quarter to quarter and year to year, which makes them difficult to predict.***

We expect our financial condition and results of operations to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

***We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.***

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 the appreciation of their 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.***

Prior to this offering, our executive officers, directors and 5% stockholders beneficially owned approximately % of our voting stock as of , and, upon the closing of this offering, that same group will continue to beneficially own a significant percentage of our outstanding voting stock. Accordingly, even after this offering, these stockholders will have the ability to influence us through this ownership position and significantly affect the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to significantly affect the outcome of 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.

***If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.***

The initial public offering price is substantially higher than the pro forma as adjusted net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted book value of our tangible assets after subtracting our liabilities. Based on the assumed initial public offering price of \$ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$ per share, representing the difference between our pro forma as adjusted net tangible book value per share after this offering and the initial public offering price per share. After this offering, we will also have outstanding options and a warrant to purchase common stock with exercise prices lower than the initial public offering price. To the extent these outstanding options or warrant are exercised, there will be further dilution to investors in this offering. See the section entitled “Dilution” for additional information.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including 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 votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we complete this offering, although circumstances could cause us to lose that status earlier. We

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will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply for a period of time with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. 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.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this 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 we (i) are no longer an emerging growth company or (ii) 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 new or revised accounting pronouncements as of public company effective dates.

***As a public company, we will be subject to more stringent federal and state law requirements.***

As a public company, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or 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, or Nasdaq, and other applicable securities rules and regulations. Despite reforms made possible by the JOBS Act, compliance with these rules and regulations will nonetheless increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an emerging growth company. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results.

As a result of disclosure of information in this prospectus and in 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 such claims are successful, our business, results of operations, financial condition and prospects could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our brand and reputation, business, results of operations, financial condition and prospects.

We also expect that being a public company and the associated rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain adequate 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.

We may also be subject to more stringent state law requirements. For example, on September 30, 2018, California Governor Jerry Brown signed into law Senator Bill 826, which generally requires public companies with principal executive offices in California to have a minimum number of females on the company’s board of directors. As of December 31, 2019, each public company with principal executive offices in California is

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required to have at least one female on its board of directors. By December 31, 2021, each public company will be required to have at least two females on its board of directors if the company has at least five directors, and at least three females on its board of directors if the company has at least six directors. The new law does not provide a transition period for newly listed companies. If we fail to comply with this new law, we could be fined by the California Secretary of State, with a \$100,000 fine for the first violation and a \$300,000 fine for each subsequent violation, and our reputation may be adversely affected.

***We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, investor relations and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Stockholder activism, the current political environment and the current high level of U.S. government intervention and regulatory reform may also lead to substantial new regulations and disclosure obligations, which may in turn lead to additional compliance costs and impact the manner in which we operate our business in ways we do not currently anticipate. Our management and other personnel will need to devote a substantial amount of time to comply with these requirements. Moreover, these requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements.

***If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.***

Pursuant to Section 404 of the Sarbanes-Oxley Act, 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 emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the Sarbanes-Oxley Act, the requirements of being a reporting company under the Exchange Act and any complex accounting rules in the future, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. We are currently in the process of hiring additional accounting and finance staff as we grow our business. If we are unable to hire the additional accounting and finance staff necessary to comply with these requirements, we may need to retain additional outside consultants. If we or, if required, our auditors, are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

There can be no assurance that there will not be material weaknesses in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines that we have a material weakness in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over

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financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

### ***Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States.***

Generally accepted accounting principles in the United States are subject to interpretation by the Financial Accounting Standards Board, the SEC and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported financial results, may retroactively affect previously reported results, could cause unexpected financial reporting fluctuations and may require us to make costly changes to our operational processes and accounting systems.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on shares of common stock outstanding as of \_\_\_\_\_, upon the closing of this offering we will have outstanding a total of \_\_\_\_\_ shares of common stock. Of these shares, only the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable without restriction in the public market immediately following this offering. The underwriters, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

We expect that the lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our 2020 Equity Incentive Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of \_\_\_\_\_ shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. See the section entitled "Description of Capital Stock—Registration Rights." Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

### ***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.***

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short- and intermediate-term, interest-bearing instruments, certificates of deposit

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or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

***Provisions in our corporate charter documents and under 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.***

Provisions in 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 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;
- 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 charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or 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.



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***Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.***

Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering will provide that we will indemnify our directors and officers, in each case, 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 bylaws that will be in effect upon the closing of this offering 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 and executive officers. 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 connection with any action, proceeding or investigation. We believe that these amended and restated certificate of incorporation and amended and restated bylaws provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

While we maintain directors' and officers' liability insurance, such insurance may not be adequate to cover all liabilities that we may incur, which may reduce our available funds to satisfy third-party claims and may adversely impact our cash position.

***Our amended and restated certificate of incorporation that will become effective upon the closing of this offering provides that the Court of Chancery of the State of Delaware will be the exclusive forum 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 will provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts 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 or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;

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- any action or proceeding asserting a claim 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 certificate of incorporation or our bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and
- any action asserting a claim against us by any of our directors, officers or other employees governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

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 these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. For example, the Court of Chancery of the State of Delaware recently determined that a provision stating that U.S. federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. However, this decision may be reviewed and ultimately overturned by the Delaware Supreme Court. If a court were to find the exclusive-forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, including our statements regarding the benefits and timing of the roll-out of new technology, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will” or “would” or the negative of these words or other similar terms or expressions. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- our use of the net proceeds from this offering;
- our expectations regarding the potential benefits, spectrum coverage and immunogenicity of our vaccine candidates;
- our expectations regarding our preclinical study results potentially being predictive of clinical study results;
- Our belief that our PCVs could receive regulatory approval based on a demonstration of non-inferiority to the standard of care using well-defined surrogate immune endpoints rather than requiring clinical field efficacy studies;
- the timing of the initiation, progress and expected results of our preclinical studies, clinical trials and our research and development programs;
- our ability to advance vaccine candidates into, and successfully complete, preclinical studies and clinical trials;
- the commercialization of our vaccine candidates, if approved;
- estimates of our total addressable market, future revenue, expenses, capital requirements and our needs for additional financing;
- our ability to compete effectively with existing competitors and new market entrants;
- our ability to establish and maintain intellectual property protection for our products or avoid claims of infringement;
- our manufacturing capabilities and the scalable nature of our manufacturing process;
- potential effects of extensive government regulation;
- the pricing, coverage and reimbursement of our vaccine candidates, if approved;
- our ability to hire and retain key personnel;
- our ability to obtain additional financing in this or future offerings;
- the volatility of the trading price of our common stock; and
- our expectation regarding the time during which we will be an emerging growth company under the JOBS Act.

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You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this prospectus primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in the section entitled “Risk Factors” and elsewhere in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this prospectus. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

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

The forward-looking statements made in this prospectus relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this prospectus to reflect events or circumstances after the date of this prospectus or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments.

## **MARKET, INDUSTRY AND OTHER DATA**

This prospectus contains industry, market and competitive position data from our own internal estimates and research as well as industry and general publications and research surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. In some cases, we do not expressly refer to the sources from which this data is derived. Our internal data and estimates are based upon information obtained from trade and business organizations and other contacts in the markets in which we operate and our management's understanding of industry conditions. While we believe that each of these studies and publications is reliable, we have not independently verified market and industry data from third-party sources. While we believe our internal company research is reliable and the market definitions are appropriate, neither such research nor definitions have been verified by any independent source. All of the market and industry data used in this prospectus is inherently subject to uncertainties and involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information.

The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section entitled "Risk Factors" and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and 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 exercise their option to purchase additional shares in full), based on the assumed initial public offering price of \$      per share of common stock, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$      per share of common stock, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) 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 estimated 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 of common stock offered by us would increase (decrease) the net proceeds to us from this offering by approximately \$      million, assuming the assumed initial public offering price of \$      per share of common stock remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our capitalization and financial flexibility, create a public market for our common stock, facilitate future access to the public equity markets by us, our employees and our stockholders and increase our visibility in the marketplace. We currently intend to use the net proceeds we receive from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$      million to fund completion of IND-enabling activities and our clinical development of SVX-24;
- approximately \$      million to fund the ongoing development of our other vaccine candidates; and
- the remainder for general corporate purposes, including working capital, operating expenses and capital expenditures.

This expected use of the net proceeds from this offering represents our intentions based on our current plans and business conditions, which could change in the future as our plans and business conditions evolve. Further, due to the uncertainties inherent in the vaccine development process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. We cannot specify with certainty all of the particular uses for the remaining net proceeds to us from this offering. We may also use a portion of the net proceeds for acquisitions or strategic investments in complementary businesses, products, services or technologies. However, we do not have agreements or commitments to enter into any such acquisitions or investments at this time. We will have broad discretion over how to use the net proceeds to us from this offering, and our investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering. The amounts and timing of our expenditures will depend upon numerous factors including the results of our research and development efforts, the timing and success of preclinical studies and any clinical trials we may commence in the future, the timing of regulatory submissions, and the amount of cash obtained through any future collaborations.

We estimate that the net proceeds from this offering, together with our current cash and cash equivalents, will be sufficient for us to fund our operating expenses and capital expenditure requirements through at least the next      months, and including through      for SVX-24. The expected net proceeds from this offering, together with our cash and cash equivalents, will not be sufficient for us to fund a pivotal clinical trial for any of our vaccine candidates, and we will need to raise additional capital to complete the development and commercialization of our vaccine candidates. We expect to finance our cash needs through

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public or private equity or debt financings, government or other third-party funding, collaborations, strategic alliances and licensing arrangements, or a combination of these sources. We have based these estimates on assumptions that may prove to be incorrect, and we could expend our available capital resources at a rate greater than we currently expect.

We intend to invest the net proceeds to us from this offering that are not used as described above in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

## **DIVIDEND POLICY**

We have never declared or paid cash dividends on our capital stock. We currently 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 will be at the discretion of our board of directors 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, we may enter into agreements in the future that could contain restrictions on payments of cash dividends.



## CAPITALIZATION

The following table sets forth our cash and cash equivalents, and our capitalization as of December 31, 2019 as follows:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the conversion of all outstanding shares of our redeemable convertible preferred stock as of December 31, 2019 into 34,398,138 shares of common stock upon the closing of this offering, (ii) the issuance of \_\_\_\_\_ shares of our common stock as a result of the expected net exercise of an outstanding warrant to purchase 100,000 shares of our redeemable convertible preferred stock and the related reclassification of the redeemable convertible warrant liability to common stock and additional paid-in capital, assuming an initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus; (iii) the issuance of \_\_\_\_\_ shares of our common stock as a result of the expected net exercise of a warrant to purchase 53,744 shares of our common stock, assuming an initial public offering price of \$ \_\_\_\_\_ per share; (iv) the removal of gains or losses resulting from the re-measurement of the redeemable convertible preferred stock warrant liability as the warrants will be exercised for shares of common stock immediately prior to our IPO; and (v) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect upon the closing of this offering; and
- on a pro forma as adjusted basis, giving effect to (i) the pro forma adjustments set forth above and (ii) the issuance and sale of \_\_\_\_\_ shares of common stock in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with our financial statements and the related notes included elsewhere in this prospectus and in the sections entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Selected Financial Data.”

	As of December 31, 2019		
	Actual	Pro Forma Unaudited	Pro Forma As Adjusted(1)
	(in thousands, except share and per share data)		
Cash and cash equivalents	\$ 58,976	\$ —	\$ —
Redeemable convertible preferred stock tranche liability	\$ —	\$ —	\$ —
Redeemable convertible preferred stock warrant liability	450		
Series A redeemable convertible preferred stock, \$0.001 par value per share: 10,502,804 shares authorized; 10,502,804 shares issued and outstanding, actual; _____ shares issued and outstanding, pro forma and pro forma as adjusted	24,967		
Series B redeemable convertible preferred stock, \$0.001 par value per share: 11,449,515 shares authorized; 11,449,510 shares issued and outstanding, actual; _____ shares issued and outstanding, pro forma and pro forma as adjusted	55,151		
Series C redeemable convertible preferred stock, \$0.001 par value per share: 14,010,043 shares authorized; 12,445,824 shares issued and outstanding, actual; _____ shares issued and outstanding, pro forma and pro forma as adjusted	80,192		

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	As of December 31, 2019		
	Actual	Pro Forma Unaudited	Pro Forma As Adjusted(1)
(in thousands, except share and per share data)			
Stockholders' (deficit) equity:			
Preferred stock, \$0.001 par value per share; no shares authorized, issued or outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	—		
Common stock, \$0.001 par value per share: 52,000,000 shares authorized, 6,849,118 shares issued and outstanding, actual; shares authorized, shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	7		
Additional paid-in capital	2,967		
Accumulated deficit	(109,347)		
Total stockholders' equity (deficit)	(106,373)	—	—
Total capitalization	\$ 54,387	\$ —	\$ —

(1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share of common stock, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of our cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately \$ , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated 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 offered by us at the assumed initial public offering price of \$ per share of common stock would increase (decrease) the pro forma as adjusted amount of each of our cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately \$ , assuming the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma and pro forma as adjusted information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing.

The outstanding share information in the table above is based on shares of our common stock (including (i) 34,398,138 shares of our redeemable convertible preferred stock on an as-converted basis, (ii) the issuance of shares of our common stock as a result of the expected net exercise of an outstanding warrant to purchase 100,000 shares of our redeemable convertible preferred stock and (iii) the issuance of shares of our common stock as a result of the expected net exercise of an outstanding warrant to purchase 53,744 shares of our common stock) outstanding as of December 31, 2019, and excludes:

- 5,676,107 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of December 31, 2019, with a weighted-average exercise price of \$1.13 per share;
- 268,000 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted after December 31, 2019, with a weighted-average exercise price of \$2.21 per share;
- shares of our common stock reserved for future issuance under our 2020 Plan (including up to shares of our common stock comprised of (i) the shares reserved and remaining available for issuance under our 2014 Plan that will be added to our 2020 Plan reserve upon its effectiveness plus (ii) the number of shares subject to stock options or other stock awards granted under our 2014 Plan that would have otherwise returned to our 2014 Plan, which will be added as they become available (e.g., due to forfeiture of the underlying 2014 Plan award)), which includes an annual evergreen increase and will become effective in connection with this offering; and
- shares of our common stock reserved for future issuance under our ESPP, which includes an annual evergreen increase and will become effective in connection with this offering.

## DILUTION

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

Our historical net tangible book value as of December 31, 2019 was \$53.9 million, or \$7.88 per share of our common stock. Our historical net tangible book deficit represents the amount of our total tangible assets (net of deferred offering costs) less our total liabilities and our redeemable convertible preferred stock, divided by the number of shares of our common stock outstanding as of December 31, 2019.

Our pro forma net tangible book value as of December 31, 2019 was \$            million, or \$            per share. Pro forma net tangible book value per share represents the amount of our total tangible assets (net of deferred offering costs) less our total liabilities, divided by the number of shares of our common stock outstanding as of December 31, 2019, after giving effect to (i) the conversion of all shares of our redeemable convertible preferred stock outstanding as of December 31, 2019 into 34,398,138 shares of our common stock, (ii) the issuance of            shares of our common stock as a result of the expected net exercise of an outstanding warrant to purchase 100,000 shares of our redeemable convertible preferred stock and the related reclassification of the redeemable convertible warrant liability to common stock and additional paid-in capital, assuming an initial public offering price of \$            per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, (iii) the issuance of            shares of our common stock as a result of the expected net exercise of a warrant to purchase 53,744 shares of our common stock, assuming an initial public offering price of \$            per share, and (iv) the removal of gains or losses resulting from the re-measurement of the redeemable convertible preferred stock warrant liability as the warrant will be exercised for shares of common stock immediately prior to our IPO.

After giving further effect to the sale of            shares of common stock that we are offering at the assumed initial public offering price of \$            per share, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2019 would have been approximately \$            million, or approximately \$            per share. This amount represents an immediate increase in pro forma net tangible book value of \$            per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately \$            per share to new investors purchasing shares of common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Assumed initial public offering price per share	\$
Historical net tangible book value per share as of December 31, 2019	\$7.88
Pro forma increase in net tangible book value per share as of December 31, 2019 attributable to the pro forma adjustment described above	_____
Pro forma net tangible book value per share as of December 31, 2019	_____
Increase in pro forma net tangible book value per share attributable to this offering	_____
Pro forma as adjusted net tangible book value per share after this offering	_____
Dilution per share to new investors in this offering	\$ _____

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$            per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately \$            ,

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and dilution in pro forma net tangible book value per share to new investors by approximately \$ , assuming that 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 estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase of 1.0 million shares in the number of shares of common stock offered by us would increase our pro forma as adjusted net tangible book value per share after this offering by approximately \$ per share and decrease the dilution to investors participating in this offering by approximately \$ per share, assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each decrease of 1.0 million shares in the number of shares of common stock offered by us would decrease our pro forma as adjusted net tangible book value per share after this offering by approximately \$ per share and increase the dilution to investors participating in this offering by approximately \$ per share, assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters exercise their option to purchase up to additional shares of our common stock in full, the pro forma as adjusted net tangible book value after the offering would be \$ per share, the increase in pro forma net tangible book value per share to existing stockholders would be \$ per share and the dilution per share to new investors would be \$ per share, in each case assuming an initial public offering price of \$ per share.

The following table summarizes on the pro forma as adjusted basis described above, as of December 31, 2019, the differences between the number of shares of common stock purchased from us by our existing stockholders and common stock by new investors purchasing shares in this offering, the total consideration paid to us in cash and the average price per share paid by existing stockholders for shares of common stock issued prior to this offering and the price to be paid by new investors for shares of common stock in this offering. The calculation below is based on the assumed initial public offering price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	<u>Shares Purchased</u>		<u>Total Consideration</u>		<u>Weighted-Average Price Per Share</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	
Existing stockholders		%	\$	%	\$
New investors					\$
Total		100%	\$	100%	

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors to % and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors to %, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us, would increase or decrease, as applicable, the total consideration paid by new investors by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors to % and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors to %, assuming that the assumed initial public offering price of \$ per share remains the same.

If the underwriters exercise their option to purchase up to additional shares of our common stock in full, our existing stockholders would own % and the investors purchasing shares of our common stock in

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this offering would own % of the total number of shares of our common stock outstanding immediately after closing of this offering.

The outstanding share information in the table above is based on shares of our common stock (including (i) 34,398,138 shares of our redeemable convertible preferred stock on an as-converted basis, (ii) the issuance of shares of our common stock as a result of the expected net exercise of an outstanding warrant to purchase 100,000 shares of our redeemable convertible preferred stock and (iii) the issuance of shares of our common stock as a result of the expected net exercise of an outstanding warrant to purchase 53,744 shares of our common stock) outstanding as of December 31, 2019, and excludes:

- 5,676,107 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of December 31, 2019, with a weighted-average exercise price of \$1.13 per share;
- 268,000 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted after December 31, 2019, with a weighted-average exercise price of \$2.21 per share;
- shares of our common stock reserved for future issuance under our 2020 Plan (including up to shares of our common stock comprised of (i) the shares reserved and remaining available for issuance under our 2014 Plan that will be added to our 2020 Plan reserve upon its effectiveness plus (ii) the number of shares subject to stock options or other stock awards granted under our 2014 Plan that would have otherwise returned to our 2014 Plan, which will be added as they become available (e.g., due to forfeiture of the underlying 2014 Plan award)) which includes an annual evergreen increase and will become effective in connection with this offering; and
- shares of our common stock reserved for future issuance under our ESPP, which includes an annual evergreen increase and will become effective in connection with this offering.

To the extent any outstanding options or warrants are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional equity or convertible debt securities in the future, there will be further dilution to new investors.

**SELECTED FINANCIAL DATA**

The following tables set forth our selected statements of operations data for the years ended December 31, 2018 and 2019, and our selected balance sheet data as of December 31, 2018 and 2019, which have been derived 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 selected financial data together with the section entitled “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 selected 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.

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2019</b>
<b>(in thousands, except share and per share data)</b>		
<b>Statements of Operations Data:</b>		
Operating expenses:		
Research and development	\$ 30,145	\$ 45,607
General and administrative	5,388	8,546
Total operating expenses	<u>35,533</u>	<u>54,153</u>
Loss from operations	<u>(35,533)</u>	<u>(54,153)</u>
Other income (expense), net:		
Interest expense	(75)	(40)
Interest income	903	632
Grant income	—	237
Foreign currency transaction gains (losses)	42	(135)
Change in fair value of the redeemable convertible preferred stock tranche liability	5,178	3,185
Total other income (expense), net	<u>6,048</u>	<u>3,879</u>
Net loss and comprehensive loss	<u>\$ (29,485)</u>	<u>\$ (50,274)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (4.80)</u>	<u>\$ (7.85)</u>
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted <sup>(1)</sup>	<u>6,142,274</u>	<u>6,402,359</u>
Pro forma net loss per share, basic and diluted (unaudited) <sup>(1)</sup>	<u>                    </u>	<u>                    </u>
Weighted-average shares outstanding used in computing pro forma net loss per share, basic and diluted (unaudited) <sup>(1)</sup>	<u>                    </u>	<u>                    </u>

(1) See Notes 2 and 13 to our financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share, basic and diluted pro forma net loss per share and the weighted-average number of shares used in the computation of the per share amounts.

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	As of December 31,	
	2018	2019
	(in thousands)	
<b>Balance Sheet Data:</b>		
Cash and cash equivalents	\$ 66,090	\$ 58,976
Working capital <sup>(1)</sup>	59,955	50,671
Total assets	70,802	65,698
Redeemable convertible preferred stock warrant liability	462	450
Redeemable convertible preferred stock tranche liability	3,185	—
Series A redeemable convertible preferred stock	24,967	24,967
Series B redeemable convertible preferred stock	55,151	55,151
Series C redeemable convertible preferred stock	37,692	80,192
Total stockholders' deficit	(57,728)	(106,373)







(1) Working capital is defined as total current assets less total current liabilities. See our financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

**MANAGEMENT’S DISCUSSION AND ANALYSIS OF  
FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our financial statements and related notes and other financial information included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the section entitled “Risk Factors” and elsewhere in this prospectus. You should carefully read the “Risk Factors” section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled “Special Note Regarding Forward-Looking Statements.”

**Overview**

We are a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent or treat some of the most common and deadly infectious diseases worldwide. Our cell-free protein synthesis platform enables us to design and produce protein carriers and antigens, the critical building blocks of vaccines, in ways that we believe conventional vaccine technologies currently cannot. Our lead vaccine candidate, SVX-24, is a preclinical, 24-valent pneumococcal conjugate vaccine, or PCV, that we believe, if approved, has the potential to become the most broad-spectrum pneumococcal conjugate vaccine addressing the \$7 billion global pneumococcal vaccine market. We anticipate submitting our initial investigational new drug, or IND, application to the U.S. Food and Drug Administration, or FDA, in the second half of 2021 for SVX-24. Our second PCV, known as SVX-XP, leverages our scalable and modular platform and builds on the technical proof of concept established by SVX-24 and, if approved, would expand the breadth of coverage to at least 30 strains, including emerging strains responsible for invasive pneumococcal disease, or IPD, without compromising immunogenicity due to carrier suppression. In addition to our PCV franchise, we are developing a novel conjugate vaccine candidate for Group A Strep and a novel protein vaccine candidate targeting the keystone pathogen responsible for periodontitis. The following table summarizes our current vaccine candidate pipeline:

Program	Profile / Type	Vaccine Description	Target Population	Disease	Status
SVX-24	Superior Conjugate Vaccine	24-valent PCV		Invasive Pneumococcal Disease	Preclinical POC vs Prevnar 13 and Polysaccharide/Alum <sup>(1)</sup> (IND-enabling stage)
				Invasive Pneumococcal Disease and Otitis Media	Preclinical POC vs Prevnar 13 (IND-enabling stage)
SVX-XP	Superior Conjugate Vaccine	Next-generation >30-valent PCV		Invasive Pneumococcal Disease	Preclinical POC vs Prevnar 13 and Polysaccharide/Alum <sup>(2)</sup>
				Invasive Pneumococcal Disease and Otitis Media	Preclinical POC vs Prevnar 13
SVX-A1	Novel Conjugate Vaccine	Monovalent conjugate / complex protein-based vaccine		Group A Strep Infections	Preclinical POC + Grant Funding
SVX-PG	Novel Protein Vaccine	Multiple complex protein-based therapeutic vaccine		Periodontitis	Preclinical POC

 = Adults     = Children     = Infants

(1) For the Polysaccharide/Alum comparator, we used 23 polysaccharides in Pneumovax 23 at an equivalent dose with the addition of strain 6A and alum as the objective of the study was to evaluate whether SVX-24 showed a conjugate-like response in all 24 strains.  
 (2) For the Polysaccharide/Alum comparator, we used 23 polysaccharides in Pneumovax 23 and 9 additional polysaccharides with alum for comparison.



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Since our inception in November 2013, we have devoted substantially all of our resources to performing research and development, undertaking preclinical studies and enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology and vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from the sales of our redeemable convertible preferred stock. Through December 31, 2019, we have raised approximately \$167.4 million in gross proceeds from the sale of our redeemable convertible preferred stock. We will continue to require additional capital to develop our vaccine candidates and fund operations for the foreseeable future. Accordingly, until such time as we can generate significant revenue from sales of our vaccine candidates, if ever, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.

We have incurred net losses in each year since inception and expect to continue to incur net losses in the foreseeable future. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending in large part on the timing of our preclinical studies and clinical trials, and our expenditures on other research and development activities. Our net loss was \$50.3 million for the year ended December 31, 2019. As of December 31, 2019, we had an accumulated deficit of \$109.3 million. As of December 31, 2019, we had cash and cash equivalents of \$59.0 million. Based upon our current operating plan, we believe that our existing cash and cash equivalents as of the date of this prospectus, together with the net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements through at least the next months from the date of this offering.

We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our vaccine candidates, which we expect will take a number of years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance vaccine candidates through preclinical studies and clinical trials;
- require the manufacture of supplies for our preclinical studies and clinical trials, in particular our lead vaccine candidate SVX-24;
- pursue regulatory approval of vaccine candidates;
- hire additional personnel;
- operate as a public company;
- acquire, discover, validate and develop additional vaccine candidates; and
- obtain, maintain, expand and protect our intellectual property portfolio.

We rely and will continue to rely on third parties in the conduct of our preclinical studies and clinical trials and for manufacturing and supply of our vaccine candidates. We have no internal manufacturing capabilities, and we will continue to rely on third parties, of which the main suppliers are single-source suppliers, for our preclinical and clinical trial materials. Given our stage of development, we do not yet have a marketing or sales organization or commercial infrastructure. Accordingly, if we obtain regulatory approval for any of our vaccine candidates, we also expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

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Because of the numerous risks and uncertainties associated with vaccine development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of our vaccines, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

### ***Certain Significant Relationships***

#### *Sutro Biopharma*

SutroVax was formed through its relationship with Sutro Biopharma, Inc., or Sutro Biopharma, in 2013 by our three co-founders, Grant Pickering, Jeff Fairman and Ash Khanna, with the goal of utilizing Sutro Biopharma's proprietary XpressCF platform for protein synthesis in the field of vaccines addressing infectious disease.

In addition to receiving funding, we entered into a license agreement with Sutro Biopharma, or the Sutro License, on August 1, 2014. The Sutro License was amended in October 2015 and again on May 9, 2018 and May 29, 2018. Under this license, we received an exclusive, worldwide, royalty-bearing, sublicenseable license under Sutro Biopharma's patents and know-how relating to cell-free expression of proteins to (i) research, develop, use, sell, offer for sale, export, import and otherwise exploit specified vaccine compositions, such rights being sublicenseable, for the treatment or prophylaxis of infectious diseases, excluding cancer vaccines, and (ii) to manufacture, or have manufactured by an approved contract manufacturing organization, such vaccine compositions from extracts supplied by Sutro Biopharma pursuant to the Sutro Biopharma Supply Agreement (as described below). We are obligated to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize the vaccine compositions. In consideration of the rights granted under the Sutro License, we are obligated to pay Sutro Biopharma a 4% royalty on worldwide aggregate net sales of vaccine compositions for human health use and a 2% royalty on such net sales of vaccine compositions for animal health use. Such royalty rates are subject to specified reductions, including standard reductions for third-party payments and for expiration of relevant patent claims. Royalties are payable on a vaccine composition-by-vaccine composition and country-by-country basis until the later of expiration of the last valid claim in the licensed patents covering such vaccine composition in such country and ten years after the first commercial sale of such vaccine composition. In addition, we are obligated to pay Sutro Biopharma a percentage in the low-double digits of any net sublicensing revenue received for sublicense agreements executed before July 2020. Our obligation to pay sublicense fees to Sutro Biopharma expires in July 2020.

In May 2018, we entered into a supply agreement, which we refer to as the Sutro Biopharma Supply Agreement, with Sutro Biopharma pursuant to which we purchase from Sutro Biopharma extract and custom reagents for use in manufacturing non-clinical and certain clinical supply of vaccine compositions utilizing the technology licensed under the Sutro License at prices not to exceed a specified percentage above Sutro Biopharma's fully burdened manufacturing cost. If any extracts or custom reagents do not meet the specifications and warranties provided, then we will not have an obligation to pay for the non-conforming product, and Sutro Biopharma will be obligated to replace the non-conforming product within the shortest possible time with conforming product at our cost.

For additional details regarding our relationship with Sutro Biopharma, see the section entitled "Business—Intellectual Property—Sutro Biopharma Agreements" and Note 15 to our financial statements included elsewhere in this prospectus.

#### *Lonza*

In October 2016, we entered into a development and manufacturing services agreement with Lonza, which we refer to, as amended, as the 2016 Lonza agreement, pursuant to which Lonza is obligated to perform

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manufacturing process development and clinical manufacture and supply of components for SVX-24, including the manufacture of polysaccharide antigens, our proprietary eCRM protein carrier and conjugated drug substances.

In October 2018, we entered into a second development and manufacturing services agreement with Lonza, which we refer to as the 2018 Lonza Agreement, and together with the 2016 Lonza Agreement, as the Lonza Agreements, pursuant to which Lonza is obligated to perform manufacturing process development and clinical manufacture and supply of SVX-24 finished drug product.

In June 2018, we entered into a letter agreement, or the Lonza Letter Agreement, with Lonza, pursuant to which we agreed to certain terms for potential future equity payments as partial satisfaction of future obligations to Lonza under the Lonza Agreements. Specifically, we and Lonza agreed that the initial pre-IND cash payments made by us to Lonza are subject to a specified dollar cap, which we refer to as the Initial Cash Cap. After the Initial Cash Cap has been reached, then at our election, we can make any further pre-IND payments owed to Lonza under the Lonza Agreements in cash, equity at then market prevailing prices, or a combination of both. Lonza may elect to receive up to 25% of pre-IND payments in equity, up to a maximum of \$2.5 million, and no more than \$10 million of pre-IND payments may be satisfied by issuances of our common stock.

Under the Lonza Agreements, we will pay Lonza agreed upon fees for Lonza's performance of manufacturing services, and we will reimburse Lonza for its out-of-pocket costs associated with purchasing raw materials, plus a customary handling fee. Each Lonza Agreement is managed by a steering committee and any dispute at the steering committee will be resolved by senior executives of the parties.

For additional details regarding our relationship with Lonza, see the section entitled "Business— Manufacturing and Supply—Lonza Agreements" and Note 7 to our financial statements included elsewhere in this prospectus.

## **Components of Results of Operations**

### ***Operating Expenses***

#### *Research and Development*

Research and development expenses represent costs incurred in performing research, development and manufacturing activities in support of our own product development efforts and include product and development costs, personnel-related costs (such as salaries, employee benefits and stock-based compensation) for our personnel in research and development functions, professional and consulting services costs, research and development consumables costs, facility and other allocated costs, laboratory supplies and equipment costs and other costs.

Research and development expenses are expensed as incurred. Non-refundable advance payments for services that will be used or rendered for future research and development activities are recorded as prepaid expenses and recognized as expenses as the related services are performed. We do not allocate our costs by vaccine candidates, as our vaccine candidates are at an early stage of development and our research and development expenses include internal costs, such as payroll and other personnel expenses, which are not tracked by vaccine candidate. In particular, with respect to internal costs, several of our departments support multiple vaccine candidate research and development programs.

We expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance our vaccine candidates into and through preclinical studies and clinical trials, pursue regulatory approval of our vaccine candidates and expand our pipeline of vaccine candidates. The process

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of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our vaccine candidates may be affected by a variety of factors, including the safety and efficacy of our vaccine candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our vaccine candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our vaccine candidates.

Our clinical development costs may vary significantly based on factors such as:

- the cost of clinical trials of our vaccine candidates being greater than we anticipate;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- delays in adding a sufficient number of trial sites and recruiting suitable patients to participate in our clinical trials;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- patients dropping out of a study;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our vaccine candidates;
- the phase of development of our vaccine candidates; and
- the efficacy and safety profile of our vaccine candidates.

### *General and Administrative*

General and administrative expenses consist primarily of personnel-related costs (such as salaries, employee benefits and stock-based compensation) for our personnel in executive, legal, finance and accounting, human resources and other administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters, professional fees paid for accounting, auditing, consulting and tax services, insurance costs and facility and other allocated costs not otherwise included in research and development expenses. We expect our general and administrative expenses to increase substantially in absolute dollars for the foreseeable future as we increase our headcount to support our continued research and development activities and grow our business. We also anticipate that we will incur increased expenses as a result of operating as a public company, including expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with SEC rules and regulations and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services.

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### *Other Income (Expense), Net*

Other income (expense), net includes interest expense incurred on our capital leases for laboratory equipment, interest income earned from our cash and cash equivalents, grant income from our cost reimbursement award, foreign currency transaction gains (losses) incurred during the period related to our Swiss Franc cash and liability balances and changes in the fair value of our redeemable convertible preferred stock tranche liability (see the subsection entitled “—Critical Accounting Policies and Significant Judgments and Estimates” below and Notes 2, 4 and 8 to our financial statements included elsewhere in this prospectus for more detail).

## **Results of Operations**

### ***Comparison of the Years Ended December 31, 2018 and 2019***

The following table summarizes our statements of operations and comprehensive loss for the periods indicated:

	<b>Year Ended December 31,</b>		<b>Change</b>	
	<b>2018</b>	<b>2019</b>	<b>\$</b>	<b>%</b>
	<b>(in thousands, except share and per share data)</b>			
Operating expenses:				
Research and development	\$ 30,145	\$ 45,607	\$ 15,462	51.3%
General and administrative	5,388	8,546	3,158	58.6%
Total operating expenses	<u>35,533</u>	<u>54,153</u>	<u>18,620</u>	52.4%
Loss from operations	(35,533)	(54,153)	(18,620)	52.4%
Other income (expense), net:				
Interest expense	(75)	(40)	35	(46.7)%
Interest income	903	632	(271)	(30.0)%
Grant income	—	237	237	*
Foreign currency transaction gains (losses)	42	(135)	(177)	*
Change in fair value of the redeemable convertible preferred stock tranche liability	5,178	3,185	(1,993)	(38.5)%
Total other income (expense), net	<u>6,048</u>	<u>3,879</u>	<u>(2,169)</u>	(35.9)%
Net loss and comprehensive loss	<u>\$ (29,485)</u>	<u>\$ (50,274)</u>	<u>\$ (20,789)</u>	70.5%

\* *not meaningful*

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### **Research and Development Expenses**

The following table summarizes our research and development expenses incurred during the periods indicated:

	Year Ended December 31,		Change	
	2018	2019	\$	%
	(in thousands)			
Product and clinical development(1)	\$14,824	\$27,985	\$13,161	88.8%
Personnel-related expenses	5,328	5,947	619	11.6%
Professional and consulting services	3,567	4,669	1,102	30.9%
Research and development consumables	2,435	2,474	39	1.6%
Facility and other allocated expenses	1,962	2,422	460	23.4%
Laboratory supplies and equipment	951	1,174	223	23.4%
Other expenses(2)	1,078	936	(142)	(13.2)%
Total research and development expenses	<u>\$30,145</u>	<u>\$45,607</u>	<u>\$15,462</u>	51.3%

(1) Includes expenses related to third-party manufacturing and outsourced contract services, including preclinical studies and outsourced assays.

(2) Includes travel-related expenses, warrant expense and other miscellaneous office expenses.

Research and development expenses increased by \$15.5 million, or 51.3%, in 2019 compared to 2018. The increase was primarily attributable to an increase of \$13.2 million in product and clinical development expenses mainly related to our lead vaccine candidate SVX-24, driven by an \$11.5 million increase in costs related to outsourced manufacturing activities and an increase of \$1.8 million in contracted research services.

### **General and Administrative Expenses**

General and administrative expenses increased by \$3.2 million, or 58.6%, in 2019 compared to 2018. The increase was primarily attributable to an increase in personnel-related costs of \$1.7 million due to increase in the number of employees in our general and administrative function, higher employee development and stock-based compensation expenses and an increase of \$1.3 million attributable to increases in audit, tax and legal fees.

### **Other Income (Expense), Net**

Other income (expense), net decreased by \$2.2 million, or 35.9%, in 2019 compared to 2018. The decrease was primarily attributable to a decrease in income resulting from a change in the fair value of the redeemable convertible preferred stock tranche liabilities. In 2019, we recognized \$3.2 million as a result of a decrease in the fair value of the Series C preferred stock tranche liability, compared to \$3.8 million and \$1.4 million in income as a result of decreases in fair value of the Series B and Series C preferred stock tranche liabilities in 2018, respectively. The decreases in fair value of the Series B and Series C preferred stock tranche liabilities were due to a reduction in their time to maturity following their respective settlements in May 2018 and December 2019.

### **Going Concern**

The accompanying financial statements have been prepared assuming that we will continue as a going concern and do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if we are unable to continue as a going concern.

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Since inception, we have devoted substantially all of our efforts to research and development, undertaking preclinical studies and enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology and vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities. We do not have any products approved for sale and have not generated any revenue from product sales. We have incurred net losses in each year since inception and expect to continue to incur net losses in the foreseeable future. Our net loss was \$50.3 million for the year ended December 31, 2019. As of December 31, 2019, we had an accumulated deficit of \$109.3 million. We also generated negative operating cash flows of \$47.1 million for the year ended December 31, 2019. These conditions raise substantial doubt about our ability to continue as a going concern for at least one year from the issuance date of our financial statements.

We believe that our cash and cash equivalents as of December 31, 2019 will not be sufficient for us to continue as a going concern for at least one year from the issuance date of our financial statements. Consequently, we are pursuing various financing alternatives, potentially including debt and equity arrangements, to finance our future operations. However, no assurance can be given as to whether additional needed financing will be available on terms acceptable to us, if at all. If sufficient funds on acceptable terms are not available when needed, we may be required to curtail planned activities to significantly reduce our operating expenses. Failure to manage discretionary spending or raise additional financing, as needed, may have an adverse effect on our results of operations and future prospects.

### **Liquidity and Capital Resources**

We have incurred losses since inception and have incurred negative cash flows from operations from inception through December 31, 2019. We have funded our operations to date primarily from the sale of redeemable convertible preferred stock totaling approximately \$167.4 million in aggregate proceeds (\$166.7 million, net of financing costs). As of December 31, 2019, we had \$59.0 million of cash and cash equivalents. As of December 31, 2019, we had an accumulated deficit of \$109.3 million.

### **Future Funding Requirements**

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs, and to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to advance our vaccine candidates, expand our corporate infrastructure, including the costs associated with being a public company, further our research and development initiatives for our vaccine candidates, scale our laboratory and manufacturing operations, and incur marketing costs associated with potential commercialization. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We believe that our existing cash and cash equivalents as of the date of this prospectus, together with the net proceeds from this offering, will fund our current operating plans through at least the next \_\_\_\_\_ months from the date of this offering. However, we will need to raise additional capital prior to commencing pivotal trials for any of our vaccine candidates. Until we can generate a sufficient amount of revenue from the commercialization of our vaccine candidates or from collaboration agreements with third parties, if ever, we expect to finance our future cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. The sale of equity or convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financings may subject us to covenant limitations or restrictions on our ability to take

specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms favorable or acceptable to us, we may be forced to delay, reduce the scope of or eliminate one or more of our research and development programs.

Our future capital requirements will depend on many factors, including:

- the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical development and clinical trials;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies for our PCV candidates, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the cost of building a sales force in anticipation of any product commercialization;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our vaccine candidates for which we receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the revenue, if any, received from commercial sales, or sales to foreign governments, of our vaccine candidates for which we may receive marketing approval;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing our patents or other intellectual property rights;
- expenses needed to attract, hire and retain skilled personnel; and
- the costs of operating as a public company.

A change in the outcome of any of these or other variables could significantly change the costs and timing associated with the development of our vaccine candidates. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such change.



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### **Cash Flows**

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

	Year Ended	
	December 31,	
	2018	2019
	(in thousands)	
Net cash (used in) operating activities	\$(30,466)	\$(47,145)
Net cash (used in) investing activities	(1,773)	(1,195)
Net cash provided by financing activities	62,190	41,567
Effect of exchange rate changes on cash and cash equivalents	—	(341)
Net increase (decrease) in cash and cash equivalents	<u>\$ 29,951</u>	<u>\$ (7,114)</u>

### **Cash Flows Used in Operating Activities**

Net cash used in operating activities for the year ended December 31, 2019 was \$47.1 million, which primarily resulted from a net loss of \$50.3 million and net non-cash charges of \$0.8 million, offset by a net change in our operating assets and liabilities of \$3.9 million. Non-cash charges primarily consisted of a \$3.2 million decrease in the fair value of our redeemable convertible preferred stock tranche liabilities primarily related to a reduction in the time to maturity during the year and the settlement of the Series C tranche liability in December 2019, partially offset by \$1.2 million of depreciation and amortization expense and \$1.2 million of stock-based compensation expense. The net change in operating assets and liabilities of \$3.9 million was primarily due to a \$4.7 million increase in accrued liabilities resulting primarily from our increased contract manufacturing activities in 2019 and a \$0.9 million increase in accounts payable resulting from timing of billings and payments. These increases were partially offset by a \$0.8 million decrease in accrued compensation due primarily to the timing of bonus payout and by a \$1.1 million increase in prepaid expenses and other current assets resulting primarily from \$0.4 million of receivable for research and development payroll tax credit, and \$0.7 million in prepaid expenditures mainly related to contract manufacturing activities, contract research services and maintenance contracts.

Net cash used in operating activities for the year ended December 31, 2018 was \$30.5 million, which primarily resulted from a net loss of \$29.5 million and net non-cash charges of \$2.9 million, offset by a net change in our operating assets and liabilities of \$1.9 million. Non-cash charges primarily consisted of a \$5.2 million decrease in the fair value of our redeemable convertible preferred stock tranche liabilities primarily related to the settlement of the Series B tranche liability, partially offset by \$1.0 million of depreciation and amortization expense, \$0.7 million of stock-based compensation expense and \$0.5 million of warrant expense related to the preferred stock warrant issued to Sutro Biopharma in 2018. The net change in operating assets and liabilities of \$1.9 million was primarily due to a \$1.7 million increase in accrued liabilities resulting primarily from our commencement of contract manufacturing activities in 2018, a \$1.3 million increase in accounts payable resulting primarily from increased contract manufacturing activities and a \$0.5 million increase in accrued compensation. These increases were partially offset by the payment of a legal settlement of \$0.9 million and a \$0.4 million increase in prepaid expenses and other current assets.

### **Cash Flows Used in Investing Activities**

Cash used in investing activities for the years ended December 31, 2019 and 2018 was \$1.2 million and \$1.8 million, respectively, which related primarily to purchases of laboratory equipment and leasehold improvements.

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### **Cash Flows from Financing Activities**

Cash provided by financing activities for the year ended December 31, 2019 was \$41.6 million, which primarily consisted of net proceeds from the issuance of the second tranche of our Series C redeemable convertible preferred stock of \$42.5 million, partially offset by deferred offering costs of \$1.1 million.

Cash provided by financing activities for the year ended December 31, 2018 was \$62.2 million, which primarily consisted of net proceeds from the issuance of the first tranche of our Series C redeemable convertible preferred stock and the second tranche of our Series B redeemable convertible preferred stock of \$42.3 million and \$20.0 million, respectively.

### **Contractual Obligations and Commitments**

The following table summarizes our contractual obligations and commitments at December 31, 2019:

	Payments Due by Period				Total
	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years	
Operating lease obligations(1)	\$ 717	\$530	\$ —	\$ —	\$1,247
Capital lease obligations	169	—	—	—	169
Total	<u>\$ 886</u>	<u>\$530</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$1,416</u>

(1) Consists of our corporate headquarters lease that expires in August 2021, our second lease in Foster City, California that expires in October 2021 and a small office in San Diego, California that expires in March 2021.

We have certain payment obligations under various license agreements. Under these agreements, we are required to make milestone payments upon successful completion and achievement of certain intellectual property, clinical, regulatory and sales milestones. The payment obligations under the license agreements are contingent upon future events such as our achievement of specified development, clinical, regulatory and commercial milestones, and we will be required to make development milestone payments and royalty payments in connection with the sale of products developed under these agreements. As the achievement and timing of these future milestone payments are not probable or estimable, such amounts have not been included in our balance sheet as of December 31, 2019, or in the contractual obligations table above. See Note 15, "Related Party Transactions" to the audited financial statements.

We enter into agreements in the normal course of business with vendors for preclinical studies, manufacturing and supply of our preclinical materials and for other services and products used for operating purposes. These contracts are generally cancelable following a certain period after written notice, and therefore, we believe that our non-cancelable obligations under these agreements are not material and have not been included in the table above.

### **Legal Contingencies**

From time to time, we may become involved in legal proceedings arising from the ordinary course of business. We record a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment by us is required to determine both probability and the estimated amount.

### **Off-Balance Sheet Arrangements**

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

## **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, redeemable convertible preferred stock tranche liabilities and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our financial statements included elsewhere in this prospectus, we believe the following accounting policies and estimates to be most critical to the judgments and estimates used in the preparation of our financial statements.

### ***Accrued Research and Development Expenses***

We have entered into various agreements with contract manufacturing organizations, or CMOs, and may enter into contracts with clinical research organizations, or CROs, in the future. As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel and third parties to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued research and development expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We accrue for costs related to research and development activities based on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors, including CMOs, that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received. We make significant judgments and estimates in determining accrued research and development liabilities as of each reporting period based on the estimated time period over which services will be performed and the level of effort to be expended. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

### ***Redeemable Convertible Preferred Stock Tranche Liability***

We utilize the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value each preferred stock tranche liability. On a quarterly basis, we assess these assumptions and estimates as

additional information impacting the assumptions are obtained. Estimates and assumptions impacting the fair value measurement include the fair value of the series of preferred stock, the remaining contractual term of the preferred stock tranche liability, risk-free interest rate, and expected dividend yield.

We determine the fair value per share of the underlying preferred stock by taking into consideration our most recent sales of our preferred stock as well as additional factors that we deem relevant. We are a private company and lack company-specific historical and implied volatility information of our stock. Therefore, we determine expected stock volatility based on the historical volatility of publicly traded peer companies. We estimate the risk-free interest rate by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the outstanding tranche liability. We have assumed a 0% dividend considering that our board of directors has no history of declaring dividends.

We completed the closing of the second tranche of the Series C redeemable convertible preferred stock in December 2019 and there were no outstanding tranche liabilities as of December 31, 2019.

#### ***Redeemable Convertible Preferred Stock Warrant Liability***

We utilize the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value each preferred stock warrant. We assess these assumptions and estimates on a quarterly basis as additional information impacting the assumptions are obtained. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying series of preferred stock, the remaining contractual term of the warrant, risk free interest rate, expected volatility of the price of the underlying preferred stock, expected dividend yield, and to the extent the exercisable shares underlying the warrant are contingently adjustable.

We determine the fair value per share of the underlying preferred stock by taking into consideration our most recent sales of our preferred stock as well as factors that we deem relevant. We are a private company and lack company-specific historical and implied volatility information of our stock. Therefore, we determine expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. We estimate the risk-free interest rate by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. We have assumed a 0% dividend yield considering that our board of directors has no history of declaring dividends.

Upon the closing of this offering, the underlying preferred stock will be converted to common stock, the preferred stock warrants will become exercisable for common stock instead of preferred stock and the fair value of the warrant liability at that time will be reclassified to additional paid-in capital. No further re-measurement of the warrants would occur if the warrants become exercisable for common stock.

#### ***Stock-Based Compensation Expense***

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of equity awards using the Black-Scholes option pricing model and recognize forfeitures as they occur. Estimating the fair value of equity awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of variables, including:

- *Fair Value of Common Stock*—See the subsection entitled “—Common Stock Valuations” for more information.
- *Expected Term*—Expected term represents the period that our stock-based awards are expected to be outstanding. For employee options, the expected term is calculated using the simplified method where there is insufficient historical data about exercise patterns and post-vesting employment

termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the time from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term. The expected term for options issued to nonemployees is the remaining contractual term.

- *Expected Volatility*—Expected volatility is estimated from the average historical volatilities of publicly traded companies within the life sciences industry that are considered to be comparable to our business over a period approximately equal to the expected term for employees' options and the remaining contractual life for nonemployees' options. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *Expected Dividend*—We have not paid and do not anticipate paying any dividends in the near future. Accordingly, we have estimated the dividend yield to be zero.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon notes with remaining terms corresponding with the expected term of the option.

Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. See Notes 2 and 11 to our financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the years ended December 31, 2018 and 2019. As of December 31, 2019, the unrecognized stock-based compensation expense related to stock options was \$2.8 million and is expected to be recognized as expense over a weighted-average period of approximately 1.3 years. The intrinsic value of all outstanding stock options as of December 31, 2019 was approximately \$ million, based on the assumed initial public offering price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, of which approximately \$ million related to vested options and approximately \$ million related to unvested options.

#### *Common Stock Valuations*

We are required to estimate the fair value of the common stock underlying our equity awards when performing fair value calculations. The fair value of the common stock underlying our equity awards was approved on each grant date by our board of directors, determined by management and taking input from independent third-party valuation analyses. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock, on each grant date we develop an estimate of the fair value of our common stock in order to determine an exercise price for the option grants. Our determinations of the fair value of our common stock were made using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide: *Valuation of Privately Held Company Equity Securities Issued as Compensation*, or the Practice Aid. Because our common stock shares are not publicly traded, estimating their fair values can be highly complex and subjective.

Management considered various objective and subjective factors to determine the fair value of our common stock, including:

- valuations of our common stock performed with the assistance of independent third-party valuation specialists;

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- our stage of development and business strategy, including the status of research and development efforts of our vaccine candidates, and the material risks related to our business and industry;
- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock;
- the prices of our redeemable convertible preferred stock sold to investors in arm's length transactions and the rights, preferences and privileges of our redeemable convertible preferred stock relative to those of our common stock;
- the likelihood of achieving a liquidity event for the holders of our common and redeemable convertible preferred stock, such as an initial public offering or a sale of our company, given prevailing market conditions;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

The Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics. Each valuation method was considered in our analysis.

For our valuations performed prior to June 30, 2019, we generally employed an Option Pricing Method, or OPM, based analysis, primarily the OPM Backsolve methodology, to determine the estimated fair value of our common stock. Within the OPM framework, the Backsolve method for inferring the total equity value implied by a recent financing transaction involves the construction of an allocation model that takes into account the company's capital structure and the rights and preferences of each class of stock, then assumes reasonable inputs for the other OPM variables (expected time to liquidity, volatility, risk-free rate, etc.). The total equity value is then iterated in the model until the model output value for the equity class sold in a recent financing round equals the price paid in that round. The OPM is generally utilized when specific future liquidity events are difficult to forecast, i.e., the enterprise has many choices and options available, and the enterprise's value depends on how well it follows an uncharted path through the various possible opportunities and challenges. In determining the estimated fair value of our common stock, management also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity. The estimated fair value of our common stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

For our valuations performed on or after June 30, 2019, we utilized a hybrid method that combines the Probability-Weighted Expected Return Method, or PWERM, an accepted valuation method described in the Practice Aid, and the OPM. The PWERM is a scenario-based analysis that estimates the value per share of common stock based on the probability-weighted present value of expected future equity values for the common stock, under various possible future liquidity event scenarios, considering the rights and preferences of each class

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of stock, discounted for a lack of marketability. Under the hybrid method, an OPM Backsolve was utilized to determine the fair value of our common stock in certain of the PWERM scenarios (capturing situations where our development path and future liquidity events were difficult to forecast) and potential initial public offering exit events were explicitly modeled in the other PWERM scenarios. A discount for lack of marketability was applied to the value derived under each scenario to account for a lack of access to an active public market.

Following the completion of this offering, the fair value of our common stock will be based on the closing quoted market price of our common stock as reported on the date of grant on the primary stock exchange on which our common stock is traded. Estimating the fair value of our common stock will not be necessary to determine the fair values of new awards once the underlying shares begin trading.

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

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

Our cash and cash equivalents as of December 31, 2019 consisted of readily available checking and money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operations. We believe that our exposure to interest rate risks is not significant and that a hypothetical 10% movement in market interest rates would not have a significant impact on the total value of our portfolio or our interest income. In addition, we do not believe that our cash and cash equivalents have significant risk of default or illiquidity.

#### ***Foreign Currency Risk***

We are exposed to market risk related to changes in foreign currency exchange rates, mainly relating to our contract with Lonza, our CMO in Switzerland. We have also entered into a limited number of contracts with other parties with payments denominated in foreign currencies. Payments under these contracts are made in foreign currencies and are subject to fluctuations in foreign currency rates. We do not currently have a formal program in place to hedge foreign currency risks. However, from time to time, we buy Swiss Francs, or CHF, which is the majority of our foreign currency exposure, at market and are holding CHF in our bank accounts. As of December 31, 2018 and December 31, 2019, we had approximately \$16.8 million and \$10.3 million of CHF, respectively, held at two financial institutions. As of December 31, 2018 and December 31, 2019, we had foreign currency denominated accounts payable and accrued expenses of \$3.6 million and \$7.1 million, respectively. To date, foreign currency transaction gains and losses have not been material to our financial statements. A 10% increase or decrease in current exchange rates would not have a material effect on our financial results.

As our foreign currency risk increases in the future, we will evaluate alternative strategies, including hedging, to mitigate our foreign currency exposure.

#### ***Effects of Inflation***

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation had a material effect on our results of operations during the periods presented.

### **Emerging Growth Company Status**

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay the adoption of 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

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emerging growth companies include presentation of only two years of 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 Section 404 of the Sarbanes-Oxley Act of 2002, as amended, 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. However as described in Note 3 to our financial statements included elsewhere in this prospectus, we early adopted certain accounting standards, as the JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies to the extent early adoption is permitted. 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 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.

### **Recently Adopted Accounting Pronouncements**

See Note 3 to our financial statements included elsewhere in this prospectus for more information.



## BUSINESS

### Overview

We are a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent or treat some of the most common and deadly infectious diseases worldwide. Our cell-free protein synthesis platform enables us to design and produce protein carriers and antigens, the critical building blocks of vaccines, in ways that we believe conventional vaccine technologies currently cannot. Our lead vaccine candidate, SVX-24, is a 24-valent investigational broad-spectrum pneumococcal conjugate vaccine, or PCV, that we believe, if approved, has the potential to become the most broad-spectrum pneumococcal conjugate vaccine addressing the \$7 billion global pneumococcal vaccine market.

Our cell-free protein synthesis platform, which is comprised of the XpressCF platform exclusively licensed from Sutro Biopharma, Inc., or Sutro Biopharma, and our proprietary know-how, offers several advantages over conventional cell-based protein expression methods, which we believe enable us to generate potentially best-in-class, more broad-spectrum and/or more immunogenic vaccines. In the context of conjugate vaccines, we believe we can add more antigenic strains without compromising the overall immune response. In particular, our ability to specify the attachment point of antigens, including polysaccharides on protein carriers represents a significant improvement over the random conjugation that occurs with conventional technologies. This site-specific conjugation is designed to ensure that B-cell and/or T-cell epitopes are optimally exposed, maximizing the immune response, whereas random conjugation blocks these critical immunogenic epitopes, dampening the immune response and causing a phenomenon known as carrier suppression. We believe this precise control of conjugation chemistry enables us to design broader-spectrum conjugate vaccine candidates using carrier-sparing conjugates that use less protein carrier without sacrificing immunogenicity. We are also able to design novel conjugate vaccine candidates using standard amounts of protein carrier to generate heightened immunogenicity. Beyond conjugate vaccines, we believe we can also design novel protein vaccine candidates based on well-appreciated but highly complex antigens that currently cannot be made with conventional technologies to address diseases for which there are no available vaccines. In addition, our platform enables us to rapidly screen vaccine candidates and produce conjugates, thereby dramatically accelerating the development cycle of designing, producing and testing vaccine candidates.

The global vaccine market was \$36 billion in 2018 and is expected to grow at an 8% compound annual growth rate, or CAGR, to approximately \$58 billion by 2025. The global pneumococcal vaccine market has grown rapidly over the last two decades, reaching \$7 billion in sales in 2019, and is expected to grow to \$10 billion by 2025. The two leading pneumococcal vaccine franchises, Pneumovax and Prevnar, have generated over \$100 billion in combined sales and have been on the market for over 40 years and 20 years, respectively. The major types of pneumococcal disease are pneumonia (lung infection), bacteremia (bloodstream infection) and meningitis (infection of the tissue surrounding the brain and spinal cord). According to the American Thoracic Society, pneumonia is the world's leading cause of death among children under five years of age, accounting for 16% of all deaths in the age group. Pneumonia is also the most common cause of unplanned hospitalization in the United States and affects both children and adults. While bacteremia and meningitis are less common than pneumonia, they are often more severe, with fatality rates reaching up to 60% among the elderly. There are currently more than 90 circulating strains of pneumococcus, of which approximately one-third are known to be pathogenic.







The current vaccine standard of care for pneumococcal disease includes the combination of Merck's Pneumovax 23 and Pfizer's Prevnar 13 for adults, and Pfizer's Prevnar 13 for infants. Pneumovax 23 is a polysaccharide vaccine that protects against 23 strains of pneumococcus but is not thought to protect against pneumonia and provides only transient protection against bacteremia in adults, and is not effective in children under two years of age. Prevnar 13 is a PCV that protects against only 13 strains of pneumococcus but offers significantly better immunogenicity, protects against pneumonia and is suitable for both adults and infants. Routine immunization with PCVs has been effective in dramatically lowering the incidence of invasive




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pneumococcal disease, or IPD, in both adults and children in the United States and other industrialized nations. However, due to a phenomenon called serotype replacement, strains that are not covered by existing vaccines are increasing in prevalence. In 2016, over 75% of IPD incidence in both children and adults was caused by strains beyond the 13 strains covered by Prevnar 13. Efforts to improve upon current standard of care vaccines center around expanding the valency of PCVs to address the strains driving residual pneumococcal disease. However, limitations due to conventional conjugation chemistry and carrier suppression have complicated those efforts, and there remains a growing need for broader-spectrum PCVs, as evidenced by the fact that despite Prevnar 13's superior immunogenicity profile, Pneumovax 23 remains universally recommended in adults, given its broader-spectrum coverage.

The U.S. Centers for Disease Control, or CDC, its Advisory Committee on Immunization Practices, or ACIP, and similar international advisory bodies develop vaccine recommendations for both children and adults. New pediatric vaccines that receive ACIP preferred recommendations are almost universally adopted, and adult vaccines that receive a preferred recommendation are widely adopted. We believe that our PCVs will be well-positioned to obtain these preferred recommendations, by virtue of their broader-spectrum, which could drive rapid and significant market adoption.

We carefully select our target disease areas and vaccine candidates to address areas of significant unmet medical need based on the following criteria: well-defined commercial landscape and efficient market adoption, low biological risk and established clinical pathways. We are leveraging our scalable cell-free protein synthesis platform to develop potentially superior and novel conjugate and protein vaccine candidates for adult and pediatric indications using the above criteria. The following table summarizes our current pipeline:

Program	Profile / Type	Vaccine Description	Target Population	Disease	Status
SVX-24	Superior Conjugate Vaccine	24-valent PCV		Invasive Pneumococcal Disease	Preclinical POC vs Prevnar 13 and Polysaccharide/Alum <sup>(1)</sup> (IND-enabling stage)
				Invasive Pneumococcal Disease and Otitis Media	Preclinical POC vs Prevnar 13 (IND-enabling stage)
SVX-XP	Superior Conjugate Vaccine	Next-generation >30-valent PCV		Invasive Pneumococcal Disease	Preclinical POC vs Prevnar 13 and Polysaccharide/Alum <sup>(2)</sup>
				Invasive Pneumococcal Disease and Otitis Media	Preclinical POC vs Prevnar 13
SVX-A1	Novel Conjugate Vaccine	Monovalent conjugate / complex protein-based vaccine		Group A Strep infections	Preclinical POC + Grant Funding
SVX-PG	Novel Protein Vaccine	Multiple complex protein-based therapeutic vaccine		Periodontitis	Preclinical POC

 = Adults   
  = Children   
  = Infants

- (1) For the Polysaccharide/Alum comparator, we used 23 polysaccharides in Pneumovax 23 at an equivalent dose with the addition of strain 6A and alum as the objective of the study was to evaluate whether SVX-24 showed a conjugate-like response in all 24 strains.
- (2) For the Polysaccharide/Alum comparator, we used 23 polysaccharides in Pneumovax 23 and 9 additional polysaccharides with alum for comparison.

Our lead vaccine candidate, SVX-24, is a preclinical, 24-valent PCV designed to provide the broad-spectrum coverage of Pneumovax 23 with an immunogenicity profile comparable to Prevnar 13. We believe SVX-24, if approved, has the potential to become the most broad-spectrum pneumococcal conjugate vaccine addressing the \$7 billion global pneumococcal vaccine market. Our second PCV, known as SVX-XP, leverages our scalable and modular platform and builds on the technical proof of concept established by SVX-24 and would, if approved, expand the breadth of coverage to at least 30 strains, including emerging strains responsible for IPD and antibiotic resistance, without compromising immunogenicity due to carrier suppression.

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With the broadest-spectrum PCV vaccine candidates in development to our knowledge, we believe we are well-positioned to create a long-lasting PCV franchise. Our preclinical proof of concept studies for SVX-24 measured serotype-specific IgG antibody responses, the surrogate endpoint for pediatrics, and opsonophagocytic activity, or OPA, responses, the surrogate endpoint for adults of our vaccine candidates against Prevnar 13 and Pneumovax 23. In these studies, our vaccine candidates have shown comparable responses to the 13 common strains in Prevnar 13 and superior responses to the 23 common strains in Pneumovax 23.

We believe our PCVs could receive regulatory approval based on a demonstration of non-inferiority to the standard of care using well-defined surrogate immune endpoints rather than requiring clinical field efficacy studies, consistent with how other PCVs have obtained regulatory approval in the past. We believe other purposeful similarities in our development process increase our chance for streamlined regulatory approval and commercial adoption. We expect to submit an investigational new drug, or IND, application for SVX-24 to the U.S. Food and Drug Administration, or FDA, in the second half of 2021.

In addition to our PCV franchise, we are developing a novel conjugate vaccine candidate for Group A Strep. Group A Strep causes 700 million cases, the majority of which are of pharyngitis, commonly known as strep throat, worldwide each year and increases the risk for severe invasive infections, such as sepsis, necrotizing fasciitis and toxic shock syndrome. There is currently no vaccine against Group A Strep. In September 2019, we announced a grant of up to \$15.1 million, awarded by CARB-X, a global non-profit partnership dedicated to accelerating antibacterial innovation to tackle the rising global threat of drug-resistant bacteria, to develop this vaccine candidate.

We are also developing a novel protein vaccine candidate targeting the keystone pathogen responsible for periodontitis, a chronic oral inflammatory disease affecting an estimated 65 million adults in the United States. Our initial goal is to develop a therapeutic vaccine to slow or stop disease progression; however, the results from clinical trials may inform the potential adoption of prophylactic immunization.

Although we believe that our vaccine candidates have the potential to be widely adopted, we have not received regulatory approval for any of our vaccine candidates, and in order to obtain regulatory approval and commercialize our vaccine candidates, the U.S. Food and Drug Administration, or FDA, European Medicines Agency, or EMA, or other regulatory agencies will need to determine that our vaccine candidates are safe and effective. Obtaining such approval will require that we successfully complete additional studies and there can be no assurance that the results of such studies will be similar to our earlier studies. As such, we may not obtain regulatory approval for any of our vaccine candidates, and competing vaccines may ultimately reach the market faster or have more favorable safety and efficacy profiles than our vaccine candidates.

We believe that an efficient and high-quality manufacturing process is critical to our long-term success. We have strategically aligned with our contract manufacturer, Lonza, a globally recognized contract development and manufacturing organization based in Switzerland, to develop a robust and scalable manufacturing process for SVX-24. We have partnered closely with Lonza to transfer technology, develop and optimize processes and prepare for both clinical trial and potential commercial requirements for SVX-24. With this ongoing partnership, we believe we are addressing the complexity of vaccine development and production, thus establishing barriers to entry to protect our PCV franchise.

SutroVax was formed in 2013 through its relationship with Sutro Biopharma by our three co-founders, Grant Pickering, Jeff Fairman and Ash Khanna, with the goal of utilizing Sutro Biopharma's proprietary XpressCF platform in the field of vaccines to address infectious diseases. Since that time, we have assembled a distinguished group of executives, directors and advisors with extensive experience in vaccine development, manufacturing and commercialization. Our co-founder and Chief Executive Officer, Grant Pickering, played a prominent role in developing Provenge, the first therapeutic cancer vaccine to reach the market, and has served as Chief Executive Officer of multiple platform vaccines companies. Our co-founder and Vice President of Research, Jeff Fairman, our Chief Operating Officer, Jim Wassil, and our Senior Vice President of Process Development and Manufacturing, Paul Sauer, have been developing and industrializing vaccines and other

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biologics for close to 80 years, collectively. We are supported by leading investors, including TPG Growth, Abingworth LLP, Longitude Capital, Frazier Healthcare Partners, Pivotal bioVenture Partners, Medicxi, Roche Venture Fund, CTI Life Sciences Fund and Foresite Capital. We also benefit from directors and advisors that have previously served as heads of research and development for GlaxoSmithKline, Merck and Sanofi-Pasteur, including our board chairman, Moncef Slaoui, who served as the chairman of GlaxoSmithKline Vaccines. Together, our executives, directors and advisors have made essential contributions to the development of many widely used preventative and therapeutic vaccines, including pneumococcal vaccines such as Prevnar, Prevnar 13, Synflorix and Pneumovax 23, as well as other vaccines, including Provenge, Gardasil, Cervarix, Shingrix, Zostavax, Rotateq, Rotarix, Menveo and Bexsero, among others.

### **Our Opportunity in Vaccines**

Vaccines are one of the most successful and cost-effective global health interventions and prevent two to three million deaths worldwide each year. Routine pediatric vaccinations are estimated to prevent 20 million cases of disease each year, saving over \$180 billion in direct and societal costs in the United States alone. Adult vaccination rates are lower than pediatric vaccination rates, but new technologies are driving adult vaccine development, which in turn is fueling the growth of the overall vaccine market. Given the critical role vaccines play in preventing disease from childhood to adulthood, the global vaccine market is large, durable and growing. Nonetheless, there are areas of unmet medical need, including vaccines that can provide broader protection than currently marketed vaccines and novel vaccines that target pathogens for which there are no currently approved vaccines. We believe there is an opportunity for SutroVax to join the ranks of the major vaccine players by addressing these unmet needs in the adult and pediatric markets.

### **Our Approach**

We carefully select the disease areas we target and are developing vaccine candidates based on the following criteria:

- *Well-defined commercial landscape and efficient market adoption:* We select vaccine targets that are characterized by an established patient population and significant unmet medical need. Our lead vaccine candidate, SVX-24, is a PCV aimed at significantly improving the current standard of care by expanding coverage to address the strains that cause the majority of disease today without sacrificing immunogenicity. We believe that by providing the broadest strain coverage for PCVs, as well as providing novel vaccines for diseases for which there are no currently approved vaccines, we can leverage ACIP and similar international advisory body recommendations to drive rapid and significant market adoption.
- *Low biological risk:* We choose vaccine targets with well-understood mechanisms of action and strong precedents for positive preclinical study results that translated to positive clinical trial results. For example, conjugate vaccines have demonstrated effectiveness in both preclinical and clinical trials against a range of bacteria, including pneumococcus, meningococcus and Haemophilus influenza B (Hib). There is consistent evidence that antibodies directed against these bacteria are protective against their respective diseases.
- *Established clinical pathways:* We pursue vaccine targets that we believe have clear and established clinical development pathways in order to accelerate the potential time to market. For example, we believe that our PCVs could receive regulatory approval based on successful completion of clinical studies utilizing well-defined surrogate immune endpoints rather than requiring clinical field efficacy studies, consistent with how other vaccines have obtained regulatory approval. However, while there have been approvals granted for both pneumococcal conjugate vaccines and meningococcal conjugate vaccines based on surrogate immune endpoints rather than field efficacy studies, we will not be able to confirm this approach's applicability for our PCVs until we complete our Phase 2 clinical development program. For our novel vaccine candidates, where we believe

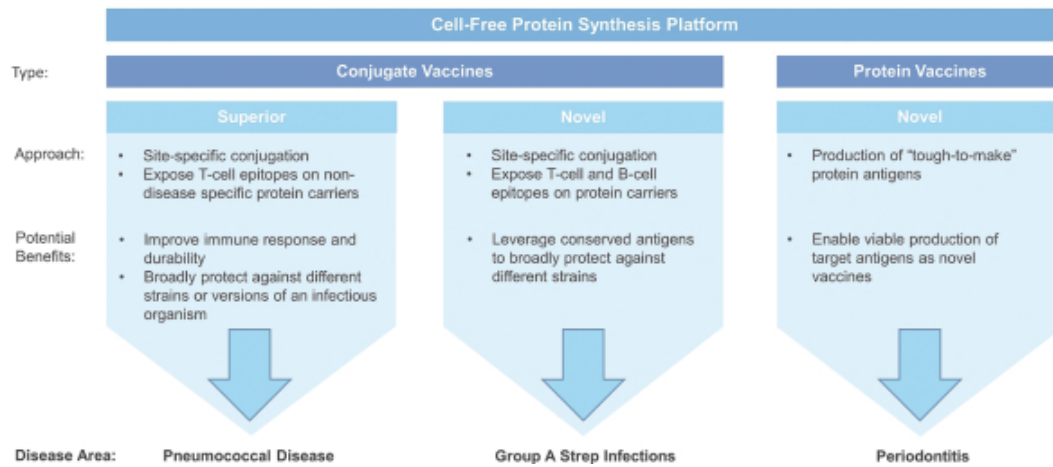
clinical field efficacy studies will be necessary, we select disease areas with high attack rates, such as Group A Strep, which may allow for more manageable study sizes. For novel protein-based therapeutic vaccine candidates, such as our periodontitis vaccine candidate, we select disease areas where we believe clinical efficacy may be evaluated based on disease progression rather than prevention, which could allow for smaller and faster trials relative to preventative vaccines.

**Our Platform**

We are leveraging our scalable cell-free protein synthesis platform to develop potentially superior and novel conjugate and protein vaccine candidates for adult and pediatric indications using the above criteria by taking advantage of the following:







- *Site-Specific Conjugation.* We are able to specify the attachment point of antigens, including polysaccharides, on protein carriers to ensure optimal exposure of B-cell and/or T-cell epitopes, thereby creating protein carriers designed to have enhanced potency. We believe this precise control of conjugation chemistry enables us to create broader-spectrum conjugate vaccine candidates using carrier-sparing conjugates that use less protein carrier without sacrificing immunogenicity. We are also able to design novel conjugate vaccine candidates using standard amounts of protein carrier to generate heightened immunogenicity.
- *Production of Novel Protein Vaccines.* We can design novel protein vaccine candidates based on well-appreciated but highly complex antigens that currently cannot be made with conventional technologies to address diseases for which there are no available vaccines, and we believe we may be able to leverage our platform to rapidly respond to new or emerging pathogens. We can design and produce these “tough-to-make” antigens that conform to the target pathogens, thereby increasing the likelihood that the vaccine will elicit a protective immune response.
- *Speed, Flexibility and Scalability of the Discovery Engine.* We are able to rapidly screen vaccine candidates and produce conjugates, thereby accelerating the process of making and testing vaccine candidates. Because cell viability is not required for cell-free protein synthesis, we can utilize a broader range of reaction conditions as we seek to optimize proteins. This flexibility enables us to develop novel vaccine candidates unachievable with current technologies. Furthermore, we believe our platform can scale linearly from discovery to commercial scale.

The table below illustrates how we utilize our platform to execute our approach to identify superior and novel conjugate and protein vaccine candidates in our initial three areas of disease focus:



## Our Pipeline

We have utilized our cell-free protein synthesis platform to generate a pipeline of vaccine candidates that we believe, if approved, may offer important advantages over existing vaccines or for which there are no vaccines available today. The following table summarizes our current pipeline:

Program	Profile / Type	Vaccine Description	Target Population	Disease	Status
SVX-24	Superior Conjugate Vaccine	24-valent PCV		Invasive Pneumococcal Disease	Preclinical POC vs Prevnar 13 and Polysaccharide/Alum <sup>(1)</sup> (IND-enabling stage)
				Invasive Pneumococcal Disease and Otitis Media	Preclinical POC vs Prevnar 13 (IND-enabling stage)
SVX-XP	Superior Conjugate Vaccine	Next-generation >30-valent PCV		Invasive Pneumococcal Disease	Preclinical POC vs Prevnar 13 and Polysaccharide/Alum <sup>(2)</sup>
				Invasive Pneumococcal Disease and Otitis Media	Preclinical POC vs Prevnar 13
SVX-A1	Novel Conjugate Vaccine	Monovalent conjugate / complex protein-based vaccine		Group A Strep Infections	Preclinical POC + Grant Funding
SVX-PG	Novel Protein Vaccine	Multiple complex protein-based therapeutic vaccine		Periodontitis	Preclinical POC

 = Adults     = Children     = Infants

- (1) For the Polysaccharide/Alum comparator, we used 23 polysaccharides in Pneumovax 23 at an equivalent dose with the addition of strain 6A and alum as the objective of the study was to evaluate whether SVX-24 showed a conjugate-like response in all 24 strains.
- (2) For the Polysaccharide/Alum comparator, we used 23 polysaccharides in Pneumovax 23 and 9 additional polysaccharides with alum for comparison.

## Our Strategy

Our goal is to become a leader in the vaccines industry by using our cell-free protein synthesis platform to develop potentially best-in-class and novel vaccines to prevent and treat serious infectious diseases. Key elements of our strategy include:

- **Advance SVX-24 through IND-enabling activities, clinical development and regulatory approval.** Our lead vaccine candidate, SVX-24, targets the pneumococcal vaccine market, a \$7 billion market in 2019 that is expected to grow to \$10 billion by 2025. We expect to advance SVX-24 along a well-understood clinical development pathway to obtain regulatory approval in adults and infants based on successful completion of clinical studies using previously established surrogate immune endpoints, potentially without the need to conduct a clinical field efficacy study, consistent with how other vaccines have obtained approval. We anticipate submitting our initial IND application to the FDA in the second half of 2021 and will seek to obtain clinical proof of concept in adults first because we believe clinical results are more easily attainable in the adult population.
- **Establish scalable production of SVX-24.** We believe high-quality and scalable manufacturing is critical to our long-term success. We have designed and developed a proprietary, scalable and portable manufacturing process that we believe can scale to supply clinical and commercial volumes of SVX-24 needed to serve both adult and pediatric populations. We have already made significant progress towards completing the production of Phase 1/2 clinical trial material for SVX-24 and are preparing for Phase 3 optimization and commercial scale-up activities. We have access to substantial manufacturing resources through our contract manufacturer, Lonza, that we

believe can facilitate an independent path to market. Moreover, our next generation SVX-XP program will use the components and core manufacturing processes established for SVX-24.

- **Create a long-lasting PCV franchise by offering the broadest-spectrum PCV available.** The two leading pneumococcal vaccine franchises, Pneumovax and Prevnar, have generated over \$100 billion in combined sales, have been on the market for over 40 years and 20 years, respectively, and can attribute their success to being the broadest-spectrum vaccines on the market. If approved, we believe SVX-24 may obtain an ACIP preferred recommendation and potentially replace both incumbents for pneumococcal disease prevention in both adult and pediatric populations because of its broader coverage. We designed SVX-24 to address the 13 pneumococcal strains covered by Prevnar 13 plus the incremental 11 strains that drive most pneumococcal disease today with the durable, boostable immune response of a conjugate vaccine. Further, we have designed SVX-XP to address these 24 strains plus 8 additional emerging strains expected to cause increasing pneumococcal disease and antibiotic resistance in the future. With these broad-spectrum vaccine candidates, we believe we are well-positioned to create a long-lasting PCV franchise.
- **Advance our novel vaccine candidates and expand our pipeline.** Our novel vaccine candidates include vaccines addressing group A strep and periodontitis, diseases for which no commercially available vaccines exist. Our group A strep vaccine candidate targets the pathogen causing 700 million cases of strep throat annually, while our periodontitis vaccine candidate targets the keystone pathogen causing disease in 65 million adults in the United States. We have established preclinical proof of concept for each of these vaccine candidates and plan to advance them into the clinic. We are also able to leverage our platform as a discovery engine given our ability to uniquely create building blocks to construct potential novel conjugate and protein vaccine candidates. We may selectively partner one or more of our novel vaccine candidates.
- **Continue to build a robust intellectual property portfolio.** We have developed and are continuing to develop a comprehensive intellectual property portfolio related to vaccine applications, including manufacturing, formulation and process applications as well as protection for our specific vaccine candidates. We currently have multiple pending patent applications in the United States and internationally that cover vaccine formulations, protein-antigen conjugates, methods of making conjugate vaccines with various protein-antigen conjugates and other processes, enhancements of immunogenicity and methods of use. Moreover, our exclusive license from Sutro Biopharma provides us access to a robust portfolio of patents and patent applications related to the XpressCF platform.

## Global Vaccine Market

The global vaccine market was approximately \$36 billion in 2018 and is expected to grow at an 8% CAGR to approximately \$58 billion by 2025. The World Health Organization, or WHO, has reported that vaccine revenues have grown at nearly twice the rate of therapeutic products over the last two decades. Conjugate vaccines, including PCVs, represent the largest segment (approximately 39% in 2018) of the global vaccine market. Prevnar 13, currently the broadest-spectrum PCV, is the highest selling vaccine product in the world, accounting for approximately 16% of global vaccine sales in 2018.

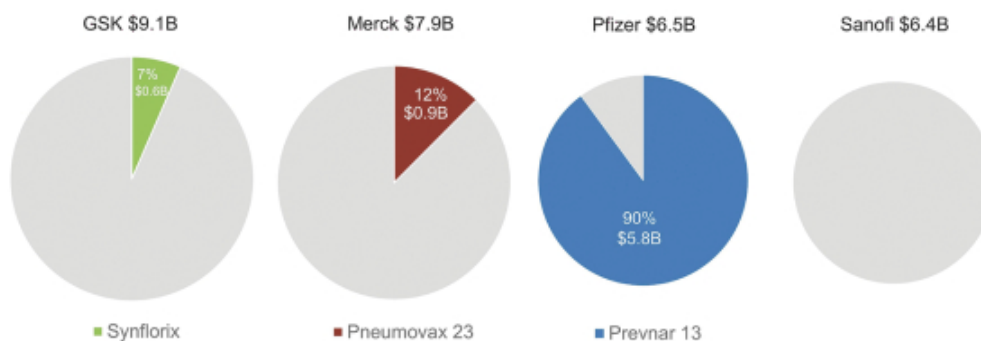
The pediatric vaccine market is large and well-established in the United States and European Union and growing in emerging countries. The annual new birth cohort, which in the United States and Europe approached nine million in 2017, drives ongoing sales year after year. In the United States, once a new vaccine is approved by the FDA, the ACIP considers whether to recommend the use of the vaccine. New pediatric vaccines that receive a preferred recommendation from ACIP are nearly universally adopted by pediatricians and parents and are required by many schools, contributing to a national immunization rate for the diseases targeted by such vaccines of approximately 90%.

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In addition, the adult vaccine market is currently undergoing rapid growth. Vaccination rates among adults have historically been lower and vary by disease, though strong initiatives are underway to increase awareness and utilization. Studies estimate that 40,000 to 80,000 adults in the United States die annually of vaccine-preventable diseases, and hundreds of thousands more are hospitalized. In recent years, manufacturers have started developing more vaccines for the adult market, with Pfizer's Prevnar 13 as the most successful example to date, with annual sales of \$1.2 billion in the adult indication in the United States. A more recent example is GlaxoSmithKline's Shingrix vaccine for shingles (herpes zoster), which debuted with over \$1 billion in sales in 2018 as it replaced Merck's incumbent vaccine, Zostavax, after receiving an ACIP preferred recommendation and generated over \$2.3 billion in sales in 2019.

The complex development and production processes of vaccines create a high barrier to entry and long product lifecycles. Four multinational companies—GlaxoSmithKline, Merck, Pfizer and Sanofi—currently comprise approximately 75% of the global vaccine market. GlaxoSmithKline, Merck and Sanofi have broad vaccine portfolios, while Pfizer offers a narrower range of vaccines. Refer to Figure 1 below for an overview of the top vaccine companies globally based on 2019 sales, with their pneumococcal vaccines highlighted.

Figure 1.



## Pneumococcal Disease

### Pneumococcal Disease Background

Pneumococcal disease is caused by *Streptococcus pneumoniae* (*S. pneumoniae* or pneumococcus) bacteria and can result in a variety of illnesses. There are more than 90 circulating strains of pneumococcus, of which approximately one-third are pathogenic. Pneumococcal disease can be characterized as invasive or non-invasive. Invasive pneumococcal disease includes bacteremic pneumonia, bacteremia, sepsis, meningitis and osteomyelitis. Non-invasive pneumococcal disease includes non-bacteremic pneumonia, acute otitis media, commonly known as middle ear infections, bronchitis and sinusitis. Pneumococcal infection is most serious for infants, young children, older adults and those with immune deficiencies or certain chronic health conditions. Despite nearly universal vaccination in infants and widespread vaccination in older adults with Prevnar 13, there are approximately 900,000 people who get pneumococcal pneumonia in the United States each year, including as many as 400,000 requiring hospitalization and approximately 28,000 deaths. Bacteremia is less common, with 5,000 annual cases but has a 20% fatality rate overall and a 60% fatality rate among older adults. There are over 2,000 annual cases of meningitis, with an 8% fatality rate in children and 22% fatality rate in adults. There are approximately 3.6 million cases of acute otitis media annually in U.S. children attributable to pneumococcal infection. Antibiotics are used to treat pneumococcal disease, but some strains of the bacteria have developed resistance to treatments. The morbidity and mortality due to pneumococcal disease are highly significant, particularly for young children and older adults, which underscores the need for a more broad-spectrum vaccine.



### *Evolution of Pneumococcal Vaccines*

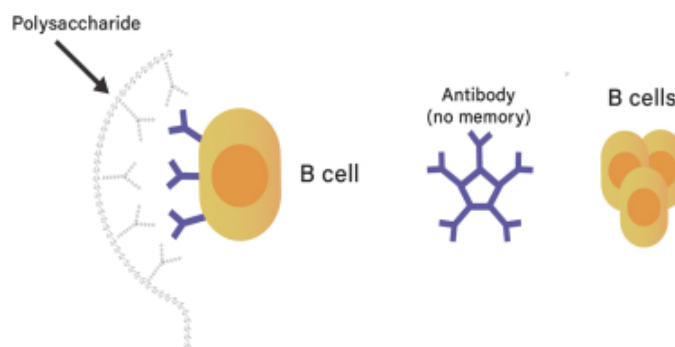
There are currently two types of vaccines targeting pneumococcal disease—polysaccharide-only vaccines and polysaccharide-conjugate vaccines. Polysaccharide vaccines contain polysaccharide antigens, which induce antibodies (B-cell responses) that bind to a bacteria's outer coating of polysaccharides and clear the bacteria. PCVs improve on polysaccharide vaccines by attaching, or conjugating, the polysaccharide antigen to a non-disease specific protein carrier. PCVs induce both an improved B-cell response and a T-cell response, resulting in a stronger and more durable immune response and longer-lasting protection, as compared to polysaccharide vaccines, which only induce a B-cell response.

#### *Pneumococcal Polysaccharide-Only Vaccines (Pneumovax)*

Pneumovax, manufactured and marketed by Merck, is the only pneumococcal polysaccharide vaccine widely available. Pneumovax is indicated for the prevention of pneumococcal disease in adults and was first approved in the United States in 1977, at which time it contained 14 different strains of pneumococcal bacteria. In 1983, it was replaced by the current version containing 23 different strains. Pneumovax 23 is routinely administered to adults to provide protection against bacteremia and generates sales of over \$900 million per year.

Polysaccharide vaccines induce a B-cell response only and do not induce a T-cell dependent immune response. In the absence of immunological memory responses, the resulting antibody responses are transient and cannot be boosted. Without the ability to provide long-lasting durable immunity, polysaccharide vaccines are not effective in children below two years of age. In addition, the antibody responses primarily consist of immunoglobulin M, or IgM, antibodies that, due to their size, are restricted to blood and are unable to penetrate into lung tissue to protect against pneumonia. Therefore, polysaccharide vaccines such as Pneumovax are only thought to protect against blood-borne infections, such as bacteremia. Figure 2 below illustrates polysaccharide-induced T-cell independent antibody responses.

Figure 2.



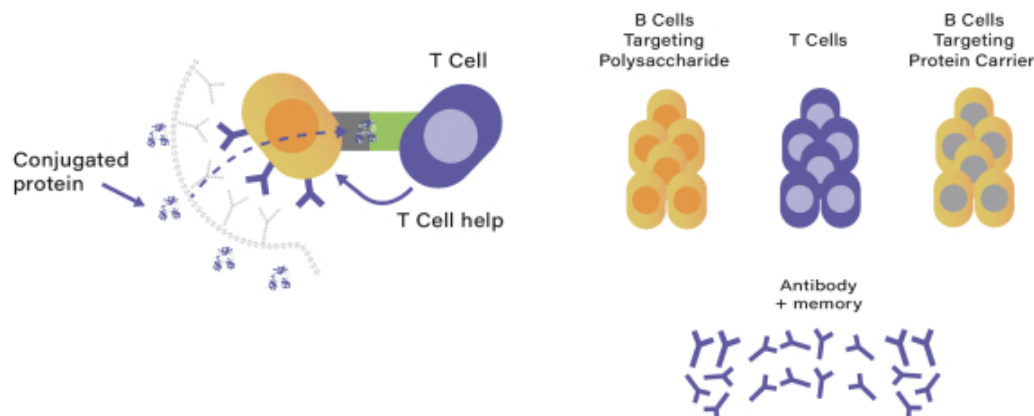
Polysaccharide vaccines also interfere with optimal use of PCVs, as they create a hyporesponsive immune effect. In particular, absent T-cell inducement, polysaccharide vaccines actually clear the memory B-cells that are formed following primary immunization with a PCV, thereby eliminating the ability to boost with subsequent vaccination. This is a significant drawback of the current standard of care in older adults, which consists of the administration of a limited spectrum PCV following the administration of a polysaccharide vaccine. Despite these shortcomings, Pneumovax 23 continues to be widely used primarily to provide protection against circulating strains not contained in the currently available PCV.

#### *Pneumococcal Conjugate Vaccine (Pneumovax)*

PCVs overcome the limitations of polysaccharide vaccines by conjugating the polysaccharide to a more immunogenic protein carrier containing T-cell epitopes. These T-cell epitopes provide CD4<sup>+</sup> help, which is

critical to the conversion of a traditional B-cell dependent immune response to a more robust combined B-cell and T-cell dependent immune response. The T-cell response causes immediate class switching of the B-cells from more rudimentary IgM antibodies prevalent with polysaccharide vaccines to more refined IgG antibodies. IgG antibodies are refined enough to penetrate into lung tissues to prevent pneumonia. Furthermore, as polysaccharide strands attach to multiple copies of the protein carrier, they create an inter-strand cross-linked matrix structure, which the immune system easily recognizes as foreign. The T-cell dependent immune response also generates memory B-cells that can be re-stimulated, creating a prime-boost immune response and enabling a more robust and durable immune response, enabling the use of PCVs in young children. Figure 3 below illustrates this immune response:

Figure 3.



The first PCV, Prevnar, was a 7-valent vaccine that was launched in the United States in 2000. It included purified capsular polysaccharides of seven serotypes of *S. pneumoniae* (4, 6B, 9V, 14, 18C, 19F and 23F), each of which was individually conjugated to a T-cell-epitope-containing, nontoxic variant of diphtheria toxin known as CRM<sub>197</sub> to produce seven monovalent conjugates. These conjugates were mixed into a final vaccine formulation and then adsorbed to aluminum, or alum, which has been commonly used in vaccines since the 1930s to increase immune responses to vaccines. To obtain approval, a large field efficacy study was conducted that demonstrated the vaccine's efficacy in infants. Efficacy correlated with serological immune endpoints, as measured by IgG titers (a measurement of concentration) and a seroconversion threshold (or reference antibody concentration) of protection was defined. Prevnar is credited with tremendous medical and commercial success, having dramatically reduced circulating disease in children. However, after a number of years of widespread use, IPD incidence caused by strains not contained in the vaccine started to opportunistically rise, a phenomenon called serotype replacement, which led to the need for a broader-spectrum version of the vaccine.

In the race to develop a broader-spectrum PCV than Prevnar, two vaccines were successfully developed: Synflorix, a 10-valent PCV from GlaxoSmithKline, and Prevnar 13, a 13-valent PCV from Wyeth (subsequently acquired by Pfizer). Based on its broader coverage of then-emerging strains, Prevnar 13 was adopted as the standard of care in the United States and Europe. Synflorix continues to be used primarily in emerging countries.

Prevnar 13 contains the seven serotypes originally included in Prevnar plus six more serotypes of *S. pneumoniae* (1, 3, 5, 6A, 7F and 19A) and was developed and launched in the United States in 2010. Each polysaccharide is conjugated to CRM<sub>197</sub> to produce 13 monovalent conjugates, which are mixed into a final vaccine formulation and then adsorbed to alum. In 2010, Prevnar 13 obtained FDA approval for the prevention of IPD in infants based on non-inferior IgG antibody responses relative to Prevnar, using the surrogate immune endpoints established by the prior Prevnar field efficacy study. While Prevnar 13 failed to achieve non-inferiority

on two of the common seven strains relative to Prevnar, it was granted approval across all 13 strains. Upon receipt of the ACIP preferred recommendation, Prevnar 13 replaced Prevnar in the infant market as the standard of care. This also created a “catch-up” population for those children previously vaccinated with Prevnar to provide protection against the incremental serotypes covered by Prevnar 13.

Prevnar 13 has also received accelerated approval for the prevention of IPD and pneumonia in adults in the United States based on non-inferior OPA responses as compared to Pneumovax 23. To fulfill a post-marketing commitment, a large-scale field efficacy study of adults in the Netherlands was completed in 2013, which showed protection against community-acquired pneumonia and concordance between OPA and protection from community-acquired pneumonia. Thus, OPA was established as a validated surrogate immune endpoint in adults to support future regulatory approvals. Prevnar 13 subsequently received an ACIP preferred recommendation for adults 65 years and older, and the standard of care was amended to first vaccinate with Prevnar 13, and then after a waiting period, Pneumovax 23. This dual vaccine regimen provides some protection against the circulating strains over and above Prevnar 13 but we believe creates coverage gaps and patient compliance and convenience challenges.

Prevnar 13 quickly became the highest selling product in the global vaccine market. However, at the time of ACIP’s recommendation in 2014, it was determined that the recommendation would be revisited in four years to evaluate the impact of Prevnar 13 on pneumococcal disease burden in older adults. In June 2019, the ACIP downgraded its recommendation of Prevnar 13 for older adults, given the lack of disease caused by the incorporated strains, and instead began directing physicians and patients to decide whether to vaccinate on a case-by-case basis while still recommending universal vaccination with Pneumovax 23 due to its broader coverage.

### ***Drawbacks for Current PCVs***

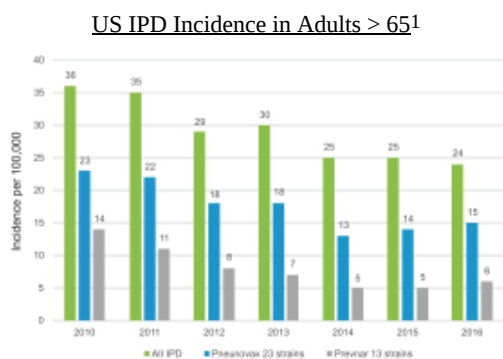
While vaccination with current PCVs has been effective in dramatically lowering the incidence of IPD in both adults and children in the United States and other industrialized nations, current PCVs suffer from the following drawbacks.

#### *Serotype Replacement*

Current PCVs do not address circulating strains causing the majority of pneumococcal disease. Since its introduction, there has been a decrease in the incidence of disease attributable to the serotypes covered by Prevnar 13 but an increase in incidence attributable to the incremental 11 strains that now cause most residual disease. Such change is driven by the void created when serotypes are taken out of circulation after widespread vaccination, which is a phenomenon known as serotype replacement. As a result of such change, broader-spectrum PCVs are required to maintain protection against historically pathogenic strains while expanding coverage to address current circulating and emerging strains.

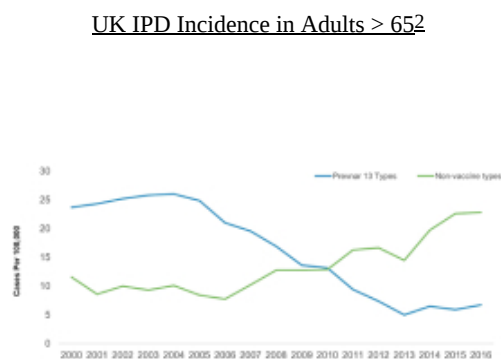
To date, the most comprehensive pneumococcal disease surveillance has been conducted by the CDC in the United States and by the National Institute of Health and Care Excellence, in the United Kingdom. As shown in Figure 4, IPD cases in adults in the United States initially declined after the introduction of Prevnar 13 but have since plateaued. In 2016, non-covered serotypes were responsible for over 75% of IPD incidence in both children and adults. The rate of serotype replacement has been more pronounced in the United Kingdom. Figure 5 shows the approximate IPD incidence rates in the United Kingdom caused by the incremental 11 strains over and above those in Prevnar 13, which have increased over the past three years.

Figure 4.



<sup>1</sup> US CDC Active Bacterial Core Surveillance Annual Reports

Figure 5.



<sup>2</sup> Ladhani et al, *Lancet Infectious Disease*, 2018 Apr.; 18(4) inclusive of unpublished raw data

While these 11 strains are covered by Pneumovax 23, that vaccine only protects against blood-borne infections and not pneumonia, leaving patients vulnerable to infection. We believe the need for both strong efficacy and broad coverage creates an opportunity for new, improved vaccines.

### Carrier Suppression

Technical constraints inherent to conventional conjugation chemistry limit the coverage of current PCVs due to a phenomenon known as carrier suppression. In particular, traditional conjugation methods cannot control where conjugation of the polysaccharide occurs on the protein carrier. The protein carrier used in Prevnar and Prevnar 13, is CRM<sub>197</sub>, a diphtheria toxin with a single point mutation rendering it non-toxic. The CRM<sub>197</sub> protein contains 39 lysines, approximately 20% of which border relevant T-cell epitopes. Conventional conjugation chemistry randomly attaches the polysaccharide to any of the numerous lysines located on the protein carrier. When a polysaccharide is covalently bound to a protein carrier at a lysine residue that is co-resident with a T-cell epitope, it blocks the presentation of the T-cell epitope to the immune system, thus preventing the induction of a T-cell response. The masking of these critical epitopes prevents the conversion to a T-cell dependent immune response and negates the benefit of the protein carrier.

Meanwhile, the B-cell epitopes of both the protein carrier and the antigen are presented to the immune system, causing B-cells to the respective immunogens to compete with one another for the T-cell help engendered by unblocked T-cell epitopes. This competition for T-cell help diminishes the immune response to the polysaccharide antigen of interest, resulting in carrier suppression.

The result of carrier suppression is a decrease in the targeted immune response to the disease-specific polysaccharides, which intensifies with higher cumulative amounts of protein carrier. This phenomenon impedes the ability to expand coverage of current PCVs and has been shown consistently when broader-spectrum versions of conventional PCVs have been compared to lesser-valent versions. When Prevnar 13 was compared to Prevnar in a well-controlled Phase 3 study in infants, the IgG antibody responses directed against the polysaccharides of interest for all seven of the common strains in each vaccine were lower for Prevnar 13. In 2019, Pfizer presented results of a well-controlled Phase 2 study in adults, aged 60 to 64, where they compared a 20-valent PCV development candidate to Prevnar 13. In that study, the OPA responses directed against the polysaccharides of interest for all thirteen of the common strains in each vaccine were lower for the 20-valent development candidate.

### *Conventional Chemistry*

The problem of carrier suppression is compounded by conventional conjugation chemistry used to make PCVs, including Prevnar 13, which requires a higher amount of CRM<sub>197</sub> protein carrier than polysaccharide antigen to complete the conjugation reaction, as well as longer reaction times and harsh conditions that can damage the critical epitopes on the polysaccharide antigens. This results in a higher ratio of protein carrier to polysaccharide antigen in their monovalent conjugates (approximately 1.1 on average), as well as a much higher amount of cumulative protein carrier in the final formulation compared to the amount of any given polysaccharide antigen. For example, in the marketed Prevnar 13 formulation there are 34 micrograms of the protein carrier, CRM<sub>197</sub>, relative to 2.2 micrograms of each polysaccharide (except serotype 6B at 4.4 micrograms). With substantially more protein carrier in the vaccine than polysaccharide antigen, the carrier suppression effect discussed above is exacerbated.

### **Our Solution**

We are leveraging our cell-free protein synthesis platform to develop potentially superior conjugate vaccines for adult and pediatric indications. Our solution to the drawbacks with conventional conjugate vaccine techniques represents the first of three main applications of our platform.

#### ***Platform Application One: Creating Superior Conjugate Vaccines***

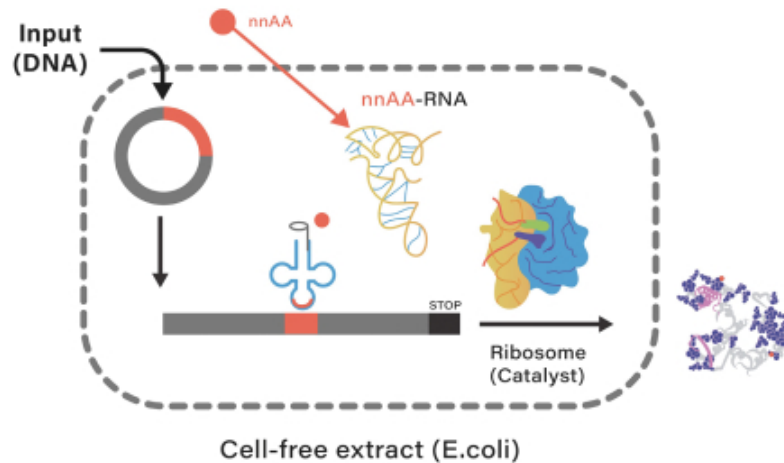
Using our cell-free protein synthesis platform, we are developing potentially best-in-class PCVs designed to have broader-spectrum coverage in an effort to address current and future residual disease in ways that conventional technologies cannot. We are able to design our investigational PCVs using site-specific conjugation in an effort to ensure optimal exposure of targeted immunogenic T-cell epitopes on protein carriers. This enables us to create broader-spectrum conjugate vaccine candidates using carrier-sparing conjugates designed to avoid carrier suppression while maintaining protective immunogenicity.

Synthesizing proteins outside of a living cell host provides us greater freedom to design and produce specific proteins of interest under optimized conditions. We separate the precise cellular machinery required for transcription, translation and energy production—the critical components for protein production—into an *E. coli*-derived extract. We can then optimally express a single protein carrier by adding the plasmid-DNA encoding that protein into the extract mixture.

#### ***Site-Specific Conjugation***

Within a protein carrier, we can substitute non-native amino acids, or nnAAs, for native amino acids at specific sites. These inserted nnAAs serve as conjugation anchors that permit the attachment of antigens, including polysaccharides, site-specifically on a protein carrier to ensure optimal exposure of B-cell and/or T-cell epitopes to induce the desired immune response. This precise site-specific linkage is not possible using conventional conjugation chemistry with conventional carrier proteins and affords an advantage to our conjugate vaccine candidates. Figure 6 below depicts our method of inserting nnAAs into a protein carrier, where the DNA sequence has been modified to permit nnAA incorporation into the protein at pre-selected sites using a nnAA-RNA permitting transcription and translation of the protein in the ribosome to yield the protein carrier with nnAAs site-specifically incorporated, facilitating conjugation to those sites.

Figure 6.



Most conjugate vaccines available today use a non-disease-specific protein carrier, CRM<sub>197</sub>, in order to leverage T-cell epitopes to induce a T-cell dependent immune response. This traditional method produces a heterogeneous mixture of conjugates with blocked and unblocked T-cell epitopes in a large immunogenic cross-linked matrix structure. In contrast, the precision and flexibility of cell-free protein expression, together with our ability to insert nnAAs, allow us to construct our proprietary enhanced protein carrier, or eCRM, with pre-determined conjugation sites. Our method produces homogenous conjugates that provide for the consistent exposure of T-cell epitopes and likewise form a large, immunogenic cross-linked matrix structure. By precisely conjugating polysaccharides to eCRM in a way that provides for optimal exposure of T-cell epitopes to the immune system, we can heighten immunogenicity attainable with conjugate vaccines.

The figures below illustrate the site-specific conjugation process. Figure 7 shows site-specific conjugation of the polysaccharide to the protein carrier, avoiding the T-cell epitopes. Figure 8 shows the inter-strand cross-linked matrix, which is the structure of each monovalent conjugate included in the final vaccine.

Figure 7.

**Precise, Consistent & Optimal  
Conjugation Sites**

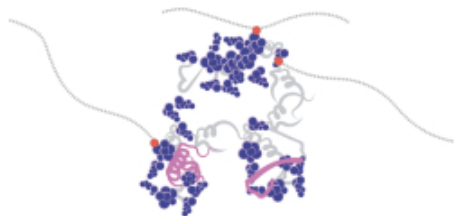
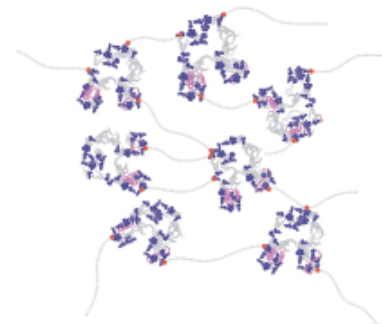


Figure 8.

**Final Product: Conjugates in  
Customary Matrix Formation**



We believe consistent exposure of T-cell epitopes should translate to higher potency of the protein carrier on a weight-to-weight basis. To harness this potential potency advantage, we have elected to construct

conjugates with a lower ratio of protein carrier to polysaccharide than Prevnar 13. We have observed in animal models that despite having approximately half as much protein on average in each monovalent conjugate, SVX-24 had comparable immunogenicity relative to Prevnar 13 on a strain-by-strain basis. As a result, we believe we can incorporate more monovalent conjugates to create an even more broad-spectrum vaccine with less protein carrier per conjugate in order to minimize carrier suppression.

### ***Better Chemistry***

We also employ a rapid and less harsh chemistry method called copper-free click chemistry to site-specifically conjugate the polysaccharides to eCRM. We believe this distinctive technique is a better controlled, more efficient and faster method of conjugation relative to conventional chemistry used to make traditional PCVs. The click chemistry conjugation reaction is designed to cause less damage to the critical immunogenic epitopes on the protein carrier or the target antigen.

### ***Our PCV Franchise***

We are developing broad-spectrum investigational PCVs designed to minimize carrier suppression.

#### *SVX-24*

Our lead vaccine candidate, SVX-24, is designed to improve upon the standard of care by covering the additional strains that are responsible for the majority of residual pneumococcal disease currently in circulation. We achieved preclinical proof of concept for SVX-24 in 2017 by demonstrating that SVX-24 has the potential to protect against the pneumococcal strains collectively covered by Prevnar 13 and Pneumovax 23 and showed the durable, boostable immune response of a conjugate vaccine. The incremental 11 strains covered by SVX-24 and not covered by Prevnar 13 are responsible for the majority of circulating invasive pneumococcal disease in both the United States and European Union and are associated with high case-fatality rates, antibiotic resistance and/or meningitis.

SVX-24 includes 24 purified capsular polysaccharides of *Streptococcus pneumoniae* (1, 2, 3, 4, 5, 6A, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F and 33F), each of which is conjugated to eCRM to produce 24 monovalent conjugates. These conjugates are mixed into a final vaccine formulation and then adsorbed to alum.

As shown in Figure 9 below, there are critical differences between SVX-24 and other currently available PCVs relating to the protein carrier, particularly the use of site-specific conjugation and the milder reaction conditions. We achieve site-specific conjugation through the insertion of multiple nnAAAs, which is not possible with the conventional chemistry used for making other PCVs. The click chemistry we use for site-specific conjugation may also minimize damage to the critical immunogenic epitopes on the protein carrier and the polysaccharides through milder and shorter reactions, while other PCVs use conventional chemistries that involve harsher and longer reaction conditions.

Figure 9.

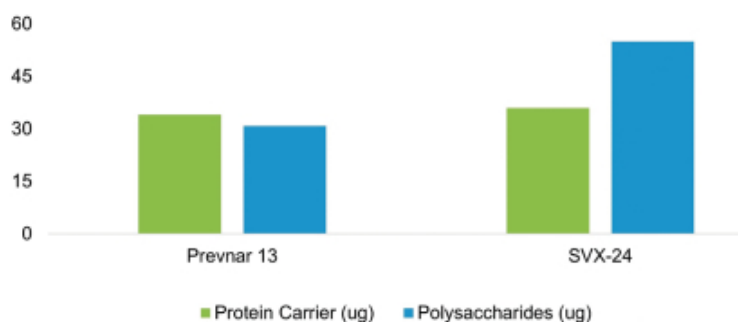
	Polysaccharide		Protein Carrier			Assays	
	CDAP / Periodate Activation	Amination for labeling PS	Incorporation of non-natural AAs	Random Lysine Conjugation	Site-Specific Click Chemistry Conjugation	CQA Release Assays (Mol Wt, Free PS)	Serological Assays (IgG & OPA)
Conventional Methods	✓	✓		✓		✓	✓
SutroVax	✓	✓	✓		✓	✓	✓

<ul style="list-style-type: none"> <li>• Can inactivate T-cell epitopes</li> </ul>	<ul style="list-style-type: none"> <li>• Inactivates T-cell epitopes</li> <li>• Harsh and long reaction conditions</li> </ul>	<ul style="list-style-type: none"> <li>• Preserves T-cell epitopes</li> <li>• Mild and short reaction conditions</li> </ul>
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Furthermore, as shown in Figure 10 below, SVX-24, as tested in preclinical studies, showed nearly double the serotype spectrum of coverage of Prevnar 13, yet contains a similar amount of protein carrier. We believe the resulting decreased carrier burden per conjugate of SVX-24 is critical for avoiding carrier suppression and producing broader-spectrum pneumococcal vaccines without sacrificing immunogenicity.

Figure 10.



Where appropriate, we capitalize on the efficiencies of well-established clinical, manufacturing and regulatory precedents by leveraging conventional methods for the development of SVX-24.

For example, our polysaccharide antigens are primarily made using conventional fermentation and purification techniques and activated through conventional methods. They are also labeled through conventional amination methods prior to being conjugated to eCRM. In addition, we use the same Critical Quality Attribute assays for molecular weight and free polysaccharide that have served as the physicochemical measures of conjugates and also serve as predictors of their immunogenicity in vivo. We also use conventional IgG and OPA serological assays to gauge the immunogenicity of our conjugates, which have served as surrogate immunological endpoints in clinical studies that enabled the approval of Prevnar 13 and other conjugate vaccines.



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We have also leveraged the same animal models that were utilized in the development of approved PCVs. In particular, our preclinical studies utilized a recognized rabbit model that Pfizer used in its development of Prevnar and Prevnar 13, and that GlaxoSmithKline used in its development of Synflorix. To date, the rabbit model has shown consistent immunological responsiveness across all strains for which we have tested our conjugates and has differentiated conjugated versus unconjugated polysaccharide responses (i.e., T-cell dependent versus T-cell independent responses). We believe the demonstration of conjugate-like immune responses in rabbits that resulted in killing of bacteria via opsonophagocytosis (OPA) and induction of IgG antibody responses are key development milestones and are critical readouts for the development of PCVs. The rabbit model has also provided evidence regarding SVX-24's potential to generate a booster response.

We expect to pursue a well-characterized clinical development path for SVX-24, consistent with other PCV developers. We anticipate that we will be able to conduct smaller and shorter clinical trials that target validated surrogate immune endpoints (e.g., OPA and IgG responses) previously recognized by regulatory authorities. Pfizer previously applied this approach to the development of Prevnar 13 and is currently implementing the same approach to development of its 20-valent PCV vaccine candidate. Merck is also following this path for development of its 15-valent PCV vaccine candidate.

We conducted a pre-IND meeting with the FDA in December 2019 to obtain feedback on our SVX-24 chemistry, manufacturing and controls plan, or CMC plan, as well as our non-clinical and clinical design plans to support our IND application. Based on FDA comments and feedback, our proposed timelines, including IND filing and clinical plans, remain materially unchanged. We expect to submit an IND application for SVX-24 to the FDA in the second half of 2021.

### *Preclinical Data*

As a prerequisite for regulatory approval, we believe that any investigational PCV will have to be compared to the current standard of care, which is currently Prevnar 13 in infants, and the combination of Prevnar 13 and Pneumovax 23 in adults. In the case of SVX-24, we believe a successful comparison would be based on demonstrating the clinical non-inferiority of the immune response to the thirteen common serotypes in Prevnar 13, and the incremental eleven common strains in Pneumovax 23. To obtain pre-clinical proof of concept on our way to the clinic, we have assessed the comparative immune responses of SVX-24 using the same rabbit model utilized by other PCV developers. We have dosed rabbits in our pre-clinical studies with 0.11µg, as measured by the amount of polysaccharide in each conjugate, for each of the 24 conjugates in SVX-24, as well as 0.11µg for the thirteen conjugates in Prevnar 13 (except serotype 6B at 0.22µg) and compared both PCVs immunogenically to each other and to Pneumovax 23, where each of the 23 polysaccharides were dosed at 1.1µg. The doses are representative of body weight differences in humans versus rabbits and roughly correspond to the dose differential between PCVs and polysaccharide-only vaccines. In humans, Prevnar 13 is dosed at 2.2µg per conjugate (except serotype 6B at 4.4µg) or approximately one-tenth the dose of Pneumovax, where each polysaccharide is dosed at 25µg. The species of rabbits used were approximately five percent of the average weight of humans in North America, thus 0.11µg approximates to the 2.2µg dose for PCVs and the 1.1µg dose approximates to the 25µg dose for Pneumovax 23.

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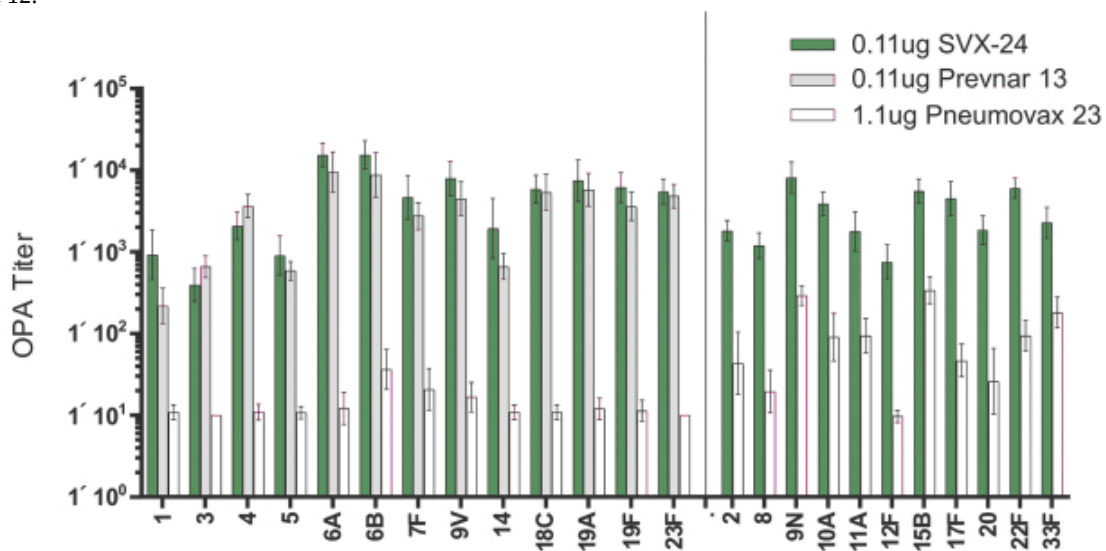
We have completed multiple pre-clinical proof of concept studies of SVX-24 compared to Prevnar 13 and Pneumovax 23 in rabbits. The endpoints of the studies were to measure, on a serotype-specific basis, IgG antibody responses, the surrogate endpoint for pediatrics, and OPA responses, the surrogate endpoint for adults. Initial proof of concept was obtained with research-grade raw materials and conjugates made at SutroVax prior to initiating technology transfer to Lonza and production scale-up. In mid-2019, conjugates were made at SutroVax at small-scale using optimized processes and procedures using Lonza-produced raw materials, including our proprietary eCRM carrier and all 24 polysaccharides that had already been tech transferred and scaled up. All 24 of the conjugates in SVX-24 met the critical quality attributes and the combination vaccine was administered in the rabbit model per Figures 11, 12, and 13. The chart in Figure 11 reflects the strains covered by each of SVX-24, Prevnar 13, and Pneumovax 23 in these experiments.

Figure 11.



As reflected in Figure 12 below, SVX-24 showed superior OPA responses at 1/10th the dose of Pneumovax 23 and comparable OPA responses to an equivalent dose of Prevnar 13 on a serotype-by-serotype basis:

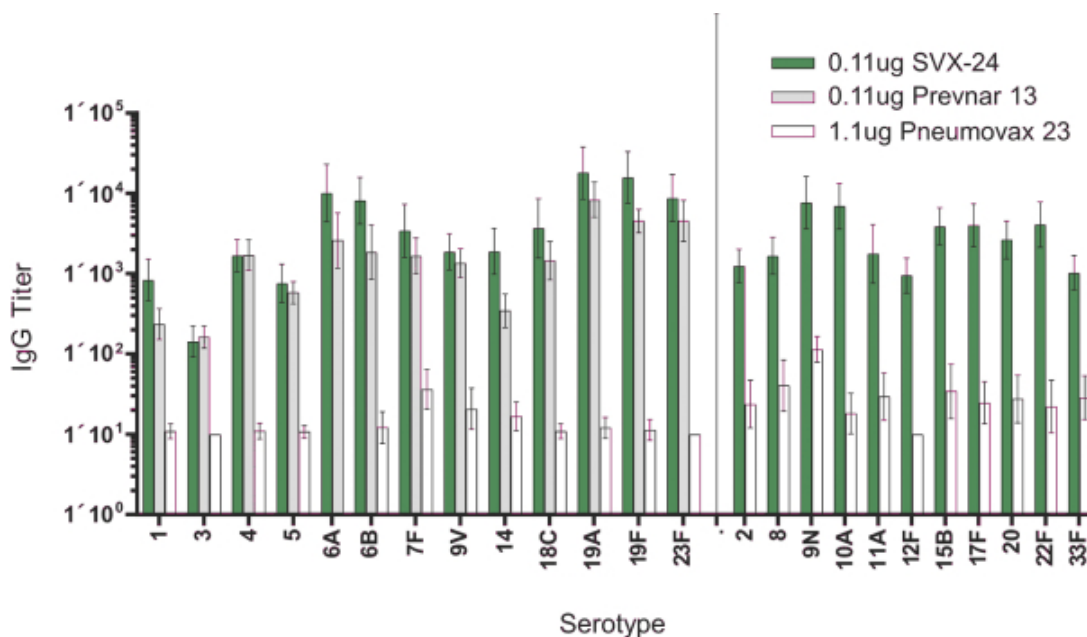
Figure 12.



+/-95% confidence interval

Similarly, as reflected in Figure 13 below, SVX-24 showed superior IgG antibody responses at 1/10th the dose of Pneumovax 23 and comparable IgG responses to an equivalent dose of Prevnar 13 on a serotype-by-serotype basis:

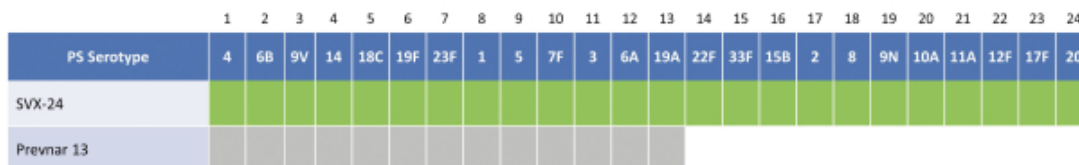
Figure 13.



+/-95% confidence interval

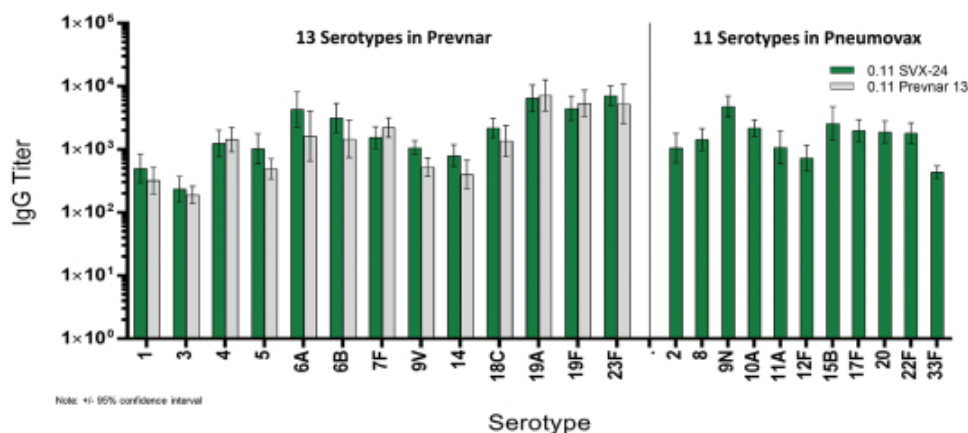
A critical milestone in product development is the scale-up of manufacturing to provide sufficient material for clinical evaluation and potential commercial launch. After having completed the technology transfer of the optimized processes and procedures for the production of each of the 24 conjugates in SVX-24, the conjugates were produced at Lonza at an over fifteen-fold scale increase to the prior scale at SutroVax, which is the equivalent of approximately 375,000 human dose equivalents. Each of the conjugates in SVX-24 made at Lonza met the critical quality attributes and the combination vaccine was administered in the rabbit model. The chart in Figure 14 reflects the strains covered by each of SVX-24 and Prevnar 13 in this experiment.

Figure 14.



The data shown below in Figure 15 confirms that the eCRM and polysaccharide raw materials and the conjugation processes for each of the conjugates in SVX-24 all were transferred to and scaled at Lonza, and the immunogenicity remained comparable to Prevnar 13 and was consistent with prior lots of SVX-24. The OPA responses from this study are forthcoming.

Figure 15.



+/-95% confidence interval

*SVX-24 Clinical Development Plan*

To accelerate our time to market, we intend to first pursue clinical proof of concept in the United States for adults and then pursue clinical development in the pediatric population. We believe the most expedient path to clinical proof of concept will be in the adult population where the standard of care involves the administration of a single dose and where an initial clinical trial could begin in the target population. We expect to initiate our pediatric development program in toddlers upon receipt of the Phase 1 safety data in adults. After completing such a toddler study, we would expect to commence clinical development in the infant population.

*Adult Indication*

We expect our first-in-human trial to be a randomized, double-blind, controlled Phase 1/2a trial designed to evaluate the safety, tolerability and immunogenicity of SVX-24 in healthy adults over the age of 50. After the completion of a standard, single-injection safety cohort in normal healthy adults aged 18 to 49 years, we intend to compare a single injection of SVX-24 at three different dose levels to the control regimen of Prevnar 13, followed by Pneumovax 23, administered four weeks apart. The trial is expected to be conducted in two identically designed stages in healthy adults over the age of 50. Our Phase 1/2a trial is designed to evaluate SVX-24 dose levels for safety as well as for an immunogenicity comparison to each of the pneumococcal serotypes contained in Prevnar 13 and the 11 additional serotypes included in Pneumovax 23. To date, our preclinical immunogenicity data suggest that lower doses of SVX-24 as compared to Prevnar 13 may be used without affecting immunogenicity. We intend to initiate this study in the second half of 2021, and expect to present safety and immunogenicity results in 2022.

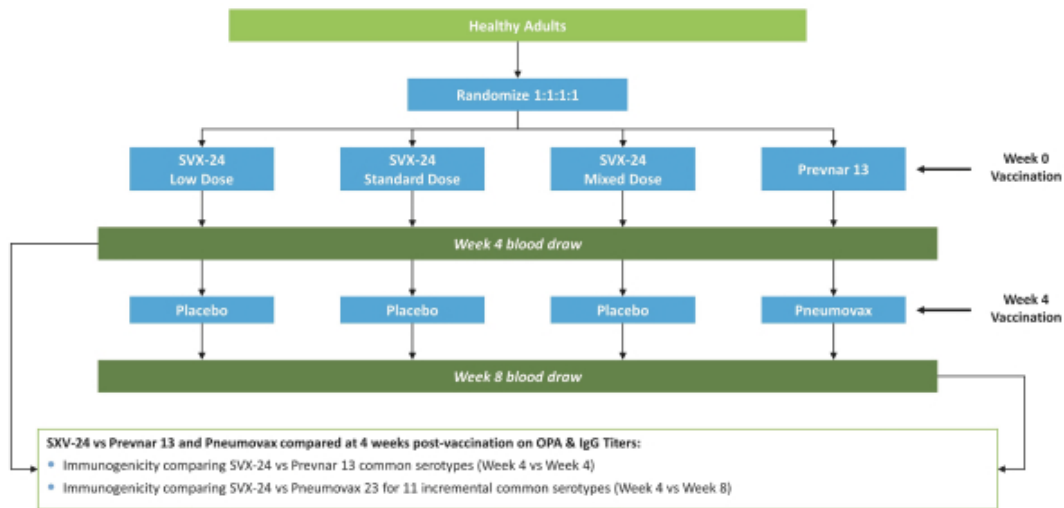
We expect to use OPA titers as the primary immunogenicity endpoint for the SVX-24 program in adults. OPA is believed to be the primary protective mechanism against pneumococcal disease. In addition, we expect to measure IgG responses as a secondary endpoint, as such responses may serve as supportive evidence of immunogenicity for comparison. We also expect to use OPA titers and IgG concentrations as endpoints in our other planned adult studies of SVX-24. We currently believe that these endpoints, if met, will be sufficient to obtain

regulatory approval of SVX-24 and do not anticipate the need for a clinical efficacy trial. However, we have not yet obtained feedback from the FDA regarding our pivotal Phase 3 clinical development plans or the acceptability of our approach.

The FDA has previously approved pneumococcal vaccines upon the establishment of non-inferiority based on a head-to-head comparison using established surrogate immune endpoints in the target population. For adults, Prevnar 13 was approved based on the establishment of non-inferiority of OPA responses relative to Pneumovax 23, on a strain-by-strain basis, where non-inferiority was defined as greater than or equal to 0.50 of the lower limit of the two-sided 95% confidence interval of the OPA geometric mean titer ratio. We have designed our Phase 1/2a study to have greater than or equal to 80% power based on the strain with the highest variability in order to show a two-fold difference between treatment groups.

Figure 16 is a schematic of the overall study design of our planned Phase 1/2a study:

Figure 16.



PCVs, as well as all other polysaccharide-conjugate vaccines, have historically had an excellent safety profile, especially in comparison to other vaccines such as rotavirus and diphtheria-tetanus-pertussis or DTP.

Based on Pfizer’s experience with Prevnar 13, we believe that SVX-24, if approved, will have the potential to serve as a “catch-up” or booster for those who have previously received Pneumovax 23 or a lower-valent PCV. We believe a study exploring serial vaccination with Prevnar 13 and/or Pneumovax 23 followed by SVX-24 at different intervals could generate valuable data supporting a recommendation for SVX-24 vaccination in previously vaccinated adults.

*Pediatric Indication*

We are also developing SVX-24 as a pediatric vaccine. If successful, we expect the data from the adult Phase 1 trial will inform the SVX-24 dose(s) to be evaluated and provide the safety data required to initiate a clinical study in pediatric populations. We plan to initially evaluate SVX-24 in an age de-escalation study. The initial Phase 2 trial would examine the safety, tolerability and immunogenicity of SVX-24 in two age groups of healthy children, those aged 2 to 5 years and those aged 12 to 15 months. A single dose, at the highest dose level planned for infants, would be administered initially to the 2 to 5-year age group. If SVX-24 is well-tolerated, the same SVX-24 dose would be administered to the 12 to 15-month age group as a replacement for the Prevnar 13

booster. For trials in the United States, toddlers would be expected to have been primed with a 3-dose primary infant series of Prevnar 13. Immune response data would reveal whether the boost achieved with SVX-24 is comparable to Prevnar 13 for the common serotypes, with the remaining 11 serotypes to be assessed for a single-dose primary immune response in the toddler age group.

If our initial Phase 2 trial in the pediatric population is completed successfully, we would expect to initiate a subsequent Phase 2 study to evaluate the safety and immunogenicity of SVX-24 administered as a three-dose primary series to infants at 2, 4 and 6 months of age. We would also expect to give these infants a booster dose at 12 to 15 months for a complete four-dose series. The decision to incorporate dose-finding as part of this trial would be made based on data from ongoing or completed adult trials and the preliminary immunogenicity data generated in children.

We plan to collect both IgG and OPA data to evaluate whether the immune responses observed in infants following vaccination with SVX-24 are similar to those seen with other PCVs. If dose-finding is performed in infants, the data would inform on the dose levels for each of the conjugates in the final SVX-24 infant formulation. Consistent with the approval process for Prevnar 13 in infants, we do not anticipate that a clinical field efficacy trial will be required for SVX-24 in the pediatric population. We expect the clinical development of SVX-24 to follow the same approach utilized for Prevnar 13, where vaccine effectiveness against IPD was inferred from immunologic surrogates. Similar to the adult population, SVX-24 approval in the pediatric population is expected to be based on a non-inferiority comparison of IgG antibody responses to Prevnar 13. However, we have not yet obtained feedback from the FDA regarding our clinical development plans or the acceptability of our approach.

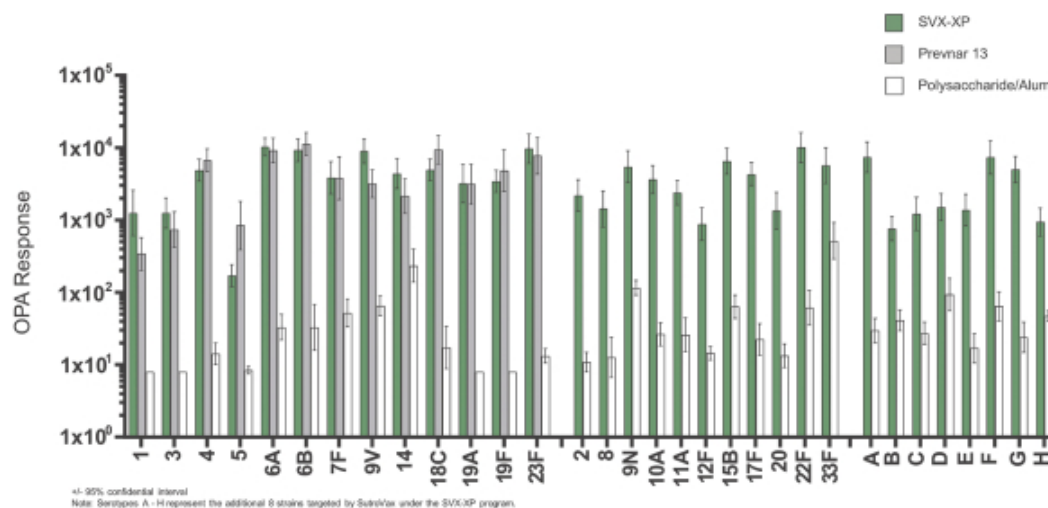
If our Phase 2 trials are completed successfully, we expect to conduct pivotal Phase 3 trials in the pediatric population that focus on evaluating non-inferiority to Prevnar 13 for immunogenicity and seroconversion or antibody concentration threshold; assessing U.S. routine vaccination responses following concomitant administration with SVX-24; and generating a sufficient safety database in infants. The Phase 3 non-inferiority results would then be used to seek approval of SVX-24 in the pediatric population. This approach is similar to the approach utilized to develop Prevnar 13, where the immunogenicity of Prevnar 13 was compared to the original 7-valent Prevnar product (standard of care at the time).

#### *SVX-XP*

SVX-XP is a franchise extension of SVX-24 that, if approved, would expand strain coverage to at least 30 strains and demonstrate the scalable and modular nature of conjugate vaccines we can develop. SVX-XP is designed to protect against emerging strains causing significant IPD and antibiotic resistance. The serotypes in SVX-XP cover nearly 93% of the circulating pneumococcal disease in the United States, although we are not disclosing the specific incremental strains at this time.

We have completed preclinical proof of concept studies for SVX-XP in rabbit models compared to Prevnar 13, as well as more than 30 polysaccharides adjuvanted with alum. OPA responses in rabbits were superior to polysaccharide alone plus alum and comparable with Prevnar 13 in the common 13 strains as illustrated in the figure below. The relatively higher OPA response observed in this study across the common 24 conjugates between SVX-XP and SVX-24 was driven by advancements in our manufacturing processes, which we plan to carry forward to our Phase 1/2a clinical trial for SVX-24.

Figure 17.



+/-95% confidence interval

**Platform Application Two: Novel Conjugate Vaccine Opportunities**

We are also developing novel conjugate vaccine candidates for other diseases for which there are no existing vaccines. By leveraging our platform, we have been able to generate novel protein carriers with site-specific incorporation of nnAAs designed to provide optimal exposure of both B-cell and T-cell epitopes on the carrier. Using these novel protein carriers, we can produce highly stable conjugate vaccine candidates through site-specific conjugation of antigens, including polysaccharides. Functionally, one significant advantage of using carriers may be the additional protective immunity that the protein itself can provide beyond the conjugated antigen itself.

*Group A Strep Disease Background and Market Opportunity*

*Streptococcus pyogenes* (*S. pyogenes* or Group A Strep), is a well-known pathogen causing 700 million cases, the majority of which are pharyngitis, commonly known as strep throat, worldwide each year. Pharyngitis is highly prevalent in school-age children and a significant source of antibiotic prescriptions and is contributing to the growing problem of antibiotic resistance globally. Group A Strep also increases the risk of severe invasive infections, such as sepsis, necrotizing fasciitis and toxic shock syndrome, and is responsible for post-infectious, immune-mediated rheumatic heart disease, or RHD, a leading cause of mortality in emerging countries. Some 30 million people are currently affected by RHD, with over 300,000 deaths in 2015 and 10.5 million disability-adjusted life years lost. The high prevalence of Group A Strep also contributes to a high economic burden due to missed days of school and work.

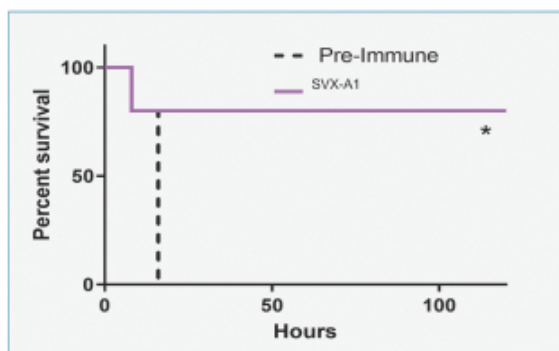
It has been established that the repeated natural infection of children with Group A Strep results in immune responses that are protective against subsequent Group A Strep infection. We believe this observation justifies the development of a rationally designed vaccine for Group A Strep that is focused on conserved antigens expressed by all strains of the bacteria.

*SVX-A1*

We have developed a conjugate vaccine candidate designed to confer broad protection against subtypes of Group A Strep by virtue of polyrhamnose, a conserved polysaccharide, conjugated to Group A Strep specific immunogenic protein carrier using our site-specific conjugation technology. The resulting conjugate is designed to

ensure optimal exposure of both the B-cell and T-cell epitopes on the protein carrier to confer robust, boostable and durable protective immune responses. We believe this single conjugate could potentially cover all Group A Strep strains. The vaccine is a combination of this novel conjugate with three virulence factors. For the initial proof of concept, we vaccinated rabbits with these three vaccine components and collected immune sera. The sera were adoptively transferred to mice, which were then challenged intraperitoneally with  $1 \times 10^7$  CFU of M1 Group A Strep. Shown in Figure 18 is the survival curve of this cohort of mice compared with pre-immune sera from the vaccinated rabbits.

Figure 18.



Our SVX-A1 vaccine development program is 50% funded by a grant obtained from CARB-X, a global non-profit partnership dedicated to accelerating antibacterial innovation to tackle the rising global threat of drug-resistant bacteria. The award commits initial funding of up to \$1.6 million and up to \$15.1 million in total funding available upon achievement of development milestones through Phase 1 human clinical trials.

### **Platform Application Three: Protein Vaccine Opportunities**

We believe we can also develop novel protein vaccine candidates constructed using “tough-to-make” protein antigens uniquely able to be expressed using the platform. In particular, the lack of a cellular membrane in our platform allows for the exogenous addition of components to manipulate transcription, translation and folding by modification of reaction conditions. Furthermore, removal of the typical restriction to maintain cell viability also creates unique avenues for optimizing and promoting protein production for antigens that might be cytotoxic to a cell-based system or require non-physiological conditions for optimal protein folding. Thus, utilizing these advantages, we believe we can express and purify important protein targets to generate unique candidates that are beyond the scope of traditional production systems. Our therapeutic periodontitis vaccine candidate is the first example of a “tough-to-make” protein-based vaccine.

#### *Periodontitis Disease Background and Market Opportunity*

Periodontal disease is a highly complex, chronic oral inflammatory disease that leads to the destruction of the soft and hard tissues supporting the teeth. The subgingival niche (below the gum margin of teeth) is populated by a diverse polymicrobial plaque. It is increasingly understood that the shift from periodontal health to disease is associated with changes in the microbial composition of the subgingival plaque, including activities of bacteria such as *Porphyromonas gingivalis* (*P. gingivalis*). The development of precise approaches to control this keystone pathogen, such as a vaccine, could then positively impact the periodontal disease burden.

Those with periodontitis also have an increased risk for heart attack, stroke and other serious cardiovascular events. In addition to gum and tooth disease, periodontal inflammation and infection with *P. gingivalis* have been linked to atherosclerotic heart disease mediated by *P. gingivalis* residing in atherosclerotic plaque. While we are focused on the treatment of periodontal disease with this vaccine candidate, if *P. gingivalis* is found to be causative in other chronic disorders, our vaccine candidate could be a highly



effective treatment and allow disease intervention at a much earlier stage of the disease. For example, recent research has suggested the potential for a link between *P. gingivalis* and Alzheimer’s disease.

Neither the natural host immune response nor currently available treatments are curative for periodontal disease. Existing treatment includes highly aggressive and invasive procedures, including scaling and root planing and surgical intervention, coupled with antibiotic use. Despite these types of aggressive treatments, diseased sites frequently progress, leading to tooth loss. Thus, the development of an effective vaccine for periodontitis would be highly desirable.

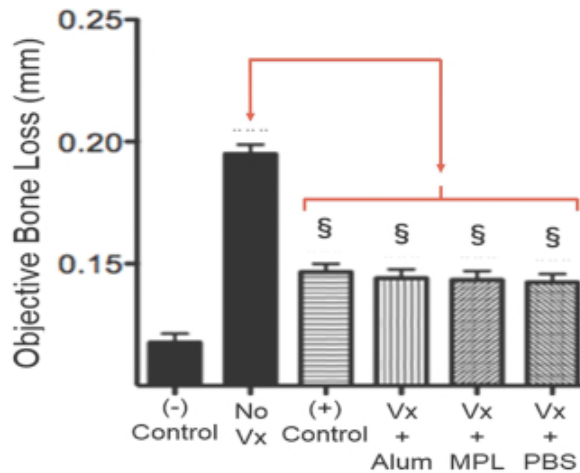
In the United States alone, an estimated 65 million adults suffer from periodontal disease. Globally, severe periodontal disease afflicts 10% to 15% of the adult population, resulting in productivity losses estimated at nearly \$54 billion in 2010.

### SVX-PG

We are developing a novel protein vaccine candidate targeting *P. gingivalis* that incorporates protein antigens that we believe are uniquely enabled with our technology. Our initial goal is to develop a therapeutic vaccine to slow or stop disease progression; however, the results from clinical trials may inform the potential adoption of prophylactic immunization.

SVX-PG, which includes cell-free produced *P. gingivalis* virulence factors, including gingipains, were tested in a preclinical model that mimics periodontal disease. The vaccine elicited protein-specific IgG response following immunization and protected mice from *P. gingivalis*-elicited oral bone loss. Shown in Figure 19 is the objective bone loss of SVX-PG with alum, Monophospholipid A, or no adjuvant. Immunization with all formulations of SVX-PG provided significant protection against oral bone loss compared to the no vaccine oral challenged control group ( $p < 0.01$ , ANOVA with Dunns multiple comparisons).

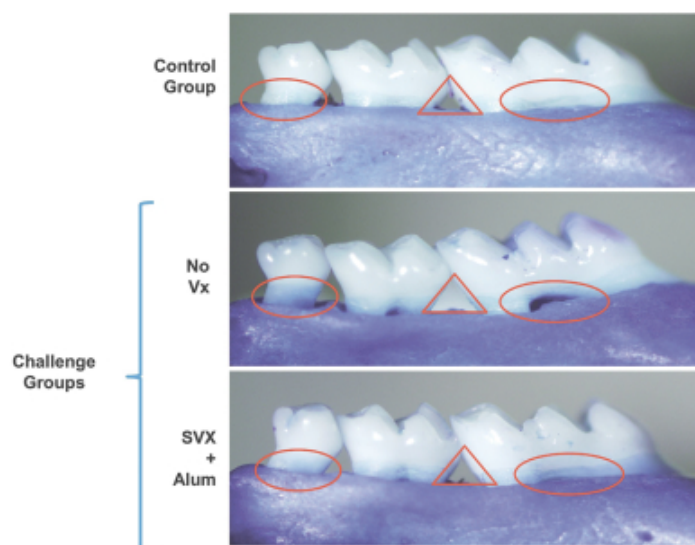
Figure 19



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Shown below in Figure 20 are pictures of representative mouse jaws from the experiment. As can be seen, the vaccinated mice had considerably less bone loss than the unvaccinated and challenged control animals.

Figure 20



Upon completion of the preclinical development program and IND-enabling activities for SVX-PG, we intend to conduct a multi-center, randomized, placebo-controlled Phase 1/2a study in adults with mild to moderate chronic periodontal disease. The primary objectives of the initial clinical trial will be to evaluate safety and tolerability. Secondary exploratory endpoints will be to measure IgG immune response to the vaccine antigens and to evaluate the ability of the antibodies produced in response to vaccination to inhibit the formation of the poly-microbial biofilm, which is characteristic of periodontal disease.

## **Manufacturing and Supply**

We have designed and developed a proprietary, scalable and portable manufacturing process for SVX-24 that we believe can scale to address clinical and commercial vaccine supply needed to serve both adult and pediatric populations. We have completed process development and technology transfer to Lonza for the critical components of the SVX-24 conjugates. We currently do not own or operate any manufacturing facilities, but our strategic partnership with Lonza provides us with access to substantial resources to facilitate an independent supply path to the market. Lonza is a leading global contract manufacturer with deep domain expertise and experience in large and small-scale production of clinical, as well as commercial-stage products. We have entered into agreements with Lonza to secure capacity, technical expertise and resources to support the production of SVX-24 clinical material and processes that are intended to scale to commercial scale at Lonza or other commercial manufacturing sites. In addition, we have entered into an agreement with Sutro Biopharma to supply us with extract and custom reagents for use in manufacturing preclinical and certain clinical supply of vaccine compositions, and in December 2019, we exercised our right to require Sutro Biopharma to establish a second supplier for extract and custom reagents to support our anticipated clinical and commercial needs. We have established alignment to ensure establishment of the manufacturing process and the delivery of the clinical material to support the IND application for SVX-24. The conjugates in SVX-24 are designed to serve as the foundation for our next generation SVX-XP program.

## **Process**

The manufacturing process for our SVX-24 vaccine candidate consists of four key components: a) our proprietary eCRM protein carrier; b) the 24 pneumococcal polysaccharides; c) the 24 conjugate drug substances and d) the mixture of these 24 drug substances into the final drug product.

### *eCRM*

Our proprietary eCRM protein carrier is produced using our cell-free protein synthesis platform. eCRM contains multiple copies of non-native *para* azido-methyl-phenylalanine, or pAMF, amino acid, exclusively licensed from Sutro Biopharma. The pAMF amino acids have a specific structure that enables eCRM to participate in the site-specific click chemistry conjugation reaction with activated pneumococcal polysaccharides.

The cell-free reaction is performed in a manner analogous to traditional fermentation but without the cells. The first step in the production of eCRM is the manufacture of critical raw materials, namely *E. coli* extracts and lysates that contain the cellular machinery required for in vitro DNA transcription and translation. The eCRM protein is then manufactured by combining these *E. coli* extracts and lysates with classic media components such as amino acids, minerals and salts, with the in vitro reaction driven by the addition of plasmid DNA coding for the eCRM protein's amino acid sequence. This cell-free reaction takes place in a standard fermenter, followed by standard protein purification chromatographic and filtration processes. The manufacturing process has consistently yielded a product of the desired quality.

### *Pneumococcal Polysaccharides*

Each of the 24 pneumococcal polysaccharides are individually isolated from *Streptococcus pneumoniae* bacterial strains. Each individual *S. pneumoniae* strain is cultured in a bioreactor using a single standardized fed-batch bioreactor process and a single standardized downstream purification process. Overall, this standardized upstream and downstream process is simple and robust, thereby reducing manufacturing cost of goods and providing an efficient path of progression for the program from process characterization and validation through to commercialization, if our vaccine candidates are approved.

### *Conjugate Drug Substances*

Each of the 24 conjugate drug substances is manufactured individually, as monovalent conjugates, by conjugating each of the 24 pneumococcal polysaccharide strains, one at a time, to the eCRM carrier protein. Click chemistry provides for a conjugation reaction that is quick, consistent and high-yielding, and which we optimized to be standardized across the various polysaccharides. Through statistical design of experiment, or DoE, studies, we have gained a significant understanding of which variables to adjust to maximize product quality and, accordingly, immunogenicity in rabbit models.

### *SVX-24 PCV Drug Product*

All 24 conjugate drug substances are mixed, formulated with appropriate excipients and adjuvanted with alum. Clinical doses are filled in vials and stored refrigerated.

### *Achievements to Date*

To date, we have achieved several IND-enabling chemistry, manufacturing and controls, or CMC, deliverables with additional work ongoing. For eCRM protein carrier, we have transferred process technology to Lonza, completed development batches and have scaled production. For polysaccharide antigens, we have established research and master cell banks for all 24 pneumococcal serotypes, completed development batches and initiated GMP production. For drug substance conjugates, we have conducted an extensive DoE study to define and

optimize conjugation process parameters for all 24 serotypes and transferred this process technology to Lonza. Further, Lonza implemented the transfer processes, successfully producing all 24 conjugates at an over fifteen-fold scale increase than previously produced. These conjugates were shown to meet certain analytical targets and showed conjugate-like immunological responses comparable to the previous conjugates made at smaller batches.

### ***Lonza Agreements***

In October 2016, we entered into a development and manufacturing services agreement with Lonza, which we refer to, as amended, as the 2016 Lonza Agreement, pursuant to which Lonza is obligated to perform manufacturing process development and clinical manufacture and supply of components for SVX-24, including the manufacture of polysaccharide antigens, our proprietary eCRM protein carrier and conjugated drug substances.

In October 2018, we entered into a second development and manufacturing services agreement with Lonza, which we refer to as the 2018 Lonza Agreement, and together with the 2016 Lonza Agreement, as the Lonza Agreements, pursuant to which Lonza is obligated to perform manufacturing process development and clinical manufacture and supply of SVX-24 finished drug product.

Under the Lonza Agreements, we will pay Lonza for its manufacturing services and reimburse Lonza for its out-of-pocket costs associated with purchasing raw materials, plus a customary handling fee.

In June 2018, we entered into a letter agreement, or the Lonza Letter Agreement, with Lonza, pursuant to which we agreed to certain terms for potential issuances of our common stock as partial satisfaction of future obligations to Lonza under the Lonza Agreements. Specifically, we and Lonza agreed that the initial pre-IND cash payments made by us to Lonza would be subject to a specified dollar cap, which we refer to as the Initial Cash Cap. After the Initial Cash Cap has been reached, then at our election, we can make any further pre-IND payments owed to Lonza under the Lonza Agreements in cash, equity at then market prevailing prices or a combination of both. Lonza may elect to receive up to 25% of pre-IND payments in equity, up to a maximum of \$2.5 million, and no more than \$10 million of pre-IND payments may be satisfied by issuances of our common stock. We also granted Lonza a right of first negotiation for manufacturing services for the commercial supply of SVX-24.

Under each Lonza Agreement, we will own all right, title and interest in and to any and all Intellectual Property (as defined in each Lonza Agreement) that Lonza and/or its affiliates, the External Laboratories (as defined in each Lonza Agreement) or other contractors or agents of Lonza develops, conceives, invents, first reduces to practice or makes, solely or jointly with us or others, in the performance of the Services (as defined in each Lonza Agreement), to the extent such Intellectual Property (the New Customer Intellectual Property) is a direct derivative of or improvement to collectively the Product, Customer Materials, Customer Information and/or Customer Background Intellectual Property (all as defined in each Lonza Agreement). Lonza shall own all right, title and interest in Intellectual Property that Lonza and/or its Affiliates, the External Laboratories or other contractors or agents of Lonza, solely or jointly with Customer, develops, conceives, invents or first reduces to practice or makes in the course of performance of the Services to the extent such Intellectual Property (New General Application Intellectual Property) (i) is generally applicable to the development or manufacture of chemical or biological products or product components, and could reasonably have been made without the use of the Customer Materials, Customer Information or Customer Background Intellectual Property and (ii) is an improvement of, or direct derivative of, any Lonza Background Intellectual Property. Additionally, under each Lonza Agreement, Lonza grants us a non-exclusive, world-wide, fully paid-up, irrevocable, transferable license under all New General Application Intellectual Property, with the right to grant sublicenses, to research, develop, make, have made, use, sell and import SVX-24. We also grant Lonza a non-exclusive right to use New Customer Intellectual Property during the term of the agreement solely for the purposes of fulfilling its obligations to us.

We have the right, at our cost, to receive a technology transfer under each Lonza Agreement or have an approved third-party manufacturer receive a technology transfer of any manufacturing process developed by

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Lonza. For any technology transfer that includes transfer of Lonza's Background Intellectual Property or Lonza Confidential Information (each as defined in the applicable Lonza agreement), we will be obligated to pay Lonza reasonable royalties and/or licensing fees.

Unless earlier terminated, each Lonza Agreement will remain in place for a period of five years. Either party has the right to terminate each Lonza Agreement upon a six-month notice period, provided that Lonza may not exercise such right until a specified future date. Either party has the right to terminate each Lonza Agreement if the other party commits a material breach under the applicable agreement and does not cure such breach within a given time period, for specified bankruptcy events or if a party receives a notice from the other party or otherwise becomes aware that a debarment, suspension, exclusion, sanction or declaration of ineligibility action has been brought against the other party, and we may terminate each Lonza Agreement for an extended force majeure event.

### **Competition**

The global vaccine market is highly concentrated among a small number of multinational pharmaceutical companies. Pfizer, Merck, GlaxoSmithKline and Sanofi together control approximately 75% of the global vaccine market. Other pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions are also working towards new solutions given the continuing unmet need globally.

Within the current PCV market, Pfizer, Merck and GlaxoSmithKline dominate, with Pfizer's Prevnar 13, Merck's Pneumovax 23 and GlaxoSmithKline's Synflorix controlling approximately 72%, 11% and 7%, respectively, of the 2018 global PCV sales. While Prevnar 13 covers fewer pneumococcal strains than Pneumovax 23, it delivers a stronger and more durable immune response than Pneumovax 23. Prevnar 13 is the current standard of care in children and the first vaccine offered under the current standard of care in adults. If approved, we believe SVX-24 may obtain an ACIP preferred recommendation and potentially replace both incumbents for pneumococcal disease prevention in both adult and pediatric populations because of its broader coverage.

Existing vaccine makers, as well as new entrants, are competing to develop the next generation of PCV vaccines. We are aware that both Pfizer and Merck have PCV candidates under development that could surpass the performance of Prevnar 13. Pfizer's PF-06482077 is a 20-valent vaccine while Merck's V114 is a 15-valent vaccine and each is under development. Astellas and Affinivax, as well as Sanofi and SK Chemicals, have also partnered to develop PCVs. We believe success will ultimately be based on the combination of immunogenicity and the broadest coverage of serotypes, leading to an ACIP recommendation. Safety, convenience and pricing may also be factors. Both Pfizer and Merck have already initiated Phase 3 trials and may obtain FDA approval and commercially launch before SVX-24. However, if approved, we believe SVX-24 should compare favorably to these PCV candidates as a 24-valent alternative. Based on our unique site-specific conjugation and carrier-sparing technology, we also believe SVX-XP has the potential to compete favorably in the PCV market.

The competitive landscape for vaccine development for Group A Strep was dormant for more than three decades. However, the FDA lifted a 30-year ban on Group A Strep vaccine clinical trials in 2005, and research has slowly started to resurface in academic institutions. However, we are not aware of other Group A Strep vaccines in clinical development that would cover all strains of the bacteria. Additionally, we are not aware of any other vaccines under clinical development to treat periodontitis. We believe the success of our vaccine candidates in these areas will be based on efficacy, safety, convenience and pricing. We are aware of some companies developing treatments for other diseases that target the same underlying pathogens that cause Group A Strep and periodontitis. For example, Cortexyme is developing an Alzheimer's treatment that targets *P. gingivalis*.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize vaccines that are safer, more effective, more convenient, less expensive or with a more favorable

label than SVX-24, SVX-XP or any other vaccine we may develop. Many of the companies against which we compete have significantly greater financial resources, and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do.

## **Intellectual Property**

We have developed, and are continuing to develop, a comprehensive intellectual property portfolio related to vaccine applications, including manufacturing, formulation and process applications as well as protection for our specific vaccine candidates.

Our success depends in part on our ability to obtain and maintain proprietary protection for our vaccine candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements and vaccine candidates that are important to the development and implementation of our business. Our patent portfolio is intended to cover our vaccine candidates and components thereof, their methods of use and processes for their manufacture, our proprietary reagents and assays and any other inventions that are commercially important to our business. We also rely on trademarks, trade secrets and know-how to develop and maintain our proprietary position.

Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the U.S. Patent and Trademark Office, or USPTO, in examining the patent application or extended to account for term effectively lost as a result of the FDA regulatory review period, or both. In addition, we cannot provide any assurance that any patents will be issued from our pending or future applications or that any issued patents will adequately protect our vaccine candidates.

Our patent portfolio as of January 31, 2020 contains approximately three pending U.S. patent applications and four pending patent cooperation treaty applications that are solely owned by us, as well as and certain foreign counterparts of a subset of these patent applications in foreign countries, including Australia, Brazil, Canada, China, India, Israel, Japan, South Korea, Mexico, New Zealand, the Philippines, Singapore, South Africa and countries within the European Patent Convention and the Eurasian Patent Organization. For our pneumococcal vaccines, these applications are directed to vaccine formulations, protein-antigen conjugates, methods of making protein-antigen conjugates and the promotion of immunogenicity using the protein-antigen conjugates and vaccines. For our periodontitis vaccine, these applications relate to vaccine formulations, protein antigens, and methods of using the vaccine. If issued, the 20-year term expiration dates of our patents will expire between 2037 and 2039, not including any extension of the patent term that may be available in certain jurisdictions. We continue to seek to maximize the scope of our patent protection for all our programs.

In addition to patents, we also rely upon trademarks, trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We maintain and are seeking both registered and common law trademarks. Common law trademark protection typically continues where and for as long as the mark is used. Registered trademarks continue in each country for as long as the trademark is registered. We believe that we have certain know-how and trade secrets relating to our technology and vaccine candidates. We rely on trade secrets to protect certain aspects of our technology related to our current and future vaccine candidates. However, trade secrets can be difficult to protect. We seek to protect our proprietary information, including trade secrets, in part, by using confidentiality agreements with our commercial partners, collaborators, employees and consultants, and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our commercial partners and selected consultants. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. We also

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seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining the physical security of our premises and physical and electronic security of our information technology systems. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Obtaining patents does not guarantee our right to practice the patented technology or commercialize the patented product. Third parties may have or obtain rights to patents that could be used to prevent or attempt to prevent us from commercializing our vaccine candidates. If third parties prepare and file patent applications in the United States or other jurisdictions that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO or similar proceedings in other jurisdictions to determine the priority of invention.

### *Sutro Biopharma Agreements*

Sutro Biopharma is a clinical stage, publicly-traded (Nasdaq: STRO) drug discovery, development and manufacturing company using precise protein engineering and rational design (enabled by Sutro Biopharma's proprietary XpressCF platform technology) to advance next-generation oncology therapeutics. Following our corporate formation, SutroVax acquired an exclusive license to Sutro Biopharma's proprietary cell-free protein synthesis platform, XpressCF, for the discovery, development and sale of vaccines for the treatment or prevention of infectious diseases, excluding cancer vaccines. Under a related supply agreement with Sutro Biopharma, we have an exclusive relationship in our field to buy extract and certain custom reagents for use in manufacturing the vaccine compositions covered by the exclusive license, which we use to produce our protein carriers and certain of our antigens. Sutro Biopharma will receive a 4% royalty on aggregate worldwide net sales of our vaccine products marketed for human health and a 2% royalty on such net sales of vaccines marketed for animal health.

### **Amended and Restated Agreement with Sutro Biopharma**

We are party to a license agreement with Sutro Biopharma, or the Sutro Biopharma License Agreement, which was originally entered into in October 2015.

Under that agreement, we received an exclusive, worldwide, royalty-bearing license under Sutro Biopharma's patents and know-how relating to XpressCF to research, develop, use, sell, offer for sale, export, import and otherwise exploit vaccine compositions for the treatment and prophylaxis of infectious diseases, excluding cancer vaccines, such rights being sublicenseable, and to manufacture, or have manufactured by an approved contract manufacturing organization, such vaccine compositions from extracts supplied by Sutro Biopharma pursuant to the Sutro Biopharma Supply Agreement (as described below).

In consideration of the rights granted under the Sutro Biopharma License Agreement, we are obligated to pay Sutro Biopharma a 4% royalty on worldwide aggregate net sales of vaccine compositions for human health and a 2% royalty on net sales of vaccine compositions for animal health use. Such royalty rates are subject to specified reductions, including standard reductions for third-party payments and for expiration of relevant patent claims. We are also obligated to pay Sutro Biopharma any royalties due to Stanford University (the upstream licensor of Sutro Biopharma), to the extent the royalties payable by Sutro Biopharma to Stanford University are greater than the royalties payable by us to Sutro Biopharma. Royalties are payable on a vaccine composition-by-vaccine composition and country-by-country basis until the later of expiration of the last valid claim in the licensed patents covering such vaccine composition in such country and ten years after the first commercial sale of such vaccine composition. The latest expiration date of a licensed Sutro Biopharma patent application, if issued, would be 2036, subject to any adjustment or extension of patent term that may be available in a particular country. In addition, we are obligated to pay Sutro Biopharma a percentage of net sublicensing revenue received in the low teen percentages. In addition, in the event we sublicense our non-manufacturing rights under the Sutro Biopharma License Agreement before a specified date, we are obligated to pay Sutro Biopharma a percentage, in the low double-digits, of the sublicensing revenue we receive under such agreement.

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The Sutro Biopharma License Agreement will remain in effect until terminated. The agreement may be terminated by either party for the other party's material breach uncured within 60 days' notice, by us at will with 60 days' notice, or by Sutro Biopharma if we challenge Sutro Biopharma's patents or if we undergo a change of control with a specified competitor of Sutro Biopharma.

In connection with our formation and the entry into the Sutro License, we issued to Sutro Biopharma 3,000,000 shares of common stock, valued at a price per share of \$0.001 per share.

### **Supply Agreement with Sutro Biopharma**

We are party to a supply agreement with Sutro Biopharma, or the Sutro Biopharma Supply Agreement, which is dated May 2018 and pursuant to which we purchase from Sutro Biopharma extract and custom reagents for use in manufacturing the non-clinical and Phase 1 and Phase 2 clinical supply of vaccine compositions utilizing the technology licensed under the Sutro License at prices not to exceed a specified percentage above Sutro Biopharma's fully burdened manufacturing cost.

The Sutro Biopharma Supply Agreement will remain in effect until the later of July 31, 2021, or the date the parties enter into and commence activities under a separate agreement for the supply of extract and custom reagents for use in manufacturing vaccine compositions for Phase 3 and commercial purposes. The Sutro Biopharma Supply Agreement may be terminated by either party for the other party's material breach uncured within 60 days' notice, by us at will with 60 days' notice, or by mutual agreement of the parties. In December 2019, we exercised our right to require Sutro Biopharma to establish a second supplier for extract and custom reagents to support our anticipated clinical and commercial needs.

### *University of California, San Diego License Agreement*

We are party to a license agreement with the University of California, San Diego, or the UCSD License, dated February 2019 whereby we are the exclusive licensee of a pending U.S. patent application related to a non-cross reactive Group A Strep carbohydrate antigen and methods of producing the antigen. We license this technology for the development of our group Strep A vaccine candidate.

Upon execution of the UCSD License, we made an upfront payment of \$10,000, and each year during the term we are obligated to pay an annual license maintenance fee in the single digit thousands. We are also obligated to pay UCSD up to approximately \$1 million in development and regulatory milestone payments for each licensed product under the agreement. Additionally, we are obligated to pay UCSD a fixed royalty on net sales of licensed products in the low single digits. Such royalty rate is subject standard reductions for third-party payments. Royalties are payable until expiration of the last licensed patent. Additionally, in the event we sublicense commercial rights under the UCSD License, we are obligated to pay UCSD a percentage of all sublicensing revenue received in the low double digit percentages up to a specified cap.

We are obligated to use commercially reasonable efforts to diligently develop, manufacture and sell licensed products and to achieve specified research and clinical development milestone events. If we are unable to meet our diligence obligations and do not agree with UCSD to modify such obligations or do not cure such obligations, then UCSD may terminate the license or convert the license to non-exclusive.

The UCSD License will remain in effect until the expiration of the last licensed patent. The UCSD patent application, if issued, would expire in 2032, subject to any adjustment or extension of patent term that may be available in the United States. The UCSD License may be terminated by us at will with 90 days' notice or by UCSD for our breach uncured within 90 days' notice or if we challenge the licensed patents.

### *Other Partners*

In addition to those listed above, we seek to partner with various academic, governmental and public or private research institutions as needed to advance the discovery or development of our vaccine candidates.



## Coverage and Reimbursement

Sales of our products in the United States will depend, in part, on the extent to which the costs of the products are covered by third-party payors, such as government health programs, commercial insurance and managed health care organizations. The process for determining whether a third-party payor will provide coverage for a pharmaceutical or biological product is typically separate from the process for setting the price of such a product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. As a result, a third-party payor's decision to provide coverage for a pharmaceutical or biological product does not imply that the reimbursement rate will be adequate.

Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As such, one third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate.

## Government Regulation

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, safety, effectiveness, manufacture, quality control, approval, post-approval monitoring and reporting, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new biological product must be licensed by the FDA through the approval of a Biologics License Application, or BLA, before it may be legally marketed in the United States.

In the United States, pharmaceutical products are regulated by the FDA under the Federal Food, Drug and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act, or PHS Act. We expect our products to be regulated by the FDA as biologics and to be reviewed by the FDA's Center for Biologics Evaluation and Research.

We anticipate our vaccine candidates will require the submission of a BLA and approval by the FDA before being marketed in the United States. Failure to comply with FDA requirements, both before and after product approval, may subject us or our partners, contract manufacturers and suppliers to administrative or judicial sanctions, including FDA refusal to approve applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, fines and/or criminal prosecution.

The steps required before a biologic may be approved for marketing of an indication in the United States generally include:

- completion of preclinical laboratory tests, animal studies, formulation studies conducted in accordance with good laboratory practices and other applicable regulations;
- submission to the FDA of an IND, which must be active before human clinical trial commencement;
- approval by an institutional review board, or IRB, or ethics committee at each clinical site before a clinical trial is commenced;
- completion of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish that the biological product is "safe, pure and potent," which is analogous to the safety and efficacy approval standard for a chemical drug product for its intended use;

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- preparation and submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity and potency from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with applicable current food manufacturing practices, or cGMPs, to assure that the facilities, methods and controls are adequate to preserve the products identify, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the BLA; and
- FDA review of the BLA and issuance of a biologics license, which is the approval necessary to market a vaccine.

Before conducting studies in humans, laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and efficacy of the biologic candidate, must be conducted. Preclinical toxicology studies in animals must be conducted in compliance with FDA regulations. The results of the preclinical tests, together with manufacturing information, known as CMC, and analytical data, are submitted to the FDA as part of an IND application. Some preclinical testing may continue even after the IND application is submitted. In addition to including the results of the preclinical testing, the IND application will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase or phases of the clinical trial lend themselves to an efficacy determination. The IND application will automatically become effective 30 days after receipt by the FDA unless the FDA within the 30-day time period places the IND application on clinical hold because of safety concerns about the vaccine candidate or the conduct of the trial described in the clinical protocol included in the IND application. The IND application sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Submission of an IND application therefore may or may not result in FDA authorization to begin a clinical trial.

All clinical trials for new drugs and biologics must be conducted under the supervision of one or more qualified principal investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. They must be conducted under protocols detailing, among other things, the objectives of the applicable phase of the trial, dosing procedures, research subject selection, exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND application, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors must also report to the FDA within specified timeframes, serious and unexpected adverse reactions, any clinically significant increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the vaccine candidate. An IRB at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that institution, approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative and monitor the trial until completed.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap, and different trials may be initiated with the same vaccine candidate within the same phase of development in similar or differing patient populations.

- *Phase 1:* Clinical trials may be conducted in a limited number of patients or healthy volunteers, as appropriate. The vaccine candidate is initially tested for safety and immunogenicity.

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- *Phase 2:* The vaccine candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3:* Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may also be made a condition to approval of the BLA. 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 application 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 relevant 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 application 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 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Assuming successful completion of all required testing in accordance with applicable regulatory requirements, the results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the vaccine candidate, are submitted to the FDA as part of a BLA requesting approval to market the vaccine candidate for a proposed indication or indications. The BLA must include all relevant data available from preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's CMC and proposed labeling, among other things. Under the Prescription Drug User Fee Act, the fees payable to the FDA for reviewing a BLA, as well as annual program user fees for approved products, can be substantial but are subject to certain limited deferrals, waivers and reductions that may be available. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. Each BLA submitted to the FDA for approval is reviewed for administrative completeness and reviewability within 60 days following receipt by the FDA of the application. If the BLA is found complete, the FDA will file the BLA, triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. The FDA's established goal is to review 90% of priority BLAs within six months after the application is accepted for filing and 90% of standard BLAs within 10 months of the acceptance date, whereupon a review decision is to be made. Priority review will direct overall attention and resources to the evaluation of applications for products that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may also

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convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions regarding approval.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product.

If a product is approved, the approval may impose limitations on the uses for which the product may be marketed, may require that warning statements be included in the product labeling, may require that additional studies be conducted following approval as a condition of the approval and may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a Risk Evaluation and Mitigation Strategy, or REMS, or otherwise limit the scope of any approval. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. In most cases, the FDA must approve a BLA supplement or a new BLA before a product may be marketed for other uses or before specific manufacturing or other changes may be made to the approved product. As a condition of approval, the FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. In addition, new government requirements may be established that could delay or prevent regulatory approval of our vaccine candidates under development.

Both before and after the FDA approves a product, the manufacturer and the holder or holders of the BLA for the product are subject to comprehensive regulatory oversight. For example, quality control and manufacturing procedures must conform, on an ongoing basis, to cGMP requirements, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to spend time, money and effort to maintain cGMP compliance.

*Post-Approval Requirements*

Any drug products manufactured or distributed by us or our partners pursuant to FDA approvals will be subject to pervasive and continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, distribution requirements, complying with individual electronic records and signature requirements and complying with FDA promotion and advertising requirements. Once approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. After approval, most changes to the approved product, such as adding new indications, specific manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Biologic manufacturers, their subcontractors and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations. Changes to the manufacturing process are strictly regulated and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Discovery of previously unknown problems, including adverse events of unanticipated severity or frequency, or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal or suspension of an approval or license, clinical holds, warning or untitled letters, product recalls, product seizures, safety alerts, Dear Healthcare Provider letters, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, consent decrees or civil or criminal penalties.

The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market and imposes requirements and restrictions on drug manufacturers, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or inpatient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict the manufacturer's communications on the subject of off-label use of their products.

*Disclosure of Clinical Trial Information*

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information on [clinicaltrials.gov](http://clinicaltrials.gov). Information related to the product, patient population, phase of the investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to

two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

#### *Additional Controls for Biologics*

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

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform specific tests on each lot of the product before it is released for distribution. If the product is subject to an 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 the manufacture of the lot and the results of all the manufacturer's tests performed on the lot. The FDA may also perform specific 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.

#### *Expedited Development and Review Programs*

A sponsor may seek approval of its vaccine candidate under programs designed to accelerate the FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. For a fast track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the application. A fast track designated vaccine candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA 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. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

In addition, a sponsor may seek FDA designation of its vaccine candidate as a breakthrough therapy if the vaccine candidate is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a product as a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough therapy designation comes with all of the benefits of fast track designation.

Even if a drug or biologic qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened.

### *Biosimilars and Exclusivity*

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires 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 product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic 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 biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

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 that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of

the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact and implementation of the BPCIA are subject to significant uncertainty.

#### *United States Healthcare Reform*

In the United States, there has been and continues to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of vaccine candidates, restrict or regulate post-approval activities and affect the profitable sale of vaccine candidates.

Among policymakers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things: (1) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations; (2) created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (3) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in specific government healthcare programs; (4) expanded the eligibility criteria for Medicaid programs; (5) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; (6) created 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; and (7) established a Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drugs.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and political challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of specific provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of individual taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on specific individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." The Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." More recently, in December 2018, CMS published a new final rule permitting further collections and payments to and from specific ACA qualified health plans and health insurance issuers under the ACA risk adjustment program. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether



the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur towards the end of 2020. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2029 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, there has recently 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 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 drug products. At the federal level, the Trump administration's budget proposals for fiscal 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of specific federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has solicited feedback on some of these measures and has implemented others under its existing authority. Although some measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on specific product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing.

#### *United States Healthcare Fraud and Abuse Laws and Compliance Requirements*

Federal and state healthcare laws and regulations restrict certain business practices in the biopharmaceutical industry, including anti-kickback and false claims laws and regulations, data privacy and security laws and regulations and transparency laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in-kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of this 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 federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act and the civil monetary penalties statute.

The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, prohibit, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be

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made or used a false record or statement material to a false or fraudulent claim to the federal government. Private individuals, commonly known as “whistleblowers,” can bring civil False Claims Act *qui tam* actions, on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal civil and criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program. 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. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, imposes specific requirements relating to the privacy, security and transmission of protected health information on HIPAA covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses and their business associates who conduct certain activities for or on their behalf involving protected health information on their behalf.

The federal Physician Payments Sunshine Act requires certain manufacturers of 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 report annually to CMS information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

Similar state, local and foreign healthcare laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure compliance with applicable healthcare laws and regulations can involve substantial costs. Violations of healthcare laws can result in significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of operations.

### *Foreign Regulation*

In addition to regulations in the United States, we expect to be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our vaccine candidates. Whether or not we obtain FDA approval for a vaccine candidate, we must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

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Certain countries outside of the United States have a process that requires the submission of a clinical trial application, much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country. In all cases, the clinical trials must be conducted in accordance with GCPs and other applicable regulatory requirements.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency, or EMA, where it will be evaluated by the Committee for Medicinal Products for Human Use, and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period.

To market a medicinal product in the European Economic Area, or EEA, (which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein), we must obtain a Marketing Authorization, or MA. There are two types of marketing authorizations:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the EMA, and which is valid throughout the entire territory of the European Economic Area, or EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced therapy products and medicinal products containing a new active substance indicated for the treatment certain diseases, such as AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune 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 in the EU; and
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in the various Member States through the Decentralized Procedure.

Under the above-described procedures, before granting the MA, the EMA, or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

### *Additional Regulation*

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by our operations. Our research and development involve the controlled use of hazardous materials, chemicals, bacteria and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biological products, government control and other changes to the healthcare system of the United States. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payers for medical goods and services may take in response to any healthcare reform proposals or legislation. We cannot predict the effect medical or healthcare reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

### **Privacy and Data Protection Laws**

We are also subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure, processing and security of personal information that identifies or may be used to identify an individual, such as names, contact information and sensitive personal data such as health data. These laws and regulations are subject to frequent revisions and differing interpretations and have generally become more stringent over time.

As of May 25, 2018, Regulation 2016/676, known as the General Data Protection Regulation, or GDPR, replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows EU member states to make new laws and regulations further limiting the processing of genetic, biometric, or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties.

### **Employees**

As of February 29, 2020, we had 41 full-time employees, 12 of whom have Ph.D. degrees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

### **Properties & Facilities**

Our corporate headquarters and secondary space are located in Foster City, California, where we currently lease approximately 22,000 square feet of office and laboratory space. We use our corporate headquarters primarily for corporate, research, development, regulatory, manufacturing and quality functions. Our primary lease for this facility expires in September 2021, and our secondary space lease expires in October 2021. We anticipate that we will need additional facility space as we move forward with our development and clinical programs. We believe that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

### **Legal Proceedings**

We are not currently subject to any legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the 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

The following table sets forth information for our executive officers and directors as of February 29, 2020:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<b>Executive Officers</b>		
Grant E. Pickering	52	President, Chief Executive Officer and Director
Jim Wassil	50	Chief Operating Officer
Paul Sauer	58	Senior Vice President, Process Development and Manufacturing
Jane Wright-Mitchell	50	General Counsel
Jeff Fairman	56	Vice President, Research
<b>Non-Employee Directors</b>		
Moncef Slaoui, Ph.D.	60	Chairman of the Board
Kurt von Emster	52	Director
Patrick Enright	58	Director
Patrick Heron	49	Director
Peter Hirth, Ph.D.	68	Director
Rob Hopfner, Ph.D.	47	Director
Heath Lukatch, Ph.D.	52	Director
William J. Newell	62	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

### Executive Officers

**Grant E. Pickering.** Mr. Pickering is our co-founder and has served as our President and Chief Executive Officer and as a member of our board of directors since November 2013. From May 2013 to April 2015, Mr. Pickering served as Strategic Advisor at Atreca, Inc., a biotechnology company. Prior to joining SutroVax, he was Chief Executive Officer of Mymetics Corporation, a developer of virosomal vaccines for infectious diseases. Prior to that, Mr. Pickering was an Executive-in-Residence at Kleiner Perkins, a venture capital firm, and Senior Vice President of Operations of Dendreon Corporation, a biopharmaceutical company. Since March 2008, Mr. Pickering has served as Chief Executive Officer of Juvaris BioTherapeutics, Inc., a biopharmaceutical company. Mr. Pickering holds a B.S. in Marketing from Penn State University and an M.B.A. from Georgetown University. Mr. Pickering was selected to serve on our board of directors because of the perspective and experience he brings as our Chief Executive Officer and his operating and management experience in the healthcare industry.

**Jim Wassil.** Mr. Wassil has served as our Chief Operating Officer since December 1, 2019. From May 2015 to December 2019, Mr. Wassil served as Vice President and Global Health and Value Business Unit Lead, Vaccines at Pfizer Inc., a multinational pharmaceutical company. From August 2008 to May 2015, Mr. Wassil served as Head, Global Product Development Meningococcal Vaccines and Head, U.S. Marketing for Meningococcal Vaccines at Novartis AG, a multinational pharmaceutical company. Prior to joining Novartis, Mr. Wassil served as Senior Director, International Marketing at Merck & Co., Inc., a multinational pharmaceutical company. Mr. Wassil is a member of the Infectious Diseases Society of America. Mr. Wassil holds a B.S. in Chemistry/Biology from the University of Notre Dame and a M.S. in BioOrganic Chemistry and an M.B.A. from Lehigh University.

**Paul Sauer.** Mr. Sauer has served as our Senior Vice President, Process Development and Manufacturing since April 2016. From January 2015 to March 2016, Mr. Sauer served as a Principal at Sauer

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Biotech Consulting, a development and manufacturing consulting services firm. From July 2011 to December 2014, Mr. Sauer served as Vice President, Process Sciences and Manufacturing at Igencia Biotherapeutics, Inc., a biotechnology company. Mr. Sauer holds a B.S. in Genetics and a B.A. in Psychology from the University of California, Davis and an M.B.A. from Santa Clara University.

**Jane Wright-Mitchell.** Ms. Wright-Mitchell has served as our General Counsel since January 2019. From November 2017 to December 2018, Ms. Wright-Mitchell served as Chief Legal Officer at Steep Hill, Inc., a cannabis testing and analytics company. From July 2014 to November 2017, Ms. Wright-Mitchell served as Chief Legal Officer at AcelRx Pharmaceuticals, Inc., a pharmaceutical company. Ms. Wright-Mitchell holds a B.S. in Biological Sciences from Clemson University, a PharmD from the University of Illinois at Chicago and a J.D. from Chicago-Kent College of Law, Illinois Institute of Technology.

**Jeff Fairman.** Mr. Fairman is our co-founder and has served as our Vice President, Research since December 2013. From July 2011 to December 2013, Mr. Fairman served as Vice President, Research at Colby Pharmaceuticals, a biopharmaceutical company. Mr. Fairman also founded Juvaris BioTherapeutics, Inc., a biopharmaceutical company, and served as its Vice President, Research from February 2002 to September 2011. Mr. Fairman is a member of the American Association of Immunologists and the Infectious Diseases Society of America. Mr. Fairman holds a B.S. in Chemistry from Northwest Missouri State University and a Ph.D. in Chemistry from the University of Arkansas.

### **Non-Employee Directors**

**Moncef Slaoui, Ph.D.** Dr. Slaoui has served on our board of directors since July 2017 and has served as Chairman of the Board since May 2018. Dr. Slaoui currently serves as a Partner at Medicxi, a venture capital firm. From June 2009 to June 2017, Dr. Slaoui served as the Chairman of Vaccines at GlaxoSmithKline plc, a multinational pharmaceutical company, and from June 2003 to June 2006, he served as head of Worldwide Business Development at GlaxoSmithKline. Dr. Slaoui currently serves on the board of directors of Moderna, Inc., a biotechnology company, as well as on the boards of directors of private biotechnology companies. From 1984 to 1988, Dr. Slaoui served as a professor of Immunology at the University of Mons, Belgium. Dr. Slaoui holds a Ph.D. in Molecular Biology and Immunology from the Université Libre de Bruxelles, Belgium. Dr. Slaoui was selected to serve on our board of directors because of his depth of vaccine industry and public company experience.

**Kurt von Emster.** Mr. von Emster has served on our board of directors since July 2015. Since January 2015, Mr. von Emster has served as a Managing Partner at Abingworth LLP, a venture capital firm. Mr. von Emster also founded venBio LLC, an investment advisory firm, and served as Founding Partner from May 2009 to January 2015. Mr. von Emster currently serves on the board of directors of CymaBay Therapeutics, Inc., a biotechnology company, and has held board positions in several public and private life sciences companies. Mr. von Emster holds a B.S. in Business and Economics from the University of California, Santa Barbara and is a Chartered Financial Analyst. Mr. von Emster was selected to serve on our board of directors because of his experience in advising public and private life sciences companies and his expertise in finance and accounting as audit member and audit chairman for several biotechnology companies.

**Patrick Enright.** Mr. Enright has served on our board of directors since July 2015. Since January 2006, Mr. Enright has served as a Managing Partner at Longitude Capital, a healthcare venture capital firm. Mr. Enright currently serves on the boards of directors of Aptinyx Inc., a clinical-stage pharmaceutical company, Aimmune Therapeutics, Inc., a clinical-stage biopharmaceutical company, and Jazz Pharmaceuticals plc, a pharmaceutical company, as well as on the boards of directors of private life sciences companies. Mr. Enright holds a B.S. in Biologics Sciences from Stanford University and an M.B.A. from the Wharton School at the University of Pennsylvania. Mr. Enright was selected to serve on our board of directors because of his experience as a venture capital investor focused on life sciences companies and his pharmaceutical industry operations experience.

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**Patrick Heron.** Mr. Heron has served on our board of directors since March 2017. Since August 1999, Mr. Heron has served as a Managing General Partner at Frazier Healthcare Partners, a venture capital firm. Mr. Heron currently serves on the boards of directors of Iterum Therapeutics plc, a pharmaceutical company, and Mirum Pharmaceuticals, Inc., a pharmaceutical company, as well as on the boards of directors of several private life sciences companies. Mr. Heron holds a B.A. in Political Science from the University of North Carolina at Chapel Hill and an M.B.A. from Harvard Business School. Mr. Heron was selected to serve on our board of directors because of his experience in advising public and private life sciences companies.

**Peter Hirth, Ph.D.** Dr. Hirth has served on our board of directors since September 2016. In 2001, Dr. Hirth founded Plexxikon, Inc., a pharmaceutical company, and served as its Chief Executive Officer until April 2013. Dr. Hirth currently serves on the boards of directors of several private life sciences companies. Dr. Hirth holds a Ph.D. in Molecular Genetics from Heidelberg University, Germany. Dr. Hirth was selected to serve on our board of directors because of his extensive experience as an investor in and advisor to many private life sciences companies.

**Rob Hopfner, Ph.D.** Dr. Hopfner has served on our board of directors since December 2017. Since October 2017, Dr. Hopfner has served as a Managing Partner at Pivotal bioVenture Partners, a venture capital firm. Dr. Hopfner also served as a Principal at Bay City Capital, a venture capital firm, from June 2007 to October 2009 and as a Managing Director and Partner from October 2009 to September 2017. Dr. Hopfner currently serves on the boards of directors of private life sciences companies. Dr. Hopfner holds a B.Sc. in Pharmacy and a Ph.D. in Pharmacology from the University of Saskatchewan and an M.B.A. from the University of Chicago. Dr. Hopfner was selected to serve on our board of directors because of his experience in advising public and private life sciences companies, as well as his research in the pharmaceutical field.

**Heath Lukatch, Ph.D.** Dr. Lukatch has served on our board of directors since May 2018. Since May 2015, Dr. Lukatch has served as a Partner at TPG Capital, a private equity investment firm. Dr. Lukatch currently serves on the boards of directors of Flexion Therapeutics, Inc., a biopharmaceutical company, and Inogen, Inc., a medical technology company, as well as on the boards of directors of several private life sciences companies. Dr. Lukatch holds a B.A. in Biochemistry from the University of California, Berkeley and a Ph.D. in Neuroscience from Stanford University. Dr. Lukatch was selected to serve on our board of directors because of his extensive experience as an investor in and advisor to several biopharmaceutical and healthcare companies.

**William J. Newell.** Mr. Newell has served on our board of directors since November 2013. Since February 2009, Mr. Newell has served as Chief Executive Officer at Sutro Biopharma, a biotechnology company. From January 2006 to August 2007, Mr. Newell served as President and as Executive Vice President at Aerovance, Inc., a venture-backed company developing clinical assets for respiratory diseases. Mr. Newell holds an A.B. in Government from Dartmouth College and a J.D. from the University of Michigan. Mr. Newell was selected to serve on our board of directors because of his decades of senior management experience in the biotechnology industry.

### **Composition of Our Board of Directors**

Our business and affairs are managed under the direction of our board of directors. We currently have nine directors. The current members of our board of directors were elected pursuant to our current certificate of incorporation, as amended, and under the provisions of our amended and restated voting agreement, which requires the stockholders who are party to the agreement to vote their respective shares of our capital stock to elect directors as follows:

- Grant E. Pickering, as the individual serving as our Chief Executive Officer and elected by the holders of our common stock;
- William J. Newell, as the individual serving as the Chief Executive Officer of Sutro Biopharma, Inc. and elected by the holders of our common stock;



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- Kurt von Emster, as the individual designated by Abingworth LLP and elected by the holders of our Series A preferred stock;
- Patrick Enright, as the individual designated by Longitude Venture Partners II, L.P. and elected by the holders of our Series A preferred stock;
- Rob Hopfner, as the individual designated by Pivotal bioVenture Partners Fund I L.P. and elected by the holders of our Series B preferred stock;
- Patrick Heron, as the individual designated by Frazier Life Sciences VIII, L.P. and elected by the holders of our Series B preferred stock;
- Heath Lukatch, as the individual designated by TPG Growth IV Switcheroo, L.P. and elected by the holders of our Series C preferred stock; and
- Moncef Slaoui and Peter Hirth, as independent individuals designated by our board of directors and elected by the holders of our capital stock.

The provisions of our amended and restated voting agreement relating to the election of our directors will terminate and the provisions of our current certificate of incorporation by which our directors were elected will be amended and restated in connection with this offering. After the closing of this offering, the number of directors will be fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering. Each of our current directors will continue to serve as a director until the election and qualification of their successor, or until their earlier death, resignation or removal.

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 that will be in effect upon the closing of this offering, immediately after this offering our board of directors will be divided into three classes with staggered three-year terms. At each annual general 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 our first annual meeting of stockholders following this offering;
- the Class II directors will be \_\_\_\_\_ and \_\_\_\_\_, and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their terms will expire at our third annual meeting of stockholders following this offering.

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**

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning his background, employment and affiliations, our board of directors has determined that \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_ do not have relationships that would interfere

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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 applicable listing standards. 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 held by each non-employee director and the transactions described in the section entitled “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. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

#### ***Audit Committee***

Our audit committee consists of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_. Our board of directors has determined that each member of the audit committee satisfies the independence requirements under the Nasdaq listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee is \_\_\_\_\_. Our board of directors has determined that \_\_\_\_\_ 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, our board of directors has examined each audit committee member’s scope of experience and the nature of their employment.

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 public 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.

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Our audit committee will operate under a written charter, to be effective prior to the closing of this offering, that satisfies the applicable listing standards of Nasdaq.

### **Compensation Committee**

Our compensation committee consists of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_. The chair of our compensation committee is \_\_\_\_\_. Our board of directors has determined that each member of the compensation committee is independent under the listing standards of Nasdaq, and 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 recommending to our board of directors the compensation of our chief executive officer and other executive officers;
- reviewing and recommending to our board of directors the compensation of our directors;
- 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; and
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation philosophy.

Our compensation committee will operate under a written charter, to be effective prior to the closing of this offering, that satisfies the applicable listing standards of Nasdaq.

### **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 listing standards of Nasdaq.

Specific responsibilities of our nominating and corporate governance committee include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our board of directors;
- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- 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.

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Our nominating and corporate governance committee will operate under a written charter, to be effective prior to the closing of this offering, that satisfies the applicable listing standards of Nasdaq.

### Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. Upon the closing of this offering, our code of business conduct and ethics will be available under the Corporate Governance section of our website at <https://www.sutrovax.com>. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of Nasdaq concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

### 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 officers or employees. None of our executive officers currently serves, or has served during the last 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 information regarding the compensation earned by or paid to our directors during the year ended December 31, 2019, other than Grant E. Pickering, our President and Chief Executive Officer, who is also a member of our board of directors but did not receive any additional compensation for service as a director. The compensation of Mr. Pickering as a named executive officer is set forth below in the subsection entitled “—Executive Compensation—Summary Compensation Table.”

#### 2019 Director Compensation

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$)(1)	Total (\$)
Moncef Slaoui	\$ 45,000	\$ —	\$45,000
Kurt von Emster	—	—	—
Patrick Enright	—	—	—
Patrick Heron	—	—	—
Peter Hirth	30,000	—	30,000
Rob Hopfner	—	—	—
Heath Lukatch	—	—	—
William J. Newell	—	—	—

(1) The amounts reported represent the aggregate grant date fair value of the stock options granted during fiscal year 2019 under our 2014 Plan, computed in accordance with Financial Accounting Standard Board Accounting Standards Codification, Topic 718, or ASC Topic 718. The assumptions used in calculating the grant date fair value of the stock options reported in this column are set forth in Note 11 to our financial statements included elsewhere in this prospectus. This amount does not reflect the actual economic value that may be realized by the non-employee director.

In addition, 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.

We intend to approve and implement a compensation policy for our non-employee directors, to be effective in connection with the consummation of this offering.

## EXECUTIVE COMPENSATION

Our named executive officers for the fiscal year ended December 31, 2019, consisting of our principal executive officer and the next two most highly compensated executive officers, were:

- Grant E. Pickering, our President and Chief Executive Officer;
- Elaine Sun, our former Chief Financial Officer and Chief Strategy Officer; and
- Jane Wright-Mitchell, our General Counsel.

### 2019 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, 2019.

<u>Name</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)</u>	<u>Option Awards (\$)(1)</u>	<u>Non-Equity Incentive Plan Compensation (\$)</u>	<u>All Other Compensation (\$)(2)</u>	<u>Total (\$)</u>
Grant E. Pickering <i>President and Chief Executive Officer</i>	2019	\$426,000		\$ —	\$ 170,400		\$ 596,400
Elaine Sun(3) <i>Former Chief Financial Officer and Chief Strategy Officer</i>	2019	347,000		59,021	104,100	260,250	770,371
Jane Wright-Mitchell <i>General Counsel</i>	2019	312,430	10,000	292,075	95,100	3,600	713,205

(1) The amounts disclosed represent the aggregate grant date fair value of the stock options granted to our named executive officers during fiscal year 2019 under our 2014 Plan, computed in accordance with ASC Topic 718. The assumptions used in calculating the grant date fair value of the stock options are set forth in Note 11 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 amounts disclosed represent severance payable to Ms. Sun of \$260,250 and employer contribution to Ms. Wright-Mitchell's health savings account of \$3,600.

(3) Ms. Sun resigned as our Chief Financial Officer and Chief Strategy Officer on December 31, 2019.

### Corporate Incentive Bonus Plan

We maintain a Corporate Incentive Bonus Plan which provides for the opportunity to earn cash bonuses based on performance against corporate and department goals, subject to the approval of our board of directors or a committee of our board of directors. The amounts shown in the column entitled "Non-Equity Incentive Plan Compensation" of the Summary Compensation Table above represent the amounts earned in the fiscal year ended December 31, 2019 under the Corporate Incentive Bonus Plan.

### Employment Agreements

We have entered into an employment agreement or offer letter with each of our named executive officers. Prior to the closing of this offering, we will enter into revised employment agreements with each of our named executive officers setting forth the terms and conditions of such executive's employment with us. In addition, each of our named executive officers has executed our standard proprietary information and invention assignment agreement. Any potential payments and benefits due upon a termination of employment or change in control are described and quantified below in the subsection entitled "—Potential Payments upon Termination or Change in Control."

***Grant E. Pickering***

We entered into an initial employment agreement with Mr. Pickering, our President and Chief Executive Officer, dated January 21, 2016, which set forth the initial terms and conditions of his employment with us. Prior to the closing of this offering, we will enter into a revised employment agreement with Mr. Pickering, which will replace and supersede Mr. Pickering's prior employment agreement. Pursuant to the new agreement, Mr. Pickering's base salary will be \$ \_\_\_\_\_ per year. Mr. Pickering's employment is at will and may be terminated at any time, with or without cause.

***Elaine Sun***

We entered into an employment agreement with Ms. Sun, our former Chief Financial Officer and Chief Strategy Officer, dated January 1, 2017, which set forth the initial terms and conditions of her employment with us. Pursuant to Ms. Sun's employment agreement, we agreed to an initial base salary of \$320,000. We also agreed to grant Ms. Sun options to purchase shares of our common stock, subject to approval by our board of directors. Ms. Sun's employment was at will and was terminable at any time, with or without cause. In December 2019, we entered into a separation and release agreement with Ms. Sun, pursuant to which we agreed to make a severance payment equal to nine months of Ms. Sun's then-current base salary in exchange for a release of claims in favor of the company. Ms. Sun resigned from the company effective December 31, 2019.

***Jane Wright-Mitchell***

We entered into an initial offer letter with Jane Wright-Mitchell, our General Counsel, dated December 6, 2018, which set forth the initial terms and conditions of her employment with us. Prior to the closing of this offering, we will enter into an employment agreement with Ms. Wright-Mitchell, which will replace and supersede Ms. Wright-Mitchell's prior employment agreement. Pursuant to the new agreement, Ms. Wright-Mitchell's base salary will be \$ \_\_\_\_\_ per year. Ms. Wright-Mitchell's employment is at will and may be terminated at any time, with or without cause.

**Potential Payments upon Termination or Change in Control**

Regardless of the manner in which a named executive officer's service terminates, each named executive officer is entitled to receive amounts earned during his or her term of service, including unpaid salary and unused vacation.

Prior to the completion of this offering, we did not have a formal plan with respect to severance benefits payable to our named executive officers and other key employees. From time to time, we granted equity awards to, or entered into employment agreements with, certain key employees, including our named executive officers, that provide for accelerated vesting of equity awards in the event such key employee's employment was involuntarily terminated under certain circumstances.

In addition, each of our named executive officers' stock options are subject to the terms of the 2014 Plan and form of share option agreement thereunder. A description of the termination and change in control provisions in the 2014 Plan and stock options granted thereunder is provided below in the subsection entitled "—Employee Benefit and Stock Plans—Amended and Restated 2014 Equity Incentive Plan."

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### Outstanding Equity Awards as of December 31, 2019

The following table presents the outstanding equity incentive plan awards held by each named executive officer as of December 31, 2019.

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 Unexercisable (#)		
Grant E. Pickering	4/24/2015	46,099	—	0.02	4/24/2020
	5/18/2017	596,510	271,141	1.06	5/17/2027
	7/24/2018	355,937	649,063	1.20	7/24/2028
Elaine Sun	1/13/2017	23,958	62,292	0.76	1/12/2027
	7/24/2018	27,238	168,875	1.20	7/24/2028
	3/21/2019	17,690	53,070	1.20	3/21/2029
Jane Wright-Mitchell	3/21/2019	—	350,000	1.20	3/21/2029

(1) All of the option awards were granted under the 2014 Plan, the terms of which plan is described below in the subsection entitled “—Employee Benefit and Stock Plans—Amended and Restated 2014 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.

We may in the future, on an annual basis or otherwise, grant additional equity awards to our executive officers pursuant to our 2020 Plan, the terms of which are described below in the subsection entitled “—Employee Benefit and Stock Plans—2020 Equity Incentive Plan.”

### Other Compensation and Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. We pay the premiums for the life, 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.

Our named executive officers did not participate in, or earn any benefits under, a nonqualified deferred compensation plan sponsored by us during the fiscal year ended December 31, 2019. Our board of directors may elect to provide our officers and other employees with nonqualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Our named executive officers did not participate in, or otherwise receive any benefits under, any defined benefit pension or retirement plan sponsored by us during fiscal 2019.

### Employee Benefit and Stock Plans

The principal features of our equity incentive plans and 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.

#### 2020 Equity Incentive Plan

Our board of directors adopted our 2020 Plan in 2020, and we expect our stockholders to approve our 2020 Plan prior to the completion of this offering. Our 2020 Plan is a successor to and continuation

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of our 2014 Plan. Our 2020 Plan will become effective on the date of the underwriting agreement related to this offering. The 2020 Plan came into existence upon its adoption by our board of directors, but no grants will be made under the 2020 Plan prior to its effectiveness. Once the 2020 Plan is effective, no further grants will be made under the 2014 Plan.

*Awards.* Our 2020 Plan provides for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Internal Revenue Code, or the Code, to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of our affiliates.

*Authorized Shares.* Initially, the maximum number of shares of our common stock that may be issued under our 2020 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 not to exceed \_\_\_\_\_, consisting of (A) shares that remain available for the issuance of awards under our 2014 Plan as of immediately prior to the time our 2020 Plan becomes effective and (B) shares of our common stock subject to outstanding stock options or other stock awards granted under our 2014 Plan that, on or after the 2020 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, if any, as such shares become available from time to time. In addition, the number of shares of our common stock reserved for issuance under our 2020 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2021 through January 1, 2030, in an amount equal to (i) \_\_\_\_\_ % of the total number of shares of our common stock outstanding on December 31 of the fiscal year before the date of each automatic increase, or (ii) a lesser number of shares determined by our board of directors prior to the applicable January 1. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2020 Plan is \_\_\_\_\_ shares.

Shares subject to stock awards granted under our 2020 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares do not reduce the number of shares available for issuance under our 2020 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 do not reduce the number of shares available for issuance under our 2020 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 an award or (iii) to satisfy a tax withholding obligation in connection with an award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under the 2020 Plan. Any shares previously issued which are reacquired in satisfaction of tax withholding obligations or as consideration for the exercise or purchase price of a stock award will again become available for issuance under the 2020 Plan.

*Plan Administration.* Our board of directors, or a duly authorized committee of our board of directors, will administer our 2020 Plan and is referred to as the “plan administrator” herein. Our board of directors may also 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 2020 Plan, our board of directors has the authority to determine award recipients, grant dates, the numbers and types of stock awards to be granted, the applicable fair market value, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

*Stock Options.* ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2020 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2020 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.



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The plan administrator determines the term of stock options granted under the 2020 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 approved by the plan administrator, 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 plan 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 plan administrator.

Unless the plan 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 plan 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 plan 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 plan 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 approved by the plan administrator, 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 plan 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 plan administrator determines 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.

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*Stock Appreciation Rights.* Stock appreciation rights are granted under stock appreciation right agreements adopted by the plan administrator. The plan administrator determines the purchase price or strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2020 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator. Stock appreciation rights may be settled in cash or shares of common stock or in any other form of payment as determined by the Board and specified in the stock appreciation right agreement.

The plan administrator determines the term of stock appreciation rights granted under the 2020 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 immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

*Performance Awards.* The 2020 Plan permits the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the common stock.

The performance goals may be based on any measure of performance selected by the 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 the board of directors at the time the performance award is granted, the board will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring and/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 portion of our business which is divested 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 plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan 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

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us to such non-employee director, will not exceed \$ \_\_\_\_\_ in total value; provided that 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 the 2020 Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of ISOs and (iv) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

*Corporate Transactions.* The following applies to stock awards under the 2020 Plan in the event of a corporate transaction (as defined in the 2020 Plan), 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 plan administrator at the time of grant.

In the event of a corporate transaction, any stock awards outstanding under the 2020 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 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 plan 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 per share amount payable to holders of common stock in connection with the corporate transaction 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 common stock.

*Change in Control.* Awards granted under the 2020 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control (as defined in the 2020 Plan) 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.

*Plan Amendment or Termination.* Our board of directors has the authority to amend, suspend or terminate our 2020 Plan, 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 2020 Plan. No stock awards may be granted under our 2020 Plan while it is suspended or after it is terminated.

## **2020 Employee Stock Purchase Plan**

Our board of directors adopted our ESPP in \_\_\_\_\_ and we expect our stockholders to approve our 2020 Plan prior to the completion of this offering. The ESPP will become effective immediately prior to and contingent upon the date of the underwriting agreement related to this offering. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The ESPP includes two components. One component is 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. In addition, purchase rights may be granted under a component that does not qualify for such favorable tax treatment because of 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, the ESPP authorizes 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 1 of each calendar year, beginning on January 1, 2021 through January 1, 2030, by the lesser of (i) \_\_\_\_\_ % of the total number of shares of our common stock outstanding on the last day of the fiscal year before the date of the automatic increase and (ii) \_\_\_\_\_ shares; provided that 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). As of the date hereof, no shares of our common stock have been purchased under the ESPP.

*Administration.* Our board of directors administers the ESPP and may delegate its authority to administer the ESPP to our compensation committee. The ESPP is 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 the ESPP, we may specify offerings with durations of not more than 27 months, and may 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. An offering under the ESPP may be terminated under certain circumstances.

*Payroll Deductions.* Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined in the ESPP) for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is at least the lesser of (i) 85% of the fair market value of a share of our common stock on the first date 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 the ESPP, as determined by our board of directors, including: (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 may purchase shares under the 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 the 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.* In the event that 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, the board of

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directors will make appropriate adjustments to: (1) the class(es) and maximum number of shares reserved under the ESPP, (2) the class(es) and maximum number of shares by which the share reserve may increase automatically each year, (3) the class(es) and number of shares subject to and purchase price applicable to outstanding offerings and purchase rights and (4) the class(es) and number of shares that are subject to purchase limits under ongoing offerings.

*Corporate Transactions.* In the event of certain significant corporate transactions, any then-outstanding rights to purchase our stock under the 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 the ESPP, a corporate transaction is generally the consummation of: (i) a sale of all or substantially all of our assets, (ii) the sale or disposition of more than 50% of our outstanding securities, (iii) a merger or consolidation where we do not survive the transaction and (iv) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

*ESPP Amendment or Termination.* Our board of directors has the authority to amend or terminate our ESPP, provided that 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.

### ***Amended and Restated 2014 Equity Incentive Plan***

Our board of directors adopted our 2014 Plan in January 2014, and our stockholders approved our 2014 Plan in May 2014. Our 2014 Plan has been periodically amended, most recently in May 2018. Our 2014 Plan will be terminated prior to the closing of this offering, and thereafter we will not grant any additional awards under our 2014 Plan. However, our 2014 Plan will continue to govern the terms and conditions of the outstanding awards previously granted thereunder, which include options and restricted stock awards.

*Share Reserve.* As of December 31, 2019, stock options covering 5,563,107 shares with a weighted-average exercise price of \$1.14 per share and no shares of restricted stock were outstanding under our 2014 Plan, and shares of our common stock remained available for the future grant of awards under our 2014 Plan. Any shares of our common stock remaining available for issuance under our 2014 Plan at the time our 2020 Plan becomes effective will become available for issuance under our 2020 Plan. In addition, any shares subject to options that expire or terminate prior to exercise or are withheld to satisfy tax withholding obligations with respect to or the exercise price of an option, and any shares of restricted stock that are forfeited to or repurchased by us due to failure to vest, will be added to the number of shares then available for issuance under our 2020 Plan.

*Administration.* Our board of directors or a committee delegated by our board of directors administers our 2014 Plan. Subject to the terms of our 2014 Plan, the administrator has the power to, among other things, determine who will be granted awards, to determine the terms and conditions of each award (including the number of shares, exercise price, if any, and any vesting conditions), to lower or reduce the exercise price of outstanding options, to accelerate the time(s) when an award may vest or be exercised and to construe and interpret the terms of our 2014 Plan and awards granted thereunder.

*Options and Restricted Stock.* Options and restricted stock granted under our 2014 Plan are subject to terms and conditions generally similar to those described above with respect to options and restricted stock that may be granted under our 2020 Plan.

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*Changes to Capital Structure.* In the event of any dividend or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase or exchange of shares or other change in our corporate structure affecting our shares, the plan administrator will adjust the number and class of shares that may be delivered under the 2014 Plan and/or the number, class and price of shares covered by each outstanding award in order to prevent diminution or enlargement of benefits or potential benefits intended to be made under the 2014 Plan.

*Corporate Transactions.* In the event of a merger or a change in control, each outstanding award will be treated as the plan administrator determines, without a participant's consent, which may include, without limitation, a determination that:

- awards will be assumed or substituted by the acquiring or succeeding corporation with appropriate adjustments;
- upon written notice to the participant, the participant's awards will terminate upon or immediately prior to the consummation of such merger or change in control;
- outstanding awards will vest and become exercisable, realizable or payable, or restrictions applicable to an award will lapse, in whole or in part prior to or upon consummation of such merger or change in control and, to the extent the plan administrator determines, terminate upon or immediately prior to the effectiveness of such merger or change in control;
- an award will terminate in exchange for an amount of cash and/or property, if any, equal to the amount that would have been attained upon the exercise of such award or realization of the participant's rights as of the date of the occurrence of the transaction or an award will be replaced with other rights or property selected by the plan administrator in its sole discretion; or
- any combination of the foregoing.

The administrator is not obligated to treat all awards, even those that are of the same type, in the same manner.

In the event that the successor corporation in a merger or change in control does not assume or substitute an award, the award will fully vest and become exercisable and with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met. If the award is an option, it will be exercisable for a period of time determined by the plan administrator and will terminate upon the expiration of such period.

*Change in Control.* The administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the award will be subject to additional acceleration of vesting and exercisability upon or after a change in control. Under our 2014 Plan, a change in control is generally defined to mean the occurrence of any of the following events: (i) a change in our ownership that occurs on the date that any one person, or more than one person acting as a group, acquires ownership of our stock that, together with the stock held by such person, constitutes more than 50% of our stockholders' total voting power, except as a result of a private financing approved by the board of directors; (ii) if we have a class of securities registered pursuant to Section 12 of the Exchange Act, a change in the effective control of the Company that occurs on the date that a majority of our directors on the board of directors are replaced during any 12 month period by directors whose appointment or election is not endorsed by a majority of the members of the board of directors prior to the date of the appointment or election or (iii) a change in the ownership of a substantial portion of our assets that occurs on the date that any person acquires assets from us that have a total gross fair market value equal to or more than 50% of the total gross fair market value of all of our assets immediately prior to such acquisition.

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*Plan Amendment or Termination.* Our board of directors may amend, alter, suspend or terminate our 2014 Plan at any time, subject to stockholder approval to the extent required by applicable law. No amendment to our 2014 Plan may impair the rights of any award holder unless mutually agreed otherwise between the award holder and us. As discussed above, we will terminate our 2014 Plan prior to the closing of this offering and no new awards will be granted thereunder following such termination.

### **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 of Liability and Indemnification Matters**

Upon the closing of this offering, our amended and restated certificate of incorporation 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 that will be in effect upon the closing of this offering 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 that will be in effect upon the closing of this offering 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 that will be in effect upon the closing of this offering 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 and executive officers. 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 connection with any action, proceeding or investigation. 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.

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The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.



**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, 2017 and each currently proposed transaction in which:

- we have been or are to be a participant;
- 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.

**Series C Convertible Preferred Stock Financing**

In May 2018, we sold an aggregate of 6,222,912 shares of our Series C convertible preferred stock at a purchase price of \$6.8296 per share, for an aggregate purchase price of \$42.5 million. The following table summarizes the purchases of our Series C convertible preferred stock by related persons:

<u>Stockholder</u>	<u>Shares of Series C Convertible Preferred Stock</u>	<u>Total Purchase Price</u>
TPG Growth IV Switcheroo, L.P.(1)	2,928,429	\$ 19,999,999
Medicxi(2)	1,464,215	\$ 10,000,003
Abingworth Bioventures VI LP(3)	383,634	\$ 2,620,067
Longitude Venture Partners II, L.P.(4)	335,680	\$ 2,292,560
Roche Finance Ltd(5)	239,772	\$ 1,637,547
Frazier Life Sciences VIII, L.P.(6)	190,831	\$ 1,303,299
Pivotal bioVentures Fund I L.P.(7)	190,831	\$ 1,303,299

- (1) TPG Growth IV Switcheroo, L.P. beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Dr. Lukatch, a member of our board of directors, is a Partner and Managing Director at TPG Biotechnology Partners, which is an affiliate of TPG Growth IV Switcheroo, L.P.
- (2) Shares are held by the following funds associated with Medicxi: Medicxi Ventures I LP and Medicxi Co-Invest I LP. Moncef Slaoui, a member of our board of directors, is a partner at Medicxi.
- (3) Abingworth Bioventures VI LP beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Mr. von Emster, a member of our board of directors, is a Managing Partner of Abingworth LP, which is an affiliate of Abingworth Bioventures VI LP.
- (4) Longitude Venture Partners II, LP beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Mr. Enright, a member of our board of directors, is a Managing Partner of Longitude Capital which is an affiliate of Longitude Venture Partners II, LP.
- (5) Roche Finance Ltd beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing.
- (6) Frazier Life Sciences VIII, L.P. beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Mr. Heron, a member of our board of directors, is a Managing General Partner of Frazier Healthcare Partners, which is an affiliate of Frazier Life Sciences VIII, L.P.
- (7) Pivotal bioVentures Fund I L.P. beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing.

As was contemplated by the original stock purchase agreement for the Series C convertible preferred stock financing, at a second closing in December 2019, we sold an aggregate of 6,222,912 shares of our Series C convertible preferred stock at a purchase price of \$6.8296 per share, for an aggregate purchase price of \$42.5 million.

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The following table summarizes the purchases of our Series C convertible preferred stock by related persons:

<b>Stockholder</b>	<b>Shares of Series C Convertible Preferred Stock</b>	<b>Total Purchase Price</b>
TPG Growth IV Switcheroo, L.P.(1)	2,928,429	\$ 19,999,999
Medicxi(2)	1,464,215	\$ 10,000,003
Abingworth Bioventures VI LP (3)	383,634	\$ 2,620,067
Longitude Venture Partners II, L.P.(4)	335,680	\$ 2,292,560
Roche Finance Ltd (5)	239,772	\$ 1,637,547
Frazier Life Sciences VIII, L.P.(6)	190,831	\$ 1,303,299
Pivotal bioVentures Fund I L.P.(7)	190,831	\$ 1,303,299

- (1) TPG Growth IV Switcheroo, L.P. beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Dr. Lukatch, a member of our board of directors, is a Partner and Managing Director at TPG Biotechnology Partners, which is an affiliate of TPG Growth IV Switcheroo, L.P.
- (2) Medicxi beneficially owned more than 5% of our outstanding capital stock as of the second closing of the Series C convertible preferred stock financing. Shares are held by the following funds associated with Medicxi: Medicxi Ventures I LP and Medicxi Co-Invest I LP. Moncef Slaoui, a member of our board of directors, is a partner at Medicxi.
- (3) Abingworth Bioventures VI LP beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Mr. von Emster, a member of our board of directors, is a Managing Partner of Abingworth LP, which is an affiliate of Abingworth Bioventures VI LP.
- (4) Longitude Venture Partners II, LP beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Mr. Enright, a member of our board of directors, is a Managing Partner of Longitude Capital which is an affiliate of Longitude Venture Partners II, LP.
- (5) Roche Finance Ltd beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing.
- (6) Frazier Life Sciences VIII, L.P. beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Mr. Heron, a member of our board of directors, is a Managing General Partner of Frazier Healthcare Partners, which is an affiliate of Frazier Life Sciences VIII, L.P.
- (7) Pivotal bioVentures Fund I L.P. beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing.

### **Series B Convertible Preferred Stock Financing**

From March 2017 to May 2018, we sold an aggregate of 11,449,510 shares of our Series B convertible preferred stock at a purchase price of \$5.2535 per share, for an aggregate purchase price of \$60.1 million. The following table summarizes the purchases of our Series B convertible preferred stock by related persons:

<b>Stockholder</b>	<b>Shares of Series B Convertible Preferred Stock</b>	<b>Total Purchase Price</b>
Pivotal bioVentures Fund I L.P.(1)	2,855,239	\$ 14,999,998
Frazier Life Sciences VIII, L.P.(2)	2,855,239	\$ 14,999,998
Abingworth Bioventures VI LP(3)	2,053,206	\$ 10,786,518
Longitude Venture Partners II, L.P.(4)	1,796,556	\$ 9,438,207
Roche Finance Ltd(5)	1,283,254	\$ 6,741,575

- (1) Pivotal bioVentures Fund I L.P. beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing.
- (2) Frazier Life Sciences VIII, L.P. beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Mr. Heron, a member of our board of directors, is a Managing General Partner of Frazier Healthcare Partners, which is an affiliate of Frazier Life Sciences VIII, L.P.
- (3) Abingworth Bioventures VI LP beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Mr. von Emster, a member of our board of directors, is a Managing Partner of Abingworth LP, which is an affiliate of Abingworth Bioventures VI LP.
- (4) Longitude Venture Partners II, LP beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Mr. Enright, a member of our board of directors, is a Managing Member of Longitude Capital which is an affiliate of Longitude Venture Partners II, LP.

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(5) Roche Finance Ltd beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing.

### **Series C Warrant**

In May 2018, we issued a warrant to purchase 100,000 shares of our Series C convertible preferred stock with an exercise price of \$6.8296 per share, or the Suro Warrant, in a private placement to Suro Biopharma. The Suro Warrant will be automatically net exercised immediately prior to the closing of this offering unless Suro Biopharma elects to allow the Suro Warrant to expire unexercised. Dr. Newell, a member of our board of directors, was at the time and is currently the Chief Executive Officer of Suro Biopharma.

### **Suro Biopharma License**

In May 2018, we amended our license agreement, or the Suro Biopharma License Agreement, with Suro Biopharma. Pursuant to that agreement, we received an exclusive, worldwide, royalty-bearing license under Suro Biopharma's patents and know-how relating to the cell-free expression of proteins to (i) research, develop, use, sell, offer for sale, export, import and otherwise exploit specified vaccine compositions for the treatment or prophylaxis of infectious diseases, excluding cancer vaccines compositions, such rights being sublicensable, and (ii) manufacture, or have manufactured by an approved contract manufacturing organization, such vaccine compositions from extracts supplied by Suro Biopharma pursuant to the Suro Biopharma Supply Agreement (as described below). In consideration of the rights granted under the license, we are obligated to pay Suro Biopharma a 4% royalty on worldwide aggregate net sales of vaccine compositions for human health and a 2% royalty on such net sales of vaccine compositions for animal health. Mr. Newell, a member of our board of directors, was at the time and is currently the Chief Executive Officer of Suro Biopharma. For the fiscal year ended December 31, 2019, there were no amounts paid pursuant to the Suro Biopharma License Agreement. For a further description of the Suro Biopharma License Agreement, see the section entitled "Business—Intellectual Property—Suro Biopharma Agreements—Amended and Restated Agreement with Suro Biopharma."

### **Suro Biopharma Supply Agreement**

In May 2018, we entered into a supply agreement, or the Suro Biopharma Supply Agreement, with Suro Biopharma. Pursuant to that supply agreement, we purchase from Suro Biopharma extract and custom reagents for use in manufacturing non-clinical and certain clinical supply of vaccine compositions utilizing the technology licensed under the Suro License at prices not to exceed a specified percentage above Suro Biopharma's fully burdened manufacturing cost. Mr. Newell, a member of our board of directors, was at the time and is currently the Chief Executive Officer of Suro Biopharma. For the fiscal year ended December 31, 2018 and 2019, we incurred \$1.4 million and \$1.1 million, respectively, of expenses pursuant to the Suro Biopharma Supply Agreement. For a further description of the Suro Supply Agreement, see the section entitled "Business—Intellectual Property—Suro Biopharma Agreements—Supply Agreement with Suro Biopharma."

### **Investor Rights Agreement**

We are party to an amended and restated investor rights agreement, or IRA, with certain holders of our capital stock, including the holders of more than 5% of our outstanding capital stock. The IRA provides the holders of our redeemable convertible preferred stock with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. The IRA also provides these stockholders with information rights, which will terminate on the closing of this offering, and a right of first refusal with regard to certain issuances of our capital stock, which will not apply to the shares issued pursuant to this offering and which will terminate on the closing of this offering. In connection with this offering, the holders of up to 34,398,138 shares of our common stock issuable on conversion of outstanding preferred stock, will be entitled to rights with respect to the registration of their shares under the Securities Act under this agreement. For a description of these registration rights, see the section entitled "Description of Capital Stock—Registration Rights."

## **Voting Agreement**

We are party to an amended and restated voting agreement under which certain holders of our capital stock, including the holders of more than 5% of our outstanding capital stock have agreed as to the manner in which they will vote their shares of our capital stock on certain matters, including with respect to the election of directors. On the closing of this offering, the amended and restated voting agreement will terminate, and none of our stockholders will have any special rights regarding the election or designation of members of our board of directors.

## **Indemnification Agreements**

Our amended and restated certificate of incorporation that will be in effect upon the closing of this offering will contain provisions limiting the liability of directors, and our amended and restated bylaws that will be in effect upon the closing of this offering 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 that will be in effect upon the closing of this offering 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 an indemnification agreement with each of our directors and executive officers, which requires us to indemnify them. For more information regarding these agreements, see the section entitled “Executive Compensation—Limitations of Liability and Indemnification Matters.”

## **Policies and Procedures for Related Person Transactions**

Prior to the closing of this offering, our board of directors will adopt a related person transaction policy setting forth the policies and procedures for the identification, review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and a related person were or will be participants and the amount involved exceeds \$120,000, including purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness and guarantees of indebtedness. In reviewing and approving any such transactions, our audit committee will consider all relevant facts and circumstances as appropriate, such as the purpose of the transaction, the availability of other sources of comparable products or services, whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction, management’s recommendation with respect to the proposed related person transaction, and the extent of the related person’s interest in the transaction.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our capital stock as of February 29, 2020, as adjusted to reflect the sale of our common stock offered by us in this offering assuming no exercise of the underwriters' option to purchase additional shares, for:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

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 \_\_\_\_\_ shares of common stock outstanding as of February 29, 2020, assuming the conversion of all outstanding shares of our redeemable convertible preferred stock into shares of common stock on the closing of this offering. Applicable percentage ownership after the offering is based on \_\_\_\_\_ shares of common stock outstanding immediately after the closing of this offering, assuming no exercise by the underwriters of their option to purchase additional shares. 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 February 29, 2020. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o SutroVax, Inc., 353 Hatch Drive, Foster City, California 94404. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

<u>Name of Beneficial Owner</u>	<u>Shares Beneficially Owned Prior to Offering</u>		<u>Shares Beneficially Owned After Offering</u>	
	<u>Number</u>	<u>Percentage</u>	<u>Number</u>	<u>Percentage</u>
<b><i>5% Stockholders</i></b>				
Abingworth Bioventures VI, LP(1)				%
Longitude Venture Partners II, L.P.(2)				%
Roche Finance Ltd(3)				
Grant E. Pickering(4)				
TPG Growth IV Switcheroo, L.P.(5)				
Frazier Life Sciences VIII, L.P.(6)				
Pivotal bioVenture Partners Fund I, L.P.(7)				
Sutro Biopharma(8)				
Medicxi(9)				
<b><i>Directors and Named Executive Officers</i></b>				
Grant E. Pickering(4)				
Elaine Sun(10)				
Jane Wright-Mitchell(11)				

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Name of Beneficial Owner	Shares Beneficially Owned Prior to Offering		Shares Beneficially Owned After Offering	
	Number	Percentage	Number	Percentage
Moncef Slaoui <sup>(12)</sup>				
Kurt von Emster <sup>(1)</sup>				
Patrick Enright <sup>(2)</sup>				
Peter Hirth <sup>(13)</sup>				
Rob Hopfner <sup>(7)</sup>				
Heath Lukatch				
William J. Newell <sup>(14)</sup>				
All directors and executive officers as a group (12 persons) (15)				
(1)	The shares are held by Abingworth Bioventures VI, LP (“ABV VI”). Abingworth Bioventures VI GP LP (“Abingworth GP”) serves as the general partner of ABV VI. Abingworth General Partner VI LLP, serves as the general partner of Abingworth GP. Abingworth (acting by its general partner Abingworth GP, acting by its general partner Abingworth General Partner VI LLP) has delegated to Abingworth LLP, all investment and dispositive power. Mr. von Emster is a Managing Partner of Abingworth LLP. An investment committee of Abingworth LLP, comprised of Kurt Von Emster, Bali Muralidhar, Shelley Chu, Genghis Lloyd-Harris, Brian Gallagher and Timothy Haines approves investment and voting decisions by a majority vote, and no individual member has the sole control or voting power over the securities held by ABV VI. The address for each of these entities is c/o Abingworth LLP, Princes House, 38 Jermyn Street, London, England SW1Y 6DN.			
(2)	The shares are held by Longitude Venture Partners II, L.P. (“Longitude II”). Longitude Capital Partners II, LLC, (“LCP2”), the general partner of Longitude II, may be deemed to have voting, investment and dispositive power with respect to the shares held by Longitude II. Patrick G. Enright and Juliet Tammenoms Bakker are the managing members of LCP2 and may be deemed to have voting, investment and dispositive power over the shares held by Longitude II. The address for each of these entities is 2740 Sand Hill Road, Menlo Park, CA 94025.			
(3)	The shares are held by Roche Finance Ltd (“Roche Finance”). Roche Finance is a wholly owned subsidiary of Roche Holding Ltd. (“Roche Holding”), a publicly-held corporation. The address of Roche Finance is Grenzacherstrasse 122, Basel, 4070 Switzerland and the address of Roche Holding is Grenzacherstrasse 124, Basel, 4070 Switzerland.			
(4)	Includes (i) shares of common stock held by Mr. Pickering and (ii) shares of common stock issuable upon exercise of outstanding stock options held by Mr. Pickering, which are exercisable within 60 days of February 29, 2020.			
(5)	The shares are held by TPG Growth IV Switcheroo, L.P. (“TPGGIV”). The general partner of TPGGIV is TPG Growth GenPar IV, L.P., whose general partner is TPG Growth GenPar IV Advisors, LLC. David Bonderman and James Coulter have ultimate indirect control of TPGGIV and may be deemed to be the beneficial owners of the shares held by TPGGIV. The address for each of these entities is 301 Commerce Street, Suite 3300, Fort Worth, TX 76102.			
(6)	The shares are held by Frazier Life Sciences VIII, L.P. (“FLS VIII”). FHM Life Sciences VIII, LP (“FHM LP”) is the general partner of FLS VIII and FHM Life Sciences VIII, LLC (“FHM LLC”) is the general partner of FHM Life Sciences VIII, LP. James Topper and Patrick J. Heron may be deemed to beneficially own the shares which are held by FLS VIII as they are the sole members of FHM LLC and therefore share voting and investment power over the shares held by FLS VIII. The address for each of these entities is 601 Union Street, Suite 3200, Seattle, Washington 98101.			
(7)	The shares are held by Pivotal bioVenture Partners Fund I, L.P. (“Pivotal”). The general partner of Pivotal is Pivotal bioVenture Partners Fund I G.P., L.P., (“Pivotal GP”). The general partner of Pivotal GP is Pivotal bioVenture Partners Fund I U.G.P., Ltd, (the “Ultimate General Partner”). The board of directors of the Ultimate General Partner may, along with the Ultimate General Partner, be deemed to have shared voting and dispositive power over the shares owned by Pivotal. The address for each of these entities is 1700 Owens Street, Suite 595, San Francisco, CA 94158.			
(8)	Includes (i) shares of common stock held by Sutro Biopharma and (ii) shares issuable upon the exercise of warrants exercisable within 60 days of February 29, 2020.			
(9)	Consists of (a) shares of common stock held by Medicxi Ventures I LP, a Jersey limited partnership (“MVI”), and (b) shares of common stock held by Medicxi Co-Invest I LP, a Jersey limited partnership (“Medicxi Co-Invest I” and, together with MVI, the “Funds”). Medicxi Ventures I GP Limited, a Jersey limited liability company (“MVI GP”), is the sole general partner of the Funds, and Medicxi Ventures Management (Jersey) Limited, a Jersey limited liability company (“Medicxi Manager”), is the sole manager of MVI GP. MVI GP and Medicxi Manager may be deemed to have voting and dispositive power over the shares held by the Funds. The address of the principal business office of each of the foregoing entities is c/o Intertrust Fund Services (Jersey) Limited, 44 Esplanade, St. Helier, Jersey JE4 9WG.			
(10)	Includes (i) shares of common stock held by Elaine Sun and (ii) shares of common stock issuable upon exercise of outstanding stock options held by Ms. Sun, which are exercisable within 60 days of February 29, 2020.			
(11)	Includes (i) shares of common stock held by Jane Wright-Mitchell and (ii) shares of common stock issuable upon exercise of outstanding stock options held by Dr. Wright-Mitchell, which are exercisable within 60 days of February 29, 2020.			
(12)	Includes (i) shares of common stock held by Moncef Slaoui and (ii) shares of common stock issuable upon exercise of outstanding stock options held by Dr. Slaoui, which are exercisable within 60 days of February 29, 2020.			

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- (13) Includes (i) shares of common stock held by Hirth Enterprises, LLC and (ii) shares of common stock issuable upon exercise of outstanding stock options held by Dr. Hirth, which are exercisable within 60 days of February 29, 2020. Dr. Hirth exercises voting power over the shares of common stock held by Hirth Enterprises, LLC and, as a result, may be deemed to be the beneficial owner of such shares.
- (14) Includes (i) shares of common stock held by William J. Newell, Ph.D., (ii) shares held by Mr. Newell's spouse, (iii) shares of common stock held by Sutro Biopharma and (iv) shares issuable upon the exercise of warrants exercisable within 60 days of February 29, 2020 held by Sutro Biopharma. Mr. Newell is the Chief Executive Officer of Sutro Biopharma, a public company.
- (15) Includes (i) shares held by our current directors and executive officers, and (ii) shares subject to options exercisable within 60 days of February 29, 2020.

## 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, which will each become effective upon the closing of this offering, are summaries. You should also refer to our amended and restated certificate of incorporation, our amended and restated bylaws and our amended and restated investors' rights agreement, each of which are filed as exhibits to the registration statement of which this prospectus is a part.

Upon the closing of this offering, our authorized capital stock will consist of \_\_\_\_\_ shares, all with a par value of \$0.001 per share, of which:

- \_\_\_\_\_ shares are designated as common stock; and
- \_\_\_\_\_ shares are designated as preferred stock.

### Common Stock

As of December 31, 2019, there were 41,247,256 shares of our common stock outstanding and held of record by 45 stockholders, assuming the conversion of all outstanding shares of our preferred stock into shares of common stock, which will automatically occur upon the closing of this offering.

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding. Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock. All outstanding shares of common stock are, and the common stock to be outstanding upon the closing of this offering will be, duly authorized, validly issued, fully paid and nonassessable. All authorized but unissued shares of our common stock will be available for issuance by our board of directors without any further stockholder action, except as required by the listing standards of Nasdaq. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

### Preferred Stock

As of December 31, 2019, there were 34,398,138 shares of redeemable convertible preferred stock outstanding. Immediately upon the closing of this offering, each outstanding share of redeemable convertible preferred stock will convert into one share of common stock, and no shares of preferred stock will be outstanding.

Upon the closing of this offering, our board of directors may, without further action by our stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of \_\_\_\_\_ shares of redeemable convertible preferred stock in one or more series and authorize their issuance. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation



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preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our common stock. The issuance of our redeemable convertible preferred stock could adversely affect the voting power of holders of our common stock, and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control or other corporate action.

### **Options**

As of December 31, 2019, we had outstanding options under our equity compensation plans to purchase an aggregate of 5,676,107 shares of our common stock with a weighted-average exercise price of \$1.13 per share.

### **Warrants**

As of December 31, 2019, we had outstanding one warrant to purchase an aggregate of up to 53,744 shares of our common stock with an exercise price of \$0.47 per share.

As of December 31, 2019, we had outstanding one warrant to purchase an aggregate of up to 100,000 shares of our preferred stock with an exercise price of \$6.8296 per share.

Each of the above warrants has a net exercise provision under which the holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of the net exercise of the warrant after deduction of the aggregate exercise price. These warrants also contain provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrants in the event of stock dividends, stock splits, reorganizations and reclassifications and consolidations. Each of the above warrants will be automatically net exercised immediately prior to the closing of this offering unless the holder of the warrants elects to allow the warrants to expire unexercised.

### **Registration Rights**

We are party to an amended and restated investor rights agreement that provides that certain stockholders, including certain holders of our preferred stock, including certain holders of at least 5% of our outstanding capital stock, have certain registration rights as set forth below. The registration of shares of our common stock by the exercise of registration rights described below would enable the holders to sell 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 and commissions, of the shares registered pursuant to the demand, piggyback and Form S-3 registration rights described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares such holders may include. The demand, piggyback and Form S-3 registration rights described below will expire three years after the closing of this offering, of which this prospectus is a part, or with respect to any particular stockholder, such time after the closing of this offering that such stockholder can sell all of its shares entitled to registration rights under Rule 144 of the Securities Act during any 90-day period.

#### ***Demand Registration Rights***

The holders of an aggregate of 34,398,138 shares of our common stock will be entitled to certain demand registration rights. At any time beginning the 180 days after the closing of this offering, the holders of a majority of these shares may request that we register all or a portion of their shares. We are obligated to effect only two such registrations. Such request for registration must cover shares with an anticipated aggregate offering price, net of underwriting discounts and commissions, of at least \$10.0 million.

### ***Piggyback Registration Rights***

In connection with this offering, the holders of an aggregate of 34,398,138 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. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to (i) a registration statement relating to any employee benefit plans, (ii) a registration relating to a corporate reorganization or other Rule 145 transaction, (iii) a registration relating to the offer and sale of debt securities or (iv) a registration on any registration form that does not permit secondary sales, the holders of these shares are entitled to notice of the registration and have the right to include their shares in the registration, subject to limitations that the underwriters may impose on the number of shares included in the offering.

### ***Form S-3 Registration Rights***

The holders of an aggregate of 34,398,138 shares of common stock will be entitled to certain Form S-3 registration rights. The holders 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 gross proceeds of the shares offered would equal or exceed \$1.0 million. We will not be required to effect more than three registrations on Form S-3 within any 12-month period.

### **Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws**

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain or will contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

### ***Stockholder Meetings***

Our amended and restated bylaws will provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

### ***Requirements for Advance Notification of Stockholder Nominations and Proposals***

Our amended and restated bylaws will establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

### ***Elimination of Stockholder Action by Written Consent***

Our amended and restated certificate of incorporation and amended and restated bylaws will eliminate the right of stockholders to act by written consent without a meeting.

### ***Staggered Board***

Our board of directors will be divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see the section entitled “Management—Composition of Our Board of Directors.” This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

### ***Removal of Directors***

Our amended and restated certificate of incorporation will provide that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two thirds of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

### ***Stockholders Not Entitled to Cumulative Voting***

Our amended and restated certificate of incorporation will not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

### ***Delaware Anti-Takeover Statute***

We are subject to Section 203 of the DGCL, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

### ***Choice of Forum***

Our amended and restated certificate of incorporation will provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or employees arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws; (iv) any action or proceeding to interpret, apply, enforce or

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determine the validity of our certificate of incorporation or bylaws; (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; or (vi) any action asserting a claim against us or any of our current or former directors, officers or employees governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. Our amended and restated certificate of incorporation will also provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to these choice of forum provisions. It is possible that a court of law could rule that the choice of forum provisions to be contained in our amended and restated certificate of incorporation are inapplicable or unenforceable if they are challenged in a proceeding or otherwise. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

### ***Amendment of Charter Provisions***

The amendment of any of the above provisions would require approval by holders of at least two-thirds of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock upon the closing of this offering will be . The transfer agent and registrar's address is .

### **Exchange Listing**

Our common stock is currently not listed on any securities exchange. We intend to apply to have our common stock listed on the Nasdaq Global Market under the symbol “ .”

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although we intend to apply to have our common stock listed on Nasdaq, we cannot assure you that there will be an active public market for our common stock.

Following the closing of this offering, based on the number of shares of our common stock outstanding as of December 31, 2019 and assuming (i) the issuance of shares of common stock in this offering, (ii) the conversion of all outstanding shares of our convertible preferred stock into 34,398,138 shares of our common stock, which will automatically occur upon the closing of the offering, (iii) the issuance of \_\_\_\_\_ shares of our common stock as a result of the expected net exercise of an outstanding warrant to purchase 100,000 shares of our redeemable convertible preferred stock, (iv) the issuance of \_\_\_\_\_ shares of our common stock as a result of the expected net exercise of an outstanding warrant to purchase 53,744 shares of our common stock and (v) no exercise of the underwriters' option to purchase additional shares, we will have an aggregate of approximately \_\_\_\_\_ shares of common stock outstanding.

Of these shares, all shares of common stock sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares of common stock purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of common stock outstanding after this offering will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. 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 Rule 144 or Rule 701 under the Securities Act, each of which is summarized below. We expect that all of these shares will be subject to a 180-day lock-up period under the lock-up and market stand-off agreements described below.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may also be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition, investment or other transaction.

In addition, shares of common stock that are either subject to outstanding options or warrants or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements described below and Rules 144 and 701 under the Securities Act.

### Lock-Up Agreements

We, along with our directors, executive officers and substantially all of our other stockholders and optionholders, have agreed with the underwriters that for a period of 180 days, after the date of this prospectus, subject to specified exceptions as detailed further in the section entitled "Underwriting," we or they will not, except with the prior written consent of BofA Securities, Inc. and Jefferies LLC, 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 sale of, or otherwise dispose of or transfer any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, request or demand that we file a registration statement related to our common stock or enter into any swap or other agreement that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock. All of our stockholders are subject to a market stand-off agreement with us which imposes similar restrictions.

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Upon expiration of the lock-up period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See the subsection entitled “—Registration Rights” below and the section entitled “Description of Capital Stock—Registration Rights.”

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

### **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 above.

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 above. 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 our common stock then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after this offering; or
- the average weekly trading volume in our common stock on Nasdaq 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. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

### **Rule 701**

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 above.

### **Form S-8 Registration Statement**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under the

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2014 Plan, the 2020 Plan and the ESPP. We expect to file the registration statement covering shares offered pursuant to these stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

**Registration Rights**

As of December 31, 2019, holders of up to 34,398,138 shares of our common stock, which includes all of the shares of common stock issuable upon the conversion of our redeemable convertible preferred stock upon the closing of this offering, or their transferees, will be entitled to various rights with respect to the registration of these shares under the Securities Act upon the closing of this offering and the expiration of lock-up agreements. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See the section entitled “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following summary describes the material U.S. federal income tax consequences of the acquisition, ownership, and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, and does not deal with foreign, state and local consequences that may be relevant to Non-U.S. Holders in light of their particular circumstances, nor does it address U.S. federal tax consequences (such as gift and estate taxes) other than income taxes. Special rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Internal Revenue Code of 1986, as amended, or the Code, such as financial institutions, insurance companies, tax-exempt organizations, broker-dealers and traders in securities, U.S. expatriates, “controlled foreign corporations,” “passive foreign investment companies,” corporations that accumulate earnings to avoid U.S. federal income tax, corporations organized outside of the United States, any state thereof or the District of Columbia that are nonetheless treated as U.S. taxpayers for U.S. federal income tax purposes, persons that hold our common stock as part of a “straddle,” “hedge,” “conversion transaction,” “synthetic security” or integrated investment or other risk reduction strategy, persons who acquire our common stock through the exercise of an option or otherwise as compensation, persons subject to the alternative minimum tax or federal Medicare contribution tax on net investment income, persons subject to special tax accounting rules under Section 451(b) of the Code, “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, partnerships and other pass-through entities or arrangements, and investors in such pass-through entities or arrangements. Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them. Furthermore, the discussion below is based upon the provisions of the Code, and Treasury Regulations, rulings and judicial decisions thereunder as of the date hereof, and such authorities may be repealed, revoked, or modified, perhaps retroactively, so as to result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the U.S. Internal Revenue Service, or 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 will agree with such statements and conclusions. This discussion assumes that the Non-U.S. Holder holds our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment).

This discussion is for informational purposes only and is not tax advice. Persons considering the purchase of our common stock pursuant to this offering should consult their own tax advisors concerning the U.S. federal income, estate, and other tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local or foreign tax consequences.

For the purposes of this discussion, a “Non-U.S. Holder” is, for U.S. federal income tax purposes, a beneficial owner of common stock that is neither a U.S. Holder, nor a partnership (or other entity treated as a partnership for U.S. federal income tax purposes regardless of its place of organization or formation). A “U.S. Holder” means a beneficial owner of our common stock that is for U.S. federal income tax purposes any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation or other entity treated as a corporation for U.S. federal income tax purposes created or organized in or under the laws of the U.S., any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if it (i) is subject to the primary supervision of a court within the U.S. and one or more U.S. persons have the authority to control all substantial decisions of the trust or (ii) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.



## **Distributions**

As described in the section entitled “Dividend Policy,” we have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Distributions, if any, made on our common stock to a Non-U.S. Holder to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) generally will constitute dividends for U.S. tax purposes and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty, subject to the discussions below regarding effectively connected income, backup withholding, and foreign accounts. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide us with a properly executed 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 the Non-U.S. Holder’s entitlement to benefits under that treaty. This certification must be provided to us or our paying agent prior to 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 a tax treaty, dividends will be treated as paid to the entity or to those holding an interest in that entity. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder’s behalf, the holder will be required to provide appropriate documentation to such agent. The holder’s agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty and you do not timely file the required certification, you may be able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base that such holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net income basis at the regular rates applicable to U.S. residents. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional “branch profits tax,” which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder’s effectively connected earnings and profits, subject to certain adjustments. Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will first reduce the Non-U.S. Holder’s adjusted basis in our common stock, but not below zero, and then will be treated as gain to the extent of any excess amount distributed, and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

## **Gain on Disposition of Our Common Stock**

Subject to the discussions below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless (i) the gain is effectively connected with a trade or business of such holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base that such holder maintains in the United States), (ii) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (iii) we are or have been a “United States real property holding corporation” within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or such holder’s holding period. In general, we would be a United States real property holding

corporation if our interests in U.S. real estate comprise (by fair market value) at least half of our business assets. We believe that we have not been and we are not, and do not anticipate becoming, a United States real property holding corporation. Even if we are treated as a United States real property holding corporation, gain realized by a Non-U.S. Holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, or indirectly and constructively, no more than 5% of our common stock at all times within the shorter of (A) the five-year period preceding the disposition or (B) the holder's holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance that our common stock will continue to qualify as regularly traded on an established securities market. If any gain on your disposition is taxable because we are a United States real property holding corporation and your ownership of our common stock exceeds 5%, you will be taxed on such disposition generally in the manner as gain that is effectively connected with the conduct of a U.S. trade or business (subject to the provisions under an applicable income tax treaty), except that the branch profits tax generally will not apply.

If you are a Non-U.S. Holder described in (i) above, you will be required to pay tax on the net gain derived from the sale at regular U.S. federal income tax rates, and corporate Non-U.S. Holders described in (a) above may be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. Gain described in (ii) above will be subject to U.S. federal income tax at a flat 30% rate or such lower rate as may be specified by an applicable income tax treaty, which gain may be offset by certain U.S.-source capital losses (even though you are 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.

### **Information Reporting Requirements and Backup Withholding**

Generally, we must report information to the IRS with respect to any dividends we pay on our common stock (even if the payments are exempt from withholding), including the amount of any such dividends, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-ECI, or otherwise establishes an exemption. Notwithstanding the foregoing, backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or foreign, except that information reporting and such requirements may be avoided if the holder provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E or otherwise meets documentary evidence requirements for establishing non-U.S. person status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be credited against the tax liability of persons subject to backup withholding, provided that the required information is timely furnished to the IRS.

## Foreign Accounts

Sections 1471 through 1474 of the Code (commonly referred to as FATCA) impose a U.S. federal withholding tax of 30% on certain payments, including dividends paid on, and, subject to the proposed Treasury Regulations discussed below, the gross proceeds of a disposition of, our common stock paid to a foreign financial institution (as specifically defined by applicable 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 identifying information regarding certain U.S. account holders of such institution (which includes certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). FATCA also generally imposes a federal withholding tax of 30% on certain payments, including dividends paid on, and, subject to the proposed Treasury Regulations discussed below, the gross proceeds of a disposition of, our common stock to a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding substantial direct and indirect U.S. owners of the entity. An intergovernmental agreement between the United States and an applicable foreign country may modify those requirements. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules.

The U.S. Treasury Department recently released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a disposition of our common stock. In its preamble to such proposed regulations, the U.S. Treasury Department stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. Holders are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

**EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY RECENT OR PROPOSED CHANGE IN APPLICABLE LAW.**

## UNDERWRITING

BofA Securities, Inc., Jefferies LLC and Evercore Group L.L.C. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

<u>Underwriter</u>	<u>Number of Shares</u>
BofA Securities, Inc.	
Jefferies LLC	
Evercore Group L.L.C.	
Cantor Fitzgerald & Co.	
Needham & Company, LLC	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares 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 several underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

### Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ \_\_\_\_\_ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	<u>Per Share</u>	<u>Without Option</u>	<u>With Option</u>
Public offering price	\$ —	\$ —	\$ —
Underwriting discount	\$ —	\$ —	\$ —
Proceeds, before expenses, to us	\$ —	\$ —	\$ —

The expenses of the offering, not including the underwriting discount, are estimated at \$ \_\_\_\_\_ and are payable by us. We have also agreed to reimburse the underwriters for their expenses relating to clearance of this offering with the Financial Industry Regulatory Authority.

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

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

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

We, our executive officers and directors, and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc. and Jefferies LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- transfer or otherwise dispose of any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock, or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. If the representatives, in their sole discretion, agree to release or waive the restrictions set forth in a lock-up provisions for an officer or director of the company and provides the company with notice of the impending release or waiver at least three business days before the effective date of the release or waiver, the company agrees to announce the impending release or waiver by a press release through a major news service at least two business days before the effective date of the release or waiver.

### **Nasdaq Global Market Listing**

We expect the shares to be approved for listing on the Nasdaq Global Market, subject to notice of issuance, under the symbol “ .”

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,

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- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

### **Price Stabilization, Short Positions and Penalty Bids**

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares 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 granted to them. "Naked" short sales are sales in excess of such option. 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 our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' 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. The underwriters may conduct these transactions on The Nasdaq Global Market, in the over-the-counter market or otherwise.

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. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

## **Electronic Distribution**

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

## **Other Relationships**

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their 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. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

## **Notice to Prospective Investors in the European Economic Area**

In relation to each Member State of the European Economic Area, or Member State, no shares have been offered or will be offered pursuant to this offering to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

- (i) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- (iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require the Company or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company and the representatives that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may

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give rise to an offer to the public other than their offer or resale in a Relevant Member State to qualified investors, in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in any Member 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.

The above selling restriction is in addition to any other selling restrictions set out below.

### **Notice to Prospective Investors in the United Kingdom**

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

### **Notice to Prospective Investors in Switzerland**

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document 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 document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

### **Notice to Prospective Investors in the Dubai International Financial Centre**

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject



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to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

### **Notice to Prospective Investors in Australia**

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, which we refer to as the Exempt Investors, who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

### **Notice to Prospective Investors in Hong Kong**

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (i) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (ii) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, 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 to do so 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 Securities and Futures Ordinance and any rules made under that Ordinance.

### **Notice to Prospective Investors in Japan**

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

## Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, 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 shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (i) 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
- (ii) 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 or securities-based derivatives contracts (each term as defined in Section 2(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 shares pursuant to an offer made under Section 275 of the SFA except:

- (1) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (2) where no consideration is or will be given for the transfer;
- (3) where the transfer is by operation of law; or
- (4) as specified in Section 276(7) of the SFA.

## Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) 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 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.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

## LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, San Francisco, California. Latham & Watkins LLP, Menlo Park, California, has acted as counsel to the underwriters in connection with this offering.

## EXPERTS

The financial statements as of December 31, 2018 and December 31, 2019 and for each of the two years in the period ended December 31, 2019 included in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov).

Upon the closing of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection at the web site of the SEC referred to above. We also maintain a website at <https://www.sutrovax.com>, at which, following the closing 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 on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

SUTROVAX, INC.

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of SutroVax, Inc.

### Opinion on the Financial Statements

We have audited the accompanying balance sheets of SutroVax, Inc. (the “Company”) as of December 31, 2018 and 2019, the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders’ deficit, and cash flows, for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as 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, 2018 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

### Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and negative operating cash flows that raises substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP  
San Francisco, California  
March 13, 2020

We have served as the Company’s auditor since 2017.

**SUTROVAX, INC.**  
**Balance Sheets**  
*(in thousands, except share and per share data)*

	<b>December 31,</b>		<b>Pro Forma</b>
	<b>2018</b>	<b>2019</b>	<b>2019</b>
			<b>Unaudited</b>
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 66,090	\$ 58,976	
Prepaid expenses and other current assets	578	2,747	
Total current assets	<u>66,668</u>	<u>61,723</u>	—
Property and equipment, net	3,411	3,391	
Other assets	723	584	
Total noncurrent assets	<u>4,134</u>	<u>3,975</u>	—
<b>Total assets</b>	<b><u>\$ 70,802</u></b>	<b><u>\$ 65,698</u></b>	<b><u>\$ —</u></b>
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit</b>			
Current liabilities:			
Accounts payable	\$ 2,830	\$ 3,376	
Accrued compensation	1,189	414	
Accrued expenses (including related party accrual of \$49 and \$15 in 2018 and 2019, respectively)	2,394	7,082	
Deferred rent—current portion	3	19	
Lease liability—current portion	297	161	
Total current liabilities	<u>6,713</u>	<u>11,052</u>	—
Deferred rent—long-term portion	33	17	
Lease liability—long-term portion	161	—	
Redeemable convertible preferred stock warrant liability	462	450	
Redeemable convertible preferred stock tranche liability	3,185	—	
Other liabilities	166	242	
Total liabilities	<u>10,720</u>	<u>11,761</u>	—
Commitments and contingencies (Note 7)			
<b>Redeemable Convertible Preferred Stock</b>			
Series A redeemable convertible preferred stock, \$0.001 par value; 10,502,804 shares authorized; 10,502,804 shares issued and outstanding as of December 31, 2018 and 2019; liquidation value of \$26,887 at December 31, 2018 and 2019; no shares issued and outstanding, pro forma	24,967	24,967	
Series B redeemable convertible preferred stock, \$0.001 par value; 11,449,515 shares authorized; 11,449,510 shares issued and outstanding as of December 31, 2018 and 2019; liquidation value of \$60,150 at December 31, 2018 and 2019; no shares issued and outstanding, pro forma	55,151	55,151	
Series C redeemable convertible preferred stock, \$0.001 par value; 14,010,043 shares authorized; 6,222,912 and 12,445,824 shares issued and outstanding as of December 31, 2018 and 2019, respectively; liquidation value of \$42,500 and \$85,000 at December 31, 2018 and 2019, respectively, no shares issued and outstanding, pro forma	37,692	80,192	
<b>Stockholders' Deficit</b>			
Common stock, \$0.001 par value; 52,000,000 shares authorized at December 31, 2018 and 2019; 6,338,763 and 6,849,118 shares issued and outstanding at December 31, 2018 and 2019, respectively; shares issued and outstanding, pro forma	6	7	
Additional paid-in capital	1,339	2,967	
Accumulated deficit	(59,073)	(109,347)	
Total stockholders' deficit	<u>(57,728)</u>	<u>(106,373)</u>	—
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<b><u>\$ 70,802</u></b>	<b><u>\$ 65,698</u></b>	<b><u>\$ —</u></b>

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

**SUTROVAX, INC.**  
**Statements of Operations and Comprehensive Loss**  
*(in thousands, except share and per share data)*

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2019</b>
Operating expenses:		
Research and development (including related party expense of \$1,878 and \$1,137 in 2018 and 2019, respectively)	\$ 30,145	\$ 45,607
General and administrative	5,388	8,546
Total operating expenses	<u>35,533</u>	<u>54,153</u>
Loss from operations	(35,533)	(54,153)
Other income (expense), net:		
Interest expense	(75)	(40)
Interest income	903	632
Grant income	—	237
Foreign currency transaction gains (losses)	42	(135)
Change in fair value of the redeemable convertible preferred stock tranche liability	5,178	3,185
Total other income (expense), net	<u>6,048</u>	<u>3,879</u>
Net loss and comprehensive loss	<u>\$ (29,485)</u>	<u>\$ (50,274)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (4.80)</u>	<u>\$ (7.85)</u>
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	<u>6,142,274</u>	<u>6,402,359</u>
Pro forma net loss per share, basic and diluted (unaudited)		
Weighted-average shares outstanding used in computing pro forma net loss per share, basic and diluted (unaudited)		

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

**SUTROVAX, INC.**  
**Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit**  
*(in thousands, except share data)*

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balance—January 1, 2018</b>	10,502,804	\$ 24,967	7,633,008	\$ 35,101	—	—	6,193,397	\$ 6	\$ 452	\$ (29,588)	\$ (29,130)
Issuance of Series C redeemable convertible preferred stock, net of issuance costs of \$206 and fair value of redeemable convertible preferred stock tranche liability of \$4,602	—	—	—	—	6,222,912	37,692	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of \$229	—	—	3,816,502	20,050	—	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	29,246	—	5	—	5
Issuance of common stock related to early exercised stock options	—	—	—	—	—	—	116,120	—	—	—	—
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	133	—	133
Stock-based compensation expense	—	—	—	—	—	—	—	—	749	—	749
Net loss	—	—	—	—	—	—	—	—	—	(29,485)	(29,485)
<b>Balances—December 31, 2018</b>	<u>10,502,804</u>	<u>\$ 24,967</u>	<u>11,449,510</u>	<u>\$ 55,151</u>	<u>6,222,912</u>	<u>37,692</u>	<u>6,338,763</u>	<u>6</u>	<u>1,339</u>	<u>(59,073)</u>	<u>(57,728)</u>
Issuance of Series C redeemable convertible preferred stock, net of issuance costs of \$0	—	—	—	—	6,222,912	42,500	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	410,355	1	321	—	322
Issuance of common stock related to early exercised stock options	—	—	—	—	—	—	100,000	—	—	—	—
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	122	—	122
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,185	—	1,185
Net loss	—	—	—	—	—	—	—	—	—	(50,274)	(50,274)
<b>Balance—December 31, 2019</b>	<u>10,502,804</u>	<u>\$ 24,967</u>	<u>11,449,510</u>	<u>\$ 55,151</u>	<u>12,445,824</u>	<u>\$ 80,192</u>	<u>6,849,118</u>	<u>\$ 7</u>	<u>\$ 2,967</u>	<u>\$ (109,347)</u>	<u>\$ (106,373)</u>

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



**SUTROVAX, INC.**  
**Statements of Cash Flows**  
*(in thousands)*

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2019</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (29,485)	\$ (50,274)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	1,037	1,232
Stock-based compensation expense	749	1,185
Expense on issuance of redeemable convertible preferred stock warrant	465	—
Change in fair value of redeemable convertible preferred stock warrant liability	(3)	(12)
Change in fair value of redeemable convertible preferred stock tranche liabilities	(5,178)	(3,185)
Loss on disposal of fixed assets	54	1
<b>Changes in operating assets and liabilities:</b>		
Prepaid expenses and other current assets	(378)	(1,070)
Other assets	(412)	120
Accounts payable	1,266	868
Accrued compensation	541	(775)
Accrued expenses	1,719	4,688
Accrued legal settlement	(850)	—
Deferred rent and other long-term liabilities	9	77
Net cash used in operating activities	<u>(30,466)</u>	<u>(47,145)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(1,774)	(1,195)
Proceeds from sale of property and equipment	1	—
Net cash used in investing activities	<u>(1,773)</u>	<u>(1,195)</u>
<b>Cash flows from financing activities:</b>		
Payments of capital lease obligations	(283)	(278)
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	62,345	42,500
Proceeds from exercise of common stock options	5	322
Proceeds from issuance of common stock related to early exercised stock options	123	120
Payments of deferred offering costs	—	(1,097)
Net cash provided by financing activities	<u>62,190</u>	<u>41,567</u>
Effect of exchange rate changes on cash and cash equivalents	—	(341)
Net increase (decrease) in cash and cash equivalents	29,951	(7,114)
Cash and cash equivalents, beginning of year	36,139	66,090
Cash and cash equivalents, end of year	<u>\$ 66,090</u>	<u>\$ 58,976</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	<u>\$ 75</u>	<u>\$ 40</u>
<b>Supplemental disclosures of non-cash investing and financing activities:</b>		
Purchases of property and equipment recorded in accounts payable	<u>\$ 3</u>	<u>\$ 21</u>
Deferred offering costs included in accrued expenses	<u>\$ —</u>	<u>\$ 33</u>

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

**SUTROVAX, INC.**  
**Notes to Financial Statements**

**1. Company Organization and Nature of Business**

SutroVax, Inc. (“the Company” or “SutroVax”) was incorporated in the state of California on November 27, 2013, and is headquartered in Foster City, California. The Company is a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent some of the most common and deadly infectious diseases worldwide. The Company’s cell-free protein synthesis platform enables the Company to design and produce optimized protein carriers and antigens, the critical building blocks of vaccines, in ways that are beyond the reach of conventional technology. The Company’s lead vaccine candidate, SVX-24, is a broad-spectrum pneumococcal conjugate vaccine (“PCV”) with the potential to, if approved, become the standard of care in the \$7 billion global pneumococcal vaccine market. The Company’s primary activities since incorporation have been to perform research and development, undertake preclinical studies and enable manufacturing activities in support of the Company’s product development efforts, organize and staff the Company, plan for the business and establish the Company’s intellectual property portfolio, and raise capital to support and expand such activities.

**2. Basis of Presentation and Summary of Significant Accounting Policies**

***Basis of Presentation***

These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

***Going Concern***

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern and do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

Since its inception, the Company has devoted substantially all of its efforts to research and development, undertaking preclinical studies and enabling manufacturing activities in support of its product development efforts, hiring personnel, acquiring and developing its technology and vaccine candidates, organizing and staffing its company, performing business planning, establishing its intellectual property portfolio and raising capital to support and expand such activities. The Company does not have any products approved for sale and have not generated any revenue from product sales. The Company has incurred net losses in each year since inception and expects to continue to incur net losses in the foreseeable future. The Company’s net loss was \$50.3 million for the year ended December 31, 2019. As of December 31, 2019, the Company had an accumulated deficit of \$109.3 million. The Company also generated negative operating cash flows of \$47.1 million for the year ended December 31, 2019. These conditions raise substantial doubt about the Company’s ability to continue as a going concern for at least one year from the issuance date of its financial statements.

The Company is pursuing various financing alternatives, potentially including debt and equity arrangements, to finance its future operations. However, no assurance can be given as to whether additional needed financing will be available on terms acceptable to the Company, if at all.

***Pro Forma Balance Sheet and Pro Forma Net Loss Per Share***

The unaudited pro forma basic and diluted net loss per share for the year ended December 31, 2019 has been computed to give effect to (i) the conversion of all outstanding shares of redeemable convertible preferred stock into shares of common stock as of the beginning of the reporting period or the date of issuance of the

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preferred stock, if later, (ii) the net exercise of the redeemable convertible preferred stock warrant into shares of common stock, based on an estimated offering price of \$        per share, which is the midpoint of the estimated price range, (iii) the net exercise of the common stock warrant into shares of common stock, based on an estimated offering price of \$        per share, which is the midpoint of the estimated price range; (iv) the removal of gains or losses resulting from the re-measurement of the redeemable convertible preferred stock warrant liability as the warrant will be exercised for shares of common stock immediately prior to the closing of this offering; and (v) the filing and effectiveness of the Company's amended and restated certificate of incorporation that will be in effect immediately prior to the closing of this offering. Stock-based compensation expense associated with the vesting of the service and performance-based awards is excluded from the pro forma net loss basic and diluted per share presentation.

The unaudited pro forma balance sheet data gives effect to (i) the conversion of all of the Company's outstanding shares of redeemable convertible preferred stock as of December 31, 2019 into 34,398,138 shares of the Company's common stock immediately prior to the closing of this offering; (ii) the issuance of        shares of the Company's common stock as a result of the expected net exercise of an outstanding warrant to purchase 100,000 shares of the Company's redeemable convertible preferred stock and the related reclassification of the redeemable convertible warrant liability to common stock and additional paid-in capital, assuming an initial public offering price of \$        per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus; (iii) the issuance of        shares of the Company's common stock as a result of the expected net exercise of an outstanding warrant to purchase 53,744 shares of the Company's common stock, assuming an initial public offering price of \$        per share; and (iv) the filing and effectiveness of the Company's amended and restated certificate of incorporation that will be in effect immediately upon the closing of this offering.

The shares of common stock expected to be issued and the related net proceeds expected to be received in connection with the planned IPO are excluded from such pro forma information.

### ***Use of Estimates***

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to the fair value of tranche commitments related to redeemable convertible preferred stock, determination of the fair value of the redeemable convertible preferred stock warrant liability, determination of the fair value of common stock and related stock-based compensation expense, accruals for certain research and development costs, the valuation of deferred tax assets, and income taxes. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from those estimates.

### ***Concentration of Credit Risk***

Cash and cash equivalents are financial instruments that potentially subject the Company to concentrations of credit risk. Substantially all of the Company's cash and cash equivalents are deposited in accounts with major financial institutions and amounts may exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash and cash equivalents are held. The Company has not experienced any losses on its deposits of cash and cash equivalents.

### ***Risks and Uncertainties***

The Company is subject to certain risks and uncertainties, including, but not limited to, changes in any of the following areas that the Company believes could have a material adverse effect on the future financial

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position or results of operations: ability to obtain future financing; regulatory clearance and market acceptance of, and reimbursement for, the Company's vaccine candidates; performance of third-party clinical research organizations; competition from pharmaceutical companies with greater financial resources or expertise; protection of the intellectual property; litigation or claims against the Company based on intellectual property or other factors; and the Company's ability to attract and retain employees necessary to support its growth. The Company relies on single source manufacturers and suppliers for the supply of its product candidates. Disruption from these manufacturers or suppliers would have a negative impact on the Company's business, financial position and results of operations.

Since inception, the Company has incurred significant losses from operations and expects losses to continue for the foreseeable future. The accumulated loss was \$109.3 million at December 31, 2019 and net loss was \$50.3 million for the year ended December 31, 2019. The Company's success depends primarily on the ability to successfully develop and obtain regulatory approval of its PCV program and pipeline, the ability to manufacture or source clinical and commercial supply and meet regulatory requirements, and the ability to successfully commercialize its products. Until such time, if ever, as the Company generates substantial product revenues, it expects to raise additional funds through a combination of equity offerings and debt financing.

### ***Segment and Geographical Information***

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of the Company's long-lived assets are based in the United States. Long-lived assets are comprised of property and equipment.

### ***Cash and Cash Equivalents***

The Company considers all highly liquid investments purchased with a maturity of three months or less at the date of purchase to be cash equivalents. As of December 31, 2018 and 2019, cash and cash equivalents consisted of cash and investments in short-term money market funds. Interest income reflected in the statements of operations consists primarily of interest received on the money market funds.

### ***Deferred Offering Costs***

The Company capitalizes certain legal, accounting and other third-party fees that are directly related to the Company's in-process equity financings, including the planned IPO, until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds received as a result of the offering. Should the planned equity financing be abandoned, the deferred offering costs will be immediately recognized as operating expenses. As of December 31, 2019, there were \$1.1 million of offering costs primarily consisting of legal and accounting fees that were capitalized in other assets on the balance sheet. No deferred offering costs were capitalized as of December 31, 2018.

### ***Property and Equipment, Net***

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally three to five years. Leasehold improvements are amortized over the shorter of the expected life or lease term. Repairs and maintenance expenditures, which are not considered improvements and do not extend the useful life of property and equipment, are expensed as incurred. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in the statements of operations and comprehensive loss in the period realized.

### ***Impairment of Long-Lived Assets***

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future undiscounted net cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows generated by the assets. There have been no such impairments of long-lived assets in the years ended December 31, 2018 and 2019.

### ***Redeemable Convertible Preferred Stock***

The Company records shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The redeemable convertible preferred stock is recorded outside of permanent equity because while it is not mandatorily redeemable, redemption is contingent upon the occurrence of certain events considered not solely within the Company's control. The Company has not adjusted the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such shares because it is uncertain whether or when a deemed liquidation event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of redeemable convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a deemed liquidation event will occur.

### ***Redeemable Convertible Preferred Stock Tranche Liability***

The Company has determined that its obligation to issue additional shares of redeemable convertible preferred stock upon the occurrence of certain events represents a freestanding financial instrument. The instrument is classified as a liability on the balance sheets and is subject to re-measurement at each balance sheet date and any change in fair value is recognized through other income (expense) in the statements of operations and comprehensive loss. The tranche liability is revalued right before settlement with the changes in the fair value of the liability recorded as a component of other income (expense) in the statement of operations and comprehensive loss.

### ***Redeemable Convertible Preferred Stock Warrant***

The Company's redeemable convertible preferred stock warrant requires liability classification as the underlying redeemable convertible preferred stock is considered contingently redeemable and may obligate the Company to transfer assets to the holders at a future date upon occurrence of a deemed liquidation event. The warrant is recorded at fair value upon issuance and is subject to re-measurement to fair value at each balance sheet date, with any changes in fair value recognized in the statements of operations and comprehensive loss. The Company will continue to adjust the warrant liability for changes in fair value until the earlier of the exercise or expiration of the redeemable convertible preferred stock warrant, occurrence of a deemed liquidation event or immediately prior to the closing of a firm commitment underwritten initial public offering of the Company's common stock registered under the Securities Act of 1933, as amended. The warrant will be automatically net shares settled prior to expiration based on the fair market value of the shares on the date of exercise.

### ***Fair Value Measurements***

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. The carrying amounts of the Company's financial instruments, including cash and cash equivalents, prepaid and other current assets, accounts payable, accrued expenses, and other liabilities, approximate fair value due to their short-term maturities. The redeemable convertible preferred stock tranche liability and redeemable convertible preferred stock warrant are carried at fair value (see Note 4).

### ***Research and Development***

Research and development costs are expensed as incurred. Research and development costs include salaries, stock-based compensation, and benefits of employees performing research and development activities, an allocation of facility and overhead expenses, expenses incurred under agreements with consultants, contract manufacturing organizations (“CMOs”), contract research organizations (“CROs”) and investigative sites that conduct preclinical studies, other supplies and costs associated with product development efforts, preclinical activities, and regulatory operations.

### ***Accrued Research and Development***

The Company has entered into various agreements with CROs and CMOs. The Company’s research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued expenses on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made to CROs or CMOs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

### ***Income Taxes***

The Company accounts for income taxes using the asset and liability method. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse.

In evaluating the ability to recover its deferred income tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning, and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. In the event the Company determines that it would be able to realize its deferred income tax assets in the future in excess of their net recorded amount, it would make an adjustment to the valuation allowance that would reduce the provision for income taxes. Conversely, in the event that all or part of the net deferred tax assets are determined not to be realizable in the future, an adjustment to the valuation allowance would be charged to earnings in the period when such determination is made. As of December 31, 2018 and 2019, the Company has recorded a full valuation allowance on its deferred tax assets.

Tax benefits related to uncertain tax positions are recognized when it is more likely than not that a tax position will be sustained during an audit. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax.

### ***Stock-Based Compensation Expense***

Stock-based compensation expense related to awards to employees is measured at the grant date based on the fair value of the award. The fair value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period, net of the impact of actual forfeitures recorded in the period in which they occur.

Stock-based compensation expense related to awards to nonemployees is recognized based on the then-current fair value at each measurement date over the associated service period of the award, which is generally the vesting term, using the straight-line method. The fair value of nonemployee stock options is

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estimated using the Black-Scholes valuation model with assumptions generally consistent with those used for employee stock options, with the exception of the expected term, which is the remaining contractual life at each measurement date. Refer to Notes 2 and 11 for more information on assumptions used in estimating stock-based compensation expense.

The Company uses the Black-Scholes option-pricing model (“Black-Scholes”) as the method for determining the estimated fair value of certain financial instruments, which requires the input of the following assumptions:

### *Fair Value of Common Stock*

The fair value of the Company’s common stock is determined by the Board of Directors with assistance from management and external appraisers. Management’s approach to estimate the fair value of the Company’s common stock is consistent with the methods outlined in the American Institute of Certified Public Accountants’ Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the “Practice Aid”), considering a number of objective and subjective factors including: valuations of the Company’s common stock performed with the assistance of independent third-party valuation specialists; the Company’s stage of development and business strategy, including the status of research and development efforts of the Company’s vaccine candidates, and the material risks related to the Company’s business and industry; the Company’s results of operations and financial position, including its levels of available capital resources; the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies; the lack of marketability of the Company’s common stock; the prices of the Company’s redeemable convertible preferred stock sold to investors in arm’s length transactions and the rights, preferences, and privileges of the Company’s redeemable convertible preferred stock relative to those of its common stock; the likelihood of achieving a liquidity event for the holders of the Company’s common and redeemable convertible preferred stock, such as an initial public offering or a sale, given prevailing market conditions; trends and developments in the Company’s industry; and external market conditions affecting the life sciences and biotechnology industry sectors. The fair value of the common stock shall be approved by the Board of Directors until such time as the Company’s common stock is listed on an established stock exchange or national market system.

The valuation assumptions were determined as follows:

### *Expected Term*

Expected term represents the period that the Company’s stock-based awards are expected to be outstanding. The expected term for employee stock options is calculated using the simplified method where there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the time from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term. The expected term for nonemployee stock options is the remaining contractual term.

### *Expected Volatility*

Expected volatility is estimated from the average historical volatilities of publicly traded companies within the life sciences industry that are considered to be comparable to the Company’s business over a period approximately equal to the expected term for employees’ options and the remaining contractual life for nonemployees’ options. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

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### *Expected Dividend*

The Company has not paid and does not anticipate paying any dividends in the near future. Accordingly, the Company has estimated the dividend yield to be zero.

### *Risk-Free Interest Rate*

The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon notes with remaining terms corresponding with the expected term of the option.

### **Comprehensive Loss**

Comprehensive loss includes all changes in equity (net assets) during a period from non-owner sources. There have been no items qualifying as other comprehensive income or loss, and as such, comprehensive loss was the same as net loss for the periods presented.

### **Foreign Currency Transactions**

Transactions denominated in foreign currencies are initially measured in U.S. dollars using the exchange rate on the date of the transaction. Foreign currency denominated monetary assets and liabilities are subsequently re-measured at the end of each reporting period using the exchange rate at that date, with the corresponding foreign currency transaction gain or loss recorded in the statements of operations and comprehensive loss and statements of cash flows. Nonmonetary assets and liabilities are not subsequently re-measured.

### **Net Loss Per Share**

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock, redeemable convertible preferred stock warrant, common stock subject to repurchase, and stock options are considered to be potentially dilutive securities.

Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock is considered a participating security. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

## **3. Adopted and Recent Accounting Pronouncements**

The Company is a smaller reporting company and an emerging growth company, as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Thus, the Company has 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) the Company is no longer an emerging growth company or (ii) the Company affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. However as described below, the Company early adopted certain accounting standards, as the JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies to the extent early adoption is permitted.



**Recently Adopted Accounting Pronouncements**

In August 2018, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract (a consensus of the FASB Emerging Task Force)*. The amendments in this standard align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software and hosting arrangements that include an internal-use software license. An entity is also required to apply the existing impairment guidance in Subtopic 350-40 to the capitalized implementation costs as if the costs were long-lived assets. The amendments in this standard are effective for the Company on January 1, 2021. As permitted, the Company elected to early adopt this ASU as of January 1, 2019. The adoption of this ASU had no impact on the Company’s financial statements or disclosures.

In June 2018, the FASB issued guidance ASU No. 2018-08, *Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*. The guidance clarifies the accounting for both makers and recipients of grants. The guidance amends the new revenue recognition standard as well as the long-standing contribution accounting guidance. The new standard became effective for the Company on January 1, 2019. There was no impact on the Company’s financial statements or disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Classification of Certain Cash Receipts and Cash Payments*, which clarifies the presentation and classification of certain cash receipts and cash payments in the statement of cash flows. The new standard became effective for the Company on January 1, 2019 and there was no impact on the Company’s financial statements or disclosures.

**Recently Issued Accounting Pronouncements—Not Yet Adopted**

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. ASU 2016-02 was subsequently amended by ASU 2018-01, ASU 2018-10, ASU 2018-11, ASU 2018-20, ASU 2019-01 and ASU 2019-10, which the FASB issued in January 2018, July 2018, July 2018, December 2018, March 2019 and November 2019, respectively (collectively, the amended ASU 2016-02). ASU 2016-02 requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. The new standard establishes a right-of-use model (ROU) that requires a lessee to recognize a ROU asset and a lease liability on the balance sheet for all leases with a term longer than 12 months. Under the new standard, leases will be classified as either finance leases or operating leases, with classification affecting the pattern and classification of expense recognition in the income statement.

The new standard is effective for the Company on January 1, 2021, with early adoption permitted. The Company expects to adopt the new standard on its effective date. The new standard requires an entity to adopt using one of the two approaches, either (1) retrospectively to each prior reporting period presented in the financial statements with the cumulative effect recognized at the beginning of the earliest comparative period presented, or (2) retrospectively at the beginning of the period of adoption through a cumulative-effect adjustment. The Company has not yet concluded which approach it will utilize to adopt the new standard. Although the Company is currently evaluating the impact of adoption on its financial statements and related disclosures, the Company believes the most significant changes will be the recognition of the right-of-use assets and the related lease liabilities for its operating leases on its balance sheets.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for share-based payments granted to nonemployees for good and services. This standard expands Topic 718, *Compensation-Stock Compensation*, which currently includes share-based payments to employees, to include share-based payments issued to nonemployees and employees will be substantially aligned. The ASU supersedes Subtopic 505-50, *Equity—Equity-Based Payments to Non-Employees*.

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This standard will be effective for fiscal years beginning after December 15, 2020. The new standard will be effective for the Company on January 1, 2020. The standard should be adopted on a modified retrospective basis which recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Early adoption is permitted. The Company has not yet determined whether it will elect early adoption and is currently evaluating the impact of the adoption of this update on its financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740)*. The amendments in ASU 2019-12 simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify GAAP or other areas of Topic 740 by clarifying and amending existing guidance. The new standard is effective for the Company on January 1, 2022 and for interim periods beginning on January 1, 2023. The Company is currently evaluating the impact that the standard will have on its financial statements and related disclosures.

#### **4. Fair Value Measurements and Fair Value of Financial Instruments**

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets, as well as assets and liabilities measured at fair value on a non-recurring basis or disclosed at fair value, are categorized based upon the level of judgment associated with inputs used to measure their fair values. The accounting guidance for fair value provides a framework for measuring fair value, and requires certain disclosures about how fair value is determined. Fair value is defined as the price that would be received upon the sale of an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance also establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity. The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

**Level 1**— Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

**Level 2**—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

**Level 3**—Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. The Company recognizes transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs.

Level 1 securities consist of highly liquid money market funds for which the carrying amounts approximate their fair values due to their short maturities. Level 3 liabilities that are measured at fair value on a recurring basis include the redeemable convertible preferred stock tranche liability and redeemable convertible preferred stock warrant. The redeemable convertible preferred stock tranche liability and the redeemable convertible preferred stock warrant are measured using the option pricing method by estimating the value using

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the Black-Scholes model. The inputs used in the Black-Scholes model includes the value of the redeemable convertible preferred stock, the risk-free interest rate, the expected term of the instrument and the expected volatility.

Below are inputs used for the two Level 3 liabilities as of December 31, 2018 and December 31, 2019:

	December 31, 2018		December 31, 2019
	Redeemable Convertible Preferred Stock Tranche Liability	Redeemable Convertible Preferred Stock Warrant	Redeemable Convertible Preferred Stock Warrant
Value of Series C Preferred Stock per share	\$ 5.55	\$ 5.55	\$ 6.82
Risk-free rate	2.63%	2.67%	1.90%
Volatility	40.0%	85.4%	73.5%
Term (in years)	1.0	9.42	8.42

During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at estimated fair value using Level 3 inputs. There were no transfers within the hierarchy during the years ended December 31, 2018 and 2019.

The following tables set forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy at December 31, 2018 and 2019:

	December 31, 2018			
	Total	Level 1	Level 2	Level 3
(in thousands)				
<b>Assets:</b>				
Money market funds <sup>(1)(2)</sup>	\$ 49,024	\$ 49,024	\$ —	\$ —
<b>Liabilities:</b>				
Redeemable convertible preferred stock warrant liability	\$ 462	\$ —	\$ —	\$ 462
Redeemable convertible preferred stock tranche liability	\$ 3,185	\$ —	\$ —	\$ 3,185

	December 31, 2019			
	Total Fair Value	Level 1	Level 2	Level 3
(in thousands)				
<b>Assets:</b>				
Money market funds <sup>(1)</sup>	\$ 48,168	\$ 48,168	\$ —	\$ —
<b>Liabilities:</b>				
Redeemable convertible preferred stock warrant liability	\$ 450	\$ —	\$ —	\$ 450

(1) Included within cash and cash equivalents on the balance sheet.

(2) The December 31, 2018 amount has been revised for an immaterial correction from the previously reported amount of \$(682). The correction does not impact the cash and cash equivalents balance in the accompanying balance sheet.

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The following table provides a summary of changes in the estimated fair value of the Company's Level 3 financial instruments:

	Redeemable Convertible Preferred Stock Tranche Liability	Warrant Liability
	(in thousands)	
Balance—December 31, 2017	\$ 3,760	\$ —
Fair value of the Series C redeemable convertible preferred stock tranche liability issued in 2018	4,603	—
Issuance of redeemable convertible preferred stock warrant	—	465
Change in fair value	(5,178)	(3)
Balance—December 31, 2018	\$ 3,185	\$ 462
Change in fair value	(3,185)	(12)
Balance—December 31, 2019	\$ —	\$ 450

## 5. Property and Equipment, Net

Property and equipment, net as of December 31, 2018 and 2019, consists of the following:

	December 31,	
	2018	2019
	(in thousands)	
Furniture and equipment	\$ 307	\$ 397
Computers	137	146
Lab equipment	2,299	3,260
Leasehold improvements	1,458	1,884
Capital lease—lab equipment	961	686
	5,162	6,373
Less: accumulated depreciation and amortization	(1,751)	(2,982)
Total property and equipment, net	\$ 3,411	\$ 3,391

Depreciation and amortization expense for the years ended December 31, 2018 and 2019, was \$1.0 million and \$1.2 million, respectively, of which \$0.3 million and \$0.2 million were related to the amortization of capital leases for the years ended December 31, 2018 and 2019, respectively.

## 6. Accrued Expenses

Accrued expenses as of December 31, 2018 and 2019, consist of the following:

	December 31,	
	2018	2019
	(in thousands)	
Preclinical studies	\$ 2,070	\$ 6,621
Professional fees	240	397
Other accrued expenses	84	64
Total accrued expenses	\$ 2,394	\$ 7,082

## 7. Commitments and Contingencies

### Capital Leases

The Company entered into several capital lease obligations to purchase equipment used for operations during 2016 and 2017. The terms of the leases are 36 months with interest rates ranging from 6.9% - 15.0%. Interest expense was \$0.1 million and immaterial for the years ended December 31, 2018 and 2019, respectively.

The present value of the annual rental payments, including guaranteed residual value, is equal to 90% of the fair market value of the assets at the lease inception dates. The underlying assets and related amortization were included in the appropriate fixed asset category and related amortization account, respectively.

In October 2019, the Company entered into a lease buyout agreement for one of the lease equipment. The remaining balance of the capital lease asset for this piece of equipment was transferred from capital lease—lab equipment to lab equipment.

Property and equipment, net at December 31, 2018 and 2019, include the following amounts for leases that have been capitalized:

	Useful Life (in years)	December 31,	
		2018	2019
		(in thousands)	
Capital lease—lab equipment	3 - 5	\$ 961	\$ 686
Less accumulated amortization		(440)	(471)
		<u>\$ 521</u>	<u>\$ 215</u>

Future minimum payments required under capital leases as of December 31, 2019, are as follows:

Year ending December 31,	(in thousands)
2020	169
Total future payments	169
Less amounts representing interest	(8)
Present value of future minimum payments	161
Less current portion	(161)
Long-term portion	<u>\$ —</u>

### Operating Leases

In July 2016, the Company entered into a five-year lease agreement for its headquarter facility located in Foster City, California. The term of the lease is from September 1, 2016 to August 31, 2021, with two 30-month renewal options. In addition to payment of base rent, the Company is also required to pay property taxes, insurance and common area expenses. The Foster City lease agreement provide for an escalation of rent payments each year. The Company records rent expense on a straight-line basis over the term of the lease. The Company records deferred rent which is calculated as the difference between rent expense and the cash rental payments. In July 2019, the Company leased another facility on Chess Drive in Foster City, California as a result of the growth in personnel. The lease term began on July 1, 2019 and will end on October 31, 2021. The Company also leases an office in San Diego, California (the “original San Diego Office”). The original lease term began on January 1, 2018 and ended on December 31, 2018, and was renewed automatically for a period of three months. During 2019, the original San Diego office lease was transferred to a new lease in San Diego (the “new San Diego office lease”), which will end on March 31, 2020. In December 2019, the Company renewed the new San Diego office lease for another year, which extended the term to March 31, 2021. Rent is payable monthly for all facility leases.

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Future minimum payments required under operating leases as of December 31, 2019, are as follows:

<u>Year ending December 31,</u>	<u>(in thousands)</u>
2020	\$ 717
2021	530
2022	—
2023	—
2024	—
	<u>\$ 1,247</u>

Rent expense recognized under the leases was \$0.4 million and \$0.6 million for the years ended December 31, 2018 and 2019, respectively.

### ***Legal Contingencies***

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of business. The Company records a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount.

In April 2018, the Company reached a settlement of a dispute with a group of former consultants. As a result of the settlement, the parties agreed to a mutual release of certain claims, and the Company made a one-time payment of approximately \$0.9 million, which had been previously recorded as a liability as of December 31, 2017. In addition, stock options previously issued to the consultants were returned to the Company's 2014 Plan.

Management is currently not aware of any other legal matters that could have a material adverse effect on the Company's financial position, results of operations or cash flows.

### ***Guarantees and Indemnifications***

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2018 and 2019, the Company does not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

### ***Indemnification***

To the extent permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at the Company's request in such capacity. The indemnification period covers all pertinent events and occurrences during the director's or officer's service. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is not specified in the agreements; however, the Company has director and officer insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

### ***Development and Manufacturing Services Agreement***

On October 21, 2016, the Company entered into a development and manufacturing services agreement with Lonza Pharma & Biotech (the "Lonza DMSA"), pursuant to which Lonza would provide certain process

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development and manufacturing services and the Company would pay certain fees according to specified project plans to support its efforts to develop potential best-in-class conjugate vaccines. In January, July and September 2017, the Company entered into amendments to the Lonza DMSA, which significantly expanded the scope of process development and manufacturing work to be provided by Lonza for the Company's lead PCV program. The Company has the option to cancel signed orders at any time upon written notice, which may or may not be subject to payment of a cancellation fee. The level of cancellation fees is generally dependent on the timing of the written notice in relation to the commencement date of the work, with the maximum cancellation fee equal to the full price of the work order.

In June 2018, the Company and Lonza agreed to certain terms for potential future equity payments as partial satisfaction of future obligations to Lonza. This agreement states that the initial pre-Investigational New Drug "pre-IND" cash payments will be subject to a specified dollar cap (the "Initial Cash Cap"). After the Initial Cash Cap has been reached, the Company shall have the option to make any further pre-IND payments due to Lonza in cash, equity, or a combination of both, at the Company's election, provided that Lonza may elect to receive up to 25% of pre-IND payments in equity, up to a maximum of \$2.5 million and provided that no more than \$10 million of pre-IND payments shall be made in the form of equity. The Initial Cash Cap had not been reached as of December 31, 2019 and the Company has not received any services associated with the potential equity payments. As such, no amount has been recorded with respect to the potential future payments above the Initial Cash Cap.

### 8. Redeemable Convertible Preferred Stock

As of December 31, 2019, the Company is authorized to issue 87,962,362 shares of stock with par value of \$0.001 per share, of which 52,000,000 shares are designated as common stock and 35,962,362 shares are designated as redeemable convertible preferred stock.

The authorized, issued, and outstanding shares of redeemable convertible preferred stock and liquidation preferences as of December 31, 2018 and 2019, were as follows:

	December 31, 2018				
	<u>Shares Authorized</u>	<u>Issued and Outstanding</u>	<u>Original Issuance Price</u>	<u>Carrying Value</u>	<u>Liquidation Amount</u>
				(in thousands)	
Series A Redeemable Convertible Preferred	10,502,804	10,502,804	\$ 2.56	\$ 24,967	\$ 26,887
Series B Redeemable Convertible Preferred	11,449,515	11,449,510	5.25	55,151	60,150
Series C Redeemable Convertible Preferred	14,010,043	6,222,912	6.83	37,692	42,500
	<u>35,962,362</u>	<u>28,175,226</u>		<u>117,810</u>	<u>129,537</u>

	December 31, 2019				
	<u>Shares Authorized</u>	<u>Issued and Outstanding</u>	<u>Original Issuance Price</u>	<u>Carrying Value</u>	<u>Liquidation Amount</u>
				(in thousands)	
Series A Redeemable Convertible Preferred	10,502,804	10,502,804	\$ 2.56	\$ 24,967	\$ 26,887
Series B Redeemable Convertible Preferred	11,449,515	11,449,510	5.25	55,151	60,150
Series C Redeemable Convertible Preferred	14,010,043	12,445,824	6.83	80,192	85,000
	<u>35,962,362</u>	<u>34,398,138</u>		<u>\$ 160,310</u>	<u>\$ 172,037</u>

### ***Series A Redeemable Convertible Preferred Stock***

In July 2015, the Company entered into a Series A preferred stock purchase agreement with certain investors. The Company issued 4,736,330 shares of Series A redeemable convertible preferred stock at a purchase price of \$2.56 per share and raised approximately \$12.1 million in gross proceeds as part of the initial close. In addition, in July 2015, the Company issued 248,900 shares of Series A redeemable convertible preferred stock as a result of the conversion of notes payable and accrued interest at a purchase price of \$2.56 per share. In total, the Company issued 4,985,230 shares of Series A redeemable convertible preferred stock as part of the initial close.

At the time of the initial close, the Company also granted investors the right to purchase shares of Series A redeemable convertible preferred stock in a second and third tranche upon the occurrence of certain events over time. The second tranche was issued in July 2016, in which the Company issued an additional 3,955,076 shares at a purchase price of \$2.56 per share and raised approximately \$10.1 million in gross proceeds.

For the third tranche, the Company authorized the sale and issuance of up to 1,562,498 shares of Series A redeemable convertible preferred stock at a purchase price of \$2.56 per share immediately prior to (i) the acquisition of the Company by another entity by means of any transaction or series of related transactions to which the Company is party; (ii) a sale, lease, exclusive license, or other disposition of all or substantially all of the assets of the Company and its subsidiaries taken as a whole by means of any transaction or series of related transactions, except where such sale, lease, exclusive license, or other disposition is to a wholly owned subsidiary of the Company; or (iii) the closing of a firm commitment underwritten initial public offering of the Company's common stock pursuant to an effective registration statement filed under the Securities Act of 1933, as amended.

In conjunction with the Series B redeemable convertible preferred stock financing, the Company and Series A redeemable convertible preferred stock investors agreed to amend the Series A preferred stock purchase agreement, allowing Series A redeemable convertible preferred stock investors to exercise the option to purchase the third tranche of Series A redeemable convertible preferred stock within 90 days of the closing of the Series B redeemable convertible preferred stock financing. In May 2017, Series A redeemable convertible preferred stock investors exercised the Series A third tranche option, and the Company issued 1,562,498 shares of Series A redeemable convertible preferred stock at a purchase price of \$2.56 per share and raised approximately \$4.0 million in gross proceeds.

### ***Series B Redeemable Convertible Preferred Stock***

In March 2017, the Company entered into a Series B preferred stock purchase agreement with certain investors. The Company issued 7,633,008 shares of Series B redeemable convertible preferred stock at a purchase price of \$5.2535 per share and raised approximately \$40.1 million in gross proceeds as part of the initial close.

At the time of the initial close, the Company also authorized the sale and issuance of up to 3,816,507 shares of Series B redeemable convertible preferred stock in a second tranche at a purchase price of \$5.2535 per share upon the earlier of (i) the acceptance of an Investigational New Drug ("IND") application by the U.S. Food and Drug Administration for the Company's lead program or (ii) the approval by a majority of the Board of Directors of the Company.

In conjunction with the Series C redeemable convertible preferred stock financing, the Company and Series B redeemable convertible preferred stock investors agreed that the second tranche of the Series B redeemable convertible preferred stock financing should occur immediately prior to the closing of the Series C redeemable convertible preferred stock financing. As a result, the Company issued an additional 3,816,502 shares in May 2018 at a purchase price of \$5.2535 per share and raised approximately \$20.0 million in gross proceeds.



### ***Series C Redeemable Convertible Preferred Stock***

In May 2018, the Company entered into a Series C preferred stock purchase agreement with certain investors. The Company issued 6,222,912 shares of Series C redeemable convertible preferred stock at a purchase price of \$6.8296 per share and raised approximately \$42.5 million in gross proceeds as part of the initial close.

At the time of the initial close, the Company also authorized the sale and issuance of up to 6,222,914 shares of Series C redeemable convertible preferred stock in a second tranche (“Secondary Closing”) at a purchase price of \$6.8296 per share on or after December 1, 2019 as elected by written notice by the Company to the Series C redeemable convertible preferred stock investors (“Series C Investors”); provided that the Secondary Closing may take place prior to December 1, 2019 with the mutual consent of the Company and Series C Investors representing a majority of the shares to be sold in the Secondary Closing. Each Series C Investor has the right to invest its Secondary Closing commitment at any time at or following the initial close and prior to or in connection with the Secondary Closing by providing a written notice to the Company.

In December 2019, the Company closed the second tranche of Series C redeemable convertible preferred stock financing at a purchase price of \$6.8296 per share and raised approximately \$42.5 million in gross proceeds.

Other key terms of the Series C preferred stock purchase agreement were largely consistent with terms of the Series B preferred stock purchase agreement. In conjunction with the closing of the Series C redeemable convertible preferred stock financing, the Company increased its authorized share capital to 87,962,362 shares of stock with par value of \$0.001 per share, of which 52,000,000 shares are designated as common stock and 35,962,362 shares are designated as redeemable convertible preferred stock.

### ***Series B Redeemable Convertible Preferred Stock Tranche Liability***

The Series B preferred stock purchase agreement provided the investors the right to participate in a subsequent round of the Series B redeemable convertible preferred stock financing at a specified price equal to the original issue price. This right to participate in the second tranche of the Series B redeemable convertible preferred stock financing was provided concurrently with the issuance of the original preferred stock purchase agreement. The redeemable convertible preferred stock tranche liabilities have been valued as freestanding financial instruments because they are freely separately exercisable and are classified as liabilities until exercise or expiration. The Company valued the redeemable convertible preferred stock tranche liability using an option pricing model, which included significant estimates regarding time to exercise, volatility and discount rate.

The Company recorded the initial redeemable convertible preferred stock tranche liability in March 2017 upon the initial close of the Series B redeemable convertible preferred stock financing. The fair value of the second tranche of the Series B redeemable convertible preferred stock tranche liability was determined to be approximately \$4.8 million.

As of December 31, 2017, the Company re-measured the second tranche of the Series B redeemable convertible preferred stock tranche liability prior to exercise and determined its fair value was approximately \$3.8 million. During 2017, the Company recorded the decrease in the fair value of \$1.0 million as other income in the statements of operations and comprehensive loss.

The Company re-measured the second tranche of Series B redeemable convertible preferred stock call option immediately prior to the closing of the tranche in May 2018. During 2018, the Company re-measured the tranche liability associated with the second tranche of Series B redeemable convertible preferred stock prior to exercise and recorded the \$3.8 million decrease in the fair value as other income in the statements of operations and comprehensive loss.

**Series C Redeemable Convertible Preferred Stock Tranche Liability**

The Series C preferred stock purchase agreement provides the investors the right to participate in a subsequent round of the Series C redeemable convertible preferred stock financing at a specified price equal to the original issue price of \$6.8296 per share. This right to participate in the second tranche of the Series C redeemable convertible preferred stock financing was provided concurrently with the issuance of the original preferred stock purchase agreement. The redeemable convertible preferred stock tranche liabilities have been valued as freestanding financial instruments because they are freely separately exercisable and are classified as liabilities until exercise or expiration. The Company valued the redeemable convertible preferred stock tranche liability using an option pricing model, which included significant estimates regarding volatility and discount rate.

The Company recorded the initial redeemable convertible preferred stock tranche liability in May 2018 upon the initial close of the Series C redeemable convertible preferred stock financing. The fair value of the second tranche of the Series C redeemable convertible preferred stock tranche liability was determined to be approximately \$4.6 million.

As of December 31, 2018, the Company re-measured the second tranche of the Series C redeemable convertible preferred stock tranche liability and determined its fair value was approximately \$3.2 million. During 2018, the Company recorded the decrease in the fair value of \$1.4 million as other income in the statements of operations and comprehensive loss.

The Company re-measured the tranche liability associated with the second tranche of Series C redeemable convertible preferred stock during 2019 and immediately prior to the closing of the tranche in December 2019 and recorded the \$3.2 million decrease in the fair value as other income in the statements of operations and comprehensive loss.

The significant rights, privileges, and preferences of the Company's redeemable convertible preferred stock are as follows:

**Dividends**—The holders of Series A, Series B and Series C redeemable convertible preferred stock are entitled to receive noncumulative dividends at the rate of 8% per share of the original issuance price, when, as and if declared by the Board of Directors. Any additional dividends set aside or paid in any fiscal year shall be set aside or paid among the holders of the redeemable convertible preferred stock and common stock in proportion to the greatest whole number of shares of common stock, which would be held by each such holder if all shares of redeemable convertible preferred stock were converted at the then-effective conversion rate. No dividends were declared and payable in the years ended December 31, 2018 and 2019.

**Liquidation Rights**—In the event of any liquidation, dissolution, or winding-up of the Company, including a merger, acquisition, or sale of assets, as defined in the certificate of incorporation, each holder of Series A redeemable convertible preferred stock is entitled to receive a liquidation preference amount equal to \$2.56 per share plus any dividends declared but unpaid, each holder of Series B redeemable convertible preferred stock is entitled to receive a liquidation preference amount equal to \$5.2535 per share plus any dividends declared but unpaid, and each holder of Series C redeemable convertible preferred stock is entitled to receive a liquidation preference amount equal to \$6.8296 per share plus any dividends declared but unpaid. After the payment of the full liquidation preference to holders of redeemable convertible preferred stock, the remaining assets of the Company legally available for distribution shall be distributed with equal priority and pro rata among the holders of Series A redeemable convertible preferred stock, Series B redeemable convertible preferred stock, Series C redeemable convertible preferred stock and common stock; provided that the aggregate distributions made to the holders of Series A redeemable convertible preferred stock shall not exceed an amount equal to \$3.84 per share (one and one half times the liquidation preference) plus any dividends declared but unpaid, provided that the aggregate distributions made to the holders of Series B redeemable convertible

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preferred stock shall not exceed an amount equal to \$7.88 per share (one and one half times the liquidation preference) plus any dividends declared but unpaid, and provided that the aggregate distributions made to the holders of Series C redeemable convertible preferred stock shall not exceed an amount equal to \$10.24 per share (one and one half times the liquidation preference) plus any dividends declared but unpaid.

**Conversion**—Each share of Series A redeemable convertible preferred stock is convertible, at the option of the holder, at any time after the closing of the second tranche, which occurred in July 2016, into that number of fully paid, non-assessable shares of common stock determined by dividing the original issue price by the conversion price. The redeemable convertible preferred stock will also be converted automatically into shares of common stock at the then applicable conversion rate (a) immediately prior to the closing of a firm commitment underwritten initial public offering of the Company's common stock, registered under the Securities Act of 1933, as amended, in which the offering price is not less than \$7.68 per share, which results in aggregate proceeds in excess of \$40.0 million, and the Company is listed for trading on the New York Stock Exchange, the Nasdaq Stock Market or another international exchange of similar stature, or (b) upon the receipt by the Company of a written request for such conversion from the holders of at least 55% of redeemable convertible preferred stock then outstanding. Upon the issuance of the Series C redeemable convertible preferred stock in May 2018, the conversion option was amended in the Amended and Restated Certificate of Incorporation to be the same as the conversion option under the Series C redeemable convertible preferred stock below.

Each share of Series B redeemable convertible preferred stock is convertible, at the option of the holder at any time after the closing of the second tranche, which occurred in May 2018, into that number of fully paid, non-assessable shares of common stock determined by dividing the original issue price by the conversion price. The redeemable convertible preferred stock will also be converted automatically into shares of common stock at the then applicable conversion rate (a) immediately prior to the closing of a firm commitment underwritten initial public offering of the Company's common stock, registered under the Securities Act of 1933, as amended, in which the offering price is not less than \$15.76 per share, which results in aggregate proceeds in excess of \$40.0 million, and the Company is listed for trading on the New York Stock Exchange, the Nasdaq Stock Market or another international exchange of similar stature, or (b) upon the receipt by the Company of a written request for such conversion from the holders of at least 55% of redeemable convertible preferred stock then outstanding. Upon the issuance of the Series C redeemable convertible preferred stock in May 2018, the conversion option was amended in the Amended and Restated Certificate of Incorporation to be the same as the conversion option under the Series C redeemable convertible preferred stock below.

Each share of Series C redeemable convertible preferred stock is convertible, at the option of the holder at any time on a one-for-one basis, subject to standard adjustments. Upon the election of holders of a Preferred Majority (as defined herein), all of the shares of redeemable convertible preferred stock shall automatically convert into common stock at the then applicable conversion prices. Preferred Majority shall mean: (i) on any date prior to the consummation of the Second Closing, the holders of at least 67% of the outstanding shares of the redeemable convertible preferred stock, voting together as a single class on an as-converted basis; and (ii) on any date on or following the Second Closing, the holder of at least 60% of the outstanding shares of the redeemable convertible preferred stock, voting together as a single class on an as-converted basis. In addition, the redeemable convertible preferred stock will automatically convert into shares of common stock at the then applicable conversion rate (i) immediately prior to a Qualified IPO event, with such "Qualified IPO" event meaning the Company's first underwritten offering to the public, provided that either (a) the aggregate gross proceeds to the Company exceed \$50.0 million, at a price per share of not less than \$13.66 (appropriately adjusted for stock splits, stock dividends, or other subdivisions or combinations of Common Stock) and the Company's common stock is listed for trading on the New York Stock Exchange, the Nasdaq Stock Market or such other international exchange of equal stature, including, without limitation, the Alternative Investment Market of the London Stock Exchange or Euronext Paris, S.A or (b) the public offering is approved by the Preferred Majority, or (ii) upon the receipt by the Company of a written request for such conversion from the Preferred Majority of the holders of the redeemable convertible preferred stock then outstanding.

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**Voting Rights**—Except for certain matters or as required by law, the holders of redeemable convertible preferred stock and the holders of common stock shall vote together and not as separate classes. Each holder of redeemable convertible preferred stock shall be entitled to the number of votes equal to the number of shares of common stock into which the shares of redeemable convertible preferred stock could be converted as of the record date. Fractional shares shall not be permitted.

Certain protective provisions, such as any actions that could adversely affect the redeemable convertible preferred stock, alter the capital structure, increase or decrease the size of the Company’s Board of Directors, or effect any liquidation event, shall require approval of at least 67% of the outstanding shares of redeemable convertible preferred stock, voting as a single class on an as-converted basis.

Each of the Series A redeemable convertible preferred stockholders, the Series B redeemable convertible preferred stockholders, and the common stockholders, voting as a separate class, shall be entitled to elect two members of the Company’s Board of Directors. The Series C redeemable convertible preferred stockholders, voting as a separate class, shall be entitled to elect one member of the Company’s Board of Directors. Any additional members of the Company’s Board of Directors shall be elected by the holders of redeemable convertible preferred stock and common stock, voting together as a single class on an as-converted basis.

**Redemption Features**—Upon the occurrence of certain change in control events that are outside the Company’s control, including liquidation, sale or transfer of the Company, holders of the redeemable convertible preferred stock can effectively cause redemption for cash. As a result, the Company has classified the redeemable convertible preferred stock as mezzanine equity on the balance sheets as the stock is contingently redeemable.

The Company has elected not to adjust the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of redeemable convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a liquidation event will occur.

## 9. Common Stock

At December 31, 2018 and 2019, the Company’s certificate of incorporation authorizes the Company to issue up to 52,000,000 shares of common stock with \$0.001 par value per share. As of December 31, 2018 and 2019, 6,338,763 and 6,849,118 shares were issued and outstanding, respectively. The holders of common stock are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. As of December 31, 2018 and 2019, no dividends have been declared to date. Each share of common stock is entitled to one vote.

At December 31, 2018 and 2019, the Company had reserved common stock for future issuances under the 2014 Equity Incentive Plan (the “2014 Plan”) and shares issued outside of the 2014 Plan as follows:

	December 31,	
	2018	2019
Options issued and outstanding	5,117,067	5,676,107
Shares available for future stock option grants	2,479,525	1,410,130
Conversion of redeemable convertible preferred stock	28,175,226	34,398,138
Common stock warrant	53,744	53,744
Redeemable convertible preferred stock warrant	100,000	100,000
Total	35,925,562	41,638,119

## 10. Warrants

Warrants issued and outstanding as of December 31, 2018 and 2019 were as follows:

<u>Warrants to Purchase Stock</u>	<u>Number of Warrants Outstanding</u>	<u>Issue Date</u>	<u>Expiration Date</u>	<u>Exercise Price</u>
Common stock	53,744	July 10, 2015	July 10, 2025	\$ 0.47
Series C redeemable convertible preferred stock	100,000	May 29, 2018	May 29, 2028	\$ 6.83
<b>Total</b>	<b>153,744</b>			

On July 10, 2015, the Company issued a warrant to Sutro Biopharma, Inc. (“Sutro Biopharma”) (Note 15) to purchase 53,744 shares of its common stock that is exercisable immediately. The warrant expires the earlier of (i) July 10, 2025, (ii) the occurrence of a deemed liquidation event, or (iii) immediately prior to the closing of a firm commitment underwritten initial public offering of the Company’s common stock registered under the Securities Act of 1933, as amended. The warrant will be automatically net share settled prior to expiration based on the fair market value on the date of exercise.

On May 29, 2018, the Company issued a warrant to Sutro Biopharma (Note 15) to purchase 100,000 shares of its Series C redeemable convertible preferred stock that is exercisable immediately. The warrant expires the earlier of (i) May 29, 2028, (ii) the occurrence of a deemed liquidation event, or (iii) immediately prior to the closing of a firm commitment underwritten initial public offering of the Company’s common stock registered under the Securities Act of 1933, as amended. The warrant will be automatically net exercised prior to expiration based on the fair market value on the date of exercise.

## 11. Equity Incentive Plans

In January 2014, the Company adopted the 2014 Plan, which provides for the granting of incentive stock options and nonqualified stock options to employees, consultants, and directors. The 2014 Plan also provides for the granting of stock appreciation rights, restricted stock, and restricted stock units. The Company has not granted any restricted stock or restricted stock units to date. The Company grants stock options to purchase its common stock, generally at fair value as of the date of grant. Options generally vest over a period of up to four years and expire after 10 years from the date of grants. The 2014 Plan is expected to terminate in July 2025. The Company also granted options to purchase 113,000 shares of common stock outside of the 2014 Plan during January 2014 and September 2016. The Company has not granted any options outside of the 2014 Plan since September 2016.

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Activity under the Company's 2014 Plan, which excludes options to purchase 113,000 shares granted outside of the 2014 Plan, is as follows:

<u>Stock Option Activity</u>	<u>Options Available for Grant</u>	<u>Number of Options</u>	<u>Options Outstanding</u>		<u>Aggregate Intrinsic Value (in thousands)</u>
			<u>Weighted-Average Exercise Price Per Share</u>	<u>Weighted-Average Remaining Contractual Term (in years)</u>	
Balances—December 31, 2017	837,983	3,468,620	\$ 0.89		
Additional Shares Authorized	3,322,355	—			
Options Granted	(2,728,264)	2,728,264	\$ 1.19		
Options Exercised	—	(145,366)	\$ 0.88		
Options Forfeited	1,047,451	(1,047,451)	\$ 0.39		
Balances—December 31, 2018	2,479,525	5,004,067	\$ 1.06		
Options Granted	(1,497,510)	1,497,510	\$ 1.29		
Options Exercised	—	(510,355)	\$ 0.86		
Options Forfeited	428,115	(428,115)	\$ 1.07		
Balances—December 31, 2019	1,410,130	5,563,107	\$ 1.14	8.29	\$ 1,607
Vested and expected to vest		5,563,107	\$ 1.14	8.29	\$ 1,607
Exercisable		2,514,754	\$ 1.04	7.55	\$ 969

During the years ended December 31, 2018 and 2019, 145,366 and 510,355 shares of stock options were exercised for cash at a weighted-average price per share of \$0.88 and \$0.86, respectively. Weighted-average grant date fair value of options granted in 2018 and 2019 are \$0.82 and \$0.90, respectively. The intrinsic value of the stock options exercised was immaterial for the year ended December 31, 2018 and \$0.3 million for the year ended December 31, 2019.

The following table summarizes information about stock options outstanding as of December 31, 2019.

<u>Exercise Price</u>	<u>Options Outstanding</u>		<u>Options Exercisable</u>	
	<u>Number Outstanding</u>	<u>Weighted-Average Remaining Contractual Term (in years)</u>	<u>Number Exercisable</u>	<u>Weighted-Average Exercise Price</u>
0.02	31,500	4.1	31,500	\$ 4.082
0.02	82,385	0.3	82,385	\$ 0.314
0.47	64,063	6.0	57,813	\$ 5.958
0.76	127,084	7.0	54,061	\$ 7.001
1.06	1,620,513	7.5	1,409,369	\$ 7.449
1.20	2,816,812	8.7	846,932	\$ 8.603
1.25	289,000	9.4	4,444	\$ 9.599
1.43	531,750	10.0	28,250	\$ 9.960
	5,563,107		2,514,754	

### Early Exercise of Stock Options

The terms of the 2014 Plan permit the exercise of options granted prior to vesting, subject to required approvals. The unvested shares are subject to the Company's lapsing repurchase right upon termination of

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employment at the original purchase price. The repurchase right lapses in 90 days after the termination of the employee's employment. Shares purchased by employees pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be issued until those shares vest according to their respective vesting schedules. Cash received for early exercised stock options is recorded as other liabilities on the balance sheet and is reclassified to common stock and additional paid-in capital as such shares vest.

At December 31, 2018 and 2019, 156,801 and 145,770 shares, respectively, remained subject to the Company's right of repurchase as a result of the early exercised stock options. The remaining liability related to early exercised shares as of both December 31, 2018 and 2019 was \$0.2 million and was recorded in accrued expenses and other liabilities in the balance sheets.

### **Stock-Based Compensation**

The Company estimated the fair value of employee stock options granted during 2018 and 2019 using the Black-Scholes option-pricing model at the date of grant with the following assumptions:

	Year Ended December 31,	
	2018	2019
Expected volatility	77.0% - 78.2%	78.4% - 80.4%
Expected dividend yield	0%	0%
Expected term (in years)	5.8 - 6.1	5.9 - 6.1
Risk-free interest rate	2.6% - 2.9%	1.6% - 2.4%

The Company has recorded aggregate stock-based compensation expense for 2018 and 2019 related to the issuance of stock option awards to employees and non-employees in the statements of operations and comprehensive loss as follows:

	Year Ended December 31,	
	2018	2019
	(in thousands)	
Research and development expenses	\$ 274	\$ 368
General and administrative expenses	475	817
Total stock-based compensation expense	<u>\$ 749</u>	<u>\$ 1,185</u>

Stock-based compensation expense for employees was \$0.7 million and \$1.1 million for the years ended December 31, 2018 and 2019, respectively.

Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned in exchange for services performed. The Company determined that the estimated fair value of the stock options is more readily measurable than the fair value of the services received. The fair value of stock options granted to non-employees is calculated at each grant date and re-measured at each reporting date using the Black-Scholes option pricing model. The stock-based compensation expense related to a grant will fluctuate as the estimated fair value of the common stock fluctuates over the period from the grant date to the vesting date (i.e., the measurement date). Stock-based compensation expense for non-employees was immaterial for the years ended December 31, 2018 and 2019.

As of December 31, 2019, there was \$2.8 million of unrecognized stock-based compensation expense related to the employee and nonemployee awards, which is expected to be recognized over a weighted-average period of 1.3 years.

## **12. Funding Arrangement**

In July 2019, the Company received a cost reimbursement research award from Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator ("CARB-X"), a public-private partnership funded by the

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Biomedical Advanced Research and Development Authority (“BARDA”) within the U.S. Department of Health and Human Services. In connection with this funding, the Company entered into a cost reimbursement sub-award agreement with the Trustees of Boston University, the administrator of the program. The award will provide funding over four years to develop a universal vaccine to prevent infections caused by Group A Strep bacteria, which include pharyngitis, impetigo, and necrotizing fasciitis. The award commits initial funding of up to \$1.6 million and up to \$15.1 million in total funding available upon achievement of development milestones over the next four years. Specified research expenditures are the reimbursable expenses associated with agreed-upon activities needed to advance the research project supported by the grant. These expenditures can include labor, laboratory supplies, travel, consulting and third-party vendor research and development support costs.

Income from grants is recognized in the period during which the related specified expenses are incurred, provided that the conditions under which the grants were provided have been met. Grant income of \$0.2 million was recognized under this award and recorded in Other income (expense), net in the statement of operations and comprehensive loss for the year ended December 31, 2019. A related receivable of \$0.2 million representing unreimbursed, eligible costs incurred under the CARB-X agreement was recorded and included in prepaid expenses and other current assets in the balance sheet as of December 31, 2019.

### 13. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders which excludes shares which are legally outstanding, but subject to repurchase by the Company (in thousands, except share and per share data):

	<u>2018</u>	<u>2019</u>
Net loss attributable to common stockholders	\$ (29,485)	\$ (50,274)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	<u>6,142,274</u>	<u>6,402,359</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (4.80)</u>	<u>\$ (7.85)</u>

The following potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the period presented because including them would have been antidilutive:

	<u>2018</u>	<u>2019</u>
Stock options	5,117,067	5,676,107
Redeemable convertible preferred stock:		
Series A	10,502,804	10,502,804
Series B	11,449,510	11,449,510
Series C	6,222,912	12,445,824
Common stock warrant	53,744	53,744
Redeemable convertible preferred stock warrant	<u>100,000</u>	<u>100,000</u>
Total	<u>33,446,037</u>	<u>40,227,989</u>

### Unaudited Pro Forma Net Loss Per Share

The unaudited pro forma basic and diluted net loss per share for the year ended December 31, 2019 has been computed to give effect to (i) the conversion of all outstanding shares of redeemable convertible preferred stock into shares of common stock, (ii) the net exercise of redeemable convertible preferred stock warrant and common stock warrant into shares of common stock (see Note 2), as of the beginning of the period or the date of



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issuance, if later, and (iii) the removal of gains or losses resulting from the re-measurement of the redeemable convertible preferred stock warrant liability as the warrants will be net exercised for shares of common stock immediately prior to the closing of this offering. Stock-based compensation expense associated with the vesting of the service and performance-based awards is excluded from the pro forma net loss basic and diluted per share presentation.

The following table sets forth the computation of the unaudited pro forma net loss per share (in thousands, except share and per share data):

	<b>Year Ended December 31, 2019</b>
Net loss attributable to common stockholders	\$ (50,274)
Pro forma adjustment to reflect the removal of gains or losses resulting from the re-measurement of the redeemable convertible preferred stock warrant liability	
Pro forma net loss	
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	6,402,359
Pro forma adjustment to reflect the conversion of redeemable convertible preferred stock	
Pro forma adjustment to reflect the net exercise of the redeemable convertible preferred stock warrant	
Pro forma adjustments to reflect the net exercise of the common stock warrant	
Pro forma weighted-average shares outstanding used in computing pro forma net loss per share, basic and diluted	—
Pro forma net loss per share, basic and diluted	—

## 14. Income Taxes

The Company's pre-tax book loss was derived from its business operations within the United States. The tax provision for the years ended December 31, 2018 and December 31, 2019 consists of immaterial amounts of current state taxes.

A reconciliation of the Company's effective tax rate to the statutory U.S. federal rate is as follows:

	<b>Year Ended December 31,</b>	
	<b>2018<sup>(1)</sup></b>	<b>2019</b>
Statutory Rate	21.0%	21.0%
State Tax	0.0%	0.0%
Change in FV of Tranche Liability	3.8%	1.3%
Credits	0.6%	(0.5)%
Stock Compensation	(0.5)%	(0.4)%
Other	(0.7)%	0.4%
Change in valuation allowance	(24.2)%	(21.8)%
Total	0.0%	0.0%

(1) The 2018 effective tax rate reconciliation has been updated to conform to the 2019 presentation.

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Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of the assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The following table presents significant components of the Company's deferred tax assets as of December 31, 2018 and 2019:

	December 31,	
	2018	2019
	(in thousands)	
Depreciation and amortization	\$ 419	\$ 379
Accrued expenses and reserves	563	1,338
Net operating loss carryforwards	18,390	25,582
Research credit carryforwards	475	872
Total	19,847	28,171
Valuation allowance	(19,847)	(28,171)
Net deferred tax assets	\$ —	\$ —

At December 31, 2019, the Company has net operating loss carryforwards of approximately \$110.9 million and \$28.0 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. The federal and state net operating loss carryforwards, except the federal loss carryforward arising in tax years beginning after December 31, 2017, begin to expire in 2034 unless previously utilized. Federal net operating losses arising in tax years beginning after December 31, 2017 have an indefinite carryover period and do not expire. Pursuant to the Tax Cuts and Jobs Act (the "Tax Act"), utilization of federal net operating loss carryforwards generated after 2017 is limited to 80% of taxable income.

At December 31, 2019, the Company has research credit carryforward of \$0.1 million and \$1.1 million available to offset future income tax liabilities, if any, for federal and California income tax purposes, respectively. The California tax credits can be carried forward indefinitely.

The Company has evaluated the positive and negative evidences bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2018 and 2019.

Utilization of the net operating loss carryforward and research credit carryforward may be subject to an annual limitation due to the ownership percentage change limitations under Section 382 and Section 383, respectively, provided by the Internal Revenue Code of 1986, as amended (the "Code"), and similar state provisions. The annual limitation may result in the expiration of the net operating loss before utilization. The Company has experienced ownership changes in the past. As a result of the ownership changes, the Company has determined that approximately \$1.3 million of its federal research credits will expire unutilized, and such amounts are excluded from its research credit carryforwards as of December 31, 2019. Subsequent ownership changes may affect the limitation in future years.

The Company has uncertain tax benefits ("UTBs") totaling \$0.4 million and \$0.3 million as of December 31, 2018 and 2019, respectively, which were netted against deferred tax assets subject to valuation allowance. The UTBs had no effect on the effective tax rate. The Company recognizes interest and penalties related to UTBs, when they occur, as a component of income tax expense. To the extent accrued interest and penalties do not ultimately become payable, amounts accrued will be reduced and reflected as a reduction of the provision for income taxes in the period such determination is made. There were no interest or penalties recognized for the years ended December 31, 2018 and 2019. The Company does not expect its UTBs to change significantly over the next 12 months.

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A reconciliation of the beginning and ending unrecognized tax benefit amount is as follows:

	<u>December 31,</u>	
	<u>2018</u>	<u>2019</u>
	(in thousands)	
Balance at the beginning of the year	\$119	\$ 408
Additions based on tax positions related to current year	228	217
Adjustments based on tax positions related to prior years	61	(354)
Balance at end of year	<u>\$408</u>	<u>\$ 271</u>

The Company files U.S. federal and state tax returns. The Company is generally subject to tax examinations for federal and state tax purposes. The Company does not have any tax audits or other issues pending.

On December 22, 2017, the U.S. government enacted the Tax Act, which significantly revised the Code. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, generally eliminating U.S. federal income taxes on dividends from foreign subsidiaries, requiring a current inclusion in the U.S. federal taxable income of certain earnings of controlled foreign corporations, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. The Company adjusted its deferred tax balances to reflect the expected rate of 21%.

In conjunction with the tax law changes, the SEC staff issued Staff Accounting Bulletin 118, or SAB 118, to address the application of U.S.GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In March 2018, Accounting Standards Codification, or ASC, 740, *Income Taxes*, was amended to incorporate the provisions of SAB 118. In these instances, a company can record provisional amounts in its financial statements for the income tax effects for which a reasonable estimate can be determined. For items for which a reasonable estimate cannot be determined, a company should continue to apply ASC 740 based on the provisions of the tax laws that were in effect immediately prior to the Tax Act being enacted. The Company has recognized a net tax benefit of \$0 for the provisional tax impacts related to the revaluation of deferred tax balances and included this estimate in its financial statements for the year ended December 31, 2017. In the fourth quarter of 2018, the Company completed its analysis to determine the effect of the Tax Act. No adjustments were recorded based on the completion of the analysis as of December 31, 2018.

## 15. Related Party Transactions

The Company has an ongoing relationship with Sutro Biopharma. In 2013, Sutro Biopharma provided the initial funding for the establishment of the Company. As of December 31, 2019, Sutro Biopharma owned approximately 2.7 million shares of the Company's common stock, a warrant to purchase 53,744 shares of the Company's common stock and a warrant to purchase 100,000 shares of the Company's Series C redeemable convertible stock. In the agreements and amendments identified herein, the Company licensed certain intellectual property and acquired certain supply rights from Sutro Biopharma, including the right to use the XpressCF platform to discover and develop vaccine candidates for the treatment or prophylaxis of infectious diseases. On October 12, 2015, SutroVax and Sutro Biopharma ("the Parties") entered into the Sutro Biopharma License Agreement, which amended and restated an agreement dated August 1, 2014. The Sutro Biopharma License Agreement was subsequently amended on May 9, 2018 ("License Amendment A1") and May 29, 2018 ("License Amendment A2"). The Company also entered into a separate supply agreement with Sutro Biopharma on May 29, 2018 (the "Sutro Biopharma Supply Agreement").

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Under the Sutro Biopharma License Agreement, Sutro Biopharma granted the Company an exclusive, worldwide license to research, develop, manufacture and commercialize vaccine products addressing infectious disease, which are discovered or produced based on the use of Sutro Biopharma's proprietary cell-free protein expression technology, known as XpressCF which utilizes extracts derived from strains of *E. Coli*. In connection with the Sutro Biopharma License Agreement, under the Sutro Biopharma Supply Agreement Sutro Biopharma has agreed to manufacture and supply extracts and reagents for the Company on a cost plus basis. In consideration for the rights licensed, the Company is obligated to pay a 4% royalty on worldwide aggregate annual net sales of its vaccine products for human health and a 2% royalty on such net sales of vaccine compositions for animal health. The Company's obligation to pay single-digit royalties to Sutro Biopharma expires on a country-by-country basis on the later of the expiration of the last to expire patent covering the manufacture, use, offer for sale or importation of the applicable vaccine product and ten years from first commercial sale of the applicable vaccine product. In addition, for a certain period of time, if the Company grants a sublicense to a third party to further develop or sell a vaccine product discovered or generated by SutroVax, SutroVax is obligated to pay Sutro Biopharma a percentage, in the low-double digits of any net sublicensing revenue received for sublicense agreements executed before July 2020. The Company's obligation to pay sublicense fees to Sutro Biopharma expires in July 2020.

In License Amendment A1, the Parties amended the license agreement to remove a pre-IND regulatory meeting as a diligence milestone and to agree that certain other diligence milestones had been satisfied. In License Amendment A2, the Parties amended the license agreement to add certain terms confirming the Company's obligation to purchase Sutro Biopharma's proprietary extract from *E. coli* ("Extract") from Sutro Biopharma and precluding the Company from manufacturing Extract. In addition, the Parties amended the license agreement to specify the Company's rights to a transfer of certain know-how relating to the manufacture of Extract in the event of a declaration of bankruptcy by Sutro Biopharma. Finally, the Parties agreed to terms providing for injunctive relief in the event of a breach or threatened breach by the other party.

In the Sutro Biopharma Supply Agreement, the Parties agreed to commercial terms for the supply of manufactured Extract and custom reagents by Sutro Biopharma for the Company to use in manufacturing vaccine compositions in non-clinical research or in Phase 1 or Phase 2 clinical trials. The term of the Sutro Biopharma Supply Agreement is from execution until the later of July 31, 2021, and the date the parties enter into and commence activities under unless extended through a subsequent supply agreement for the supply of Extract and custom reagents for vaccine compositions for Phase 3 and commercial uses as contemplated in the Supply Agreement.

In consideration of the License Amendment A2, the Company issued to Sutro Biopharma a warrant to purchase 100,000 shares of Series C redeemable convertible preferred stock at a purchase price of \$6.8296 per share. This warrant is exercisable and vests immediately and expires on May 29, 2028.

The Company recognized expenses of approximately \$1.4 million and \$1.1 million related to the Supply Agreement for the years ended December 31, 2018 and 2019, respectively. The Company also recognized the fair value related to the warrant issued to Sutro Biopharma of approximately \$0.5 million at the time of issuance in 2018. The Company recorded immaterial changes in the fair value for the warrant in both 2018 and 2019. The expense related to the warrant, as well as the changes in the fair value of the warrant, is included in research and development expenses in the statements of operations and comprehensive loss. The Company recorded immaterial amounts of accrued expenses payable to Sutro Biopharma as of both December 31, 2018 and 2019.

## **16. Subsequent Events**

The Company has reviewed all events occurring from December 31, 2019 through March 13, 2020, which is the date the financial statements were available for issuance.

Through and including \_\_\_\_\_, 2020 (the 25th day after the date of this prospectus) all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

## Shares



## Common Stock

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### PROSPECTUS

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**BofA Securities**

**Jefferies LLC**

**Evercore ISI**

**Cantor**

**Needham & Company**

, 2020

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**Part II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the SEC registration fee, the Financial Industry Regulatory Authority, Inc. (FINRA) filing fee and the exchange listing fee.

	<b>Amount Paid or to Be Paid</b>
SEC registration fee	\$ *
FINRA filing fee	*
Exchange listing fee	*
Accountants' fees and expenses	*
Legal fees and expenses	*
Transfer Agent's fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
<b>Total expenses</b>	<b>\$ *</b>

\* To be provided by amendment.

**Item 14. Indemnification of Directors and Officers.**

Section 145 of the Delaware General Corporation Law 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. Our amended and restated certificate of incorporation that will be in effect upon the closing of this offering permits indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law, 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 Delaware General Corporation Law.

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 SutroVax, 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 SutroVax, Inc. At present, there is no pending litigation or proceeding involving a director or officer of SutroVax, 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 Exchange Act that might be incurred by any director or officer in his or her capacity as such.

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

Since January 1, 2017, we have issued the following unregistered securities:

- (1) We granted to certain employees, consultants and directors options to purchase an aggregate of 7,431,143 shares of our common stock at exercise prices ranging from \$0.76 to \$2.21 per share.
- (2) We issued an aggregate of 918,820 shares of our common stock upon the exercise of options, at exercise prices ranging from \$0.02 to \$1.43 per share, for an aggregate exercise price of approximately \$830,655.
- (3) We issued a warrant to purchase an aggregate of 100,000 shares of Series C convertible preferred stock (convertible into 100,000 shares of common stock) in May 2018 to a strategic partner at an exercise price of \$6.8296 per share.
- (4) We issued an aggregate of 6,222,912 shares of Series C convertible preferred stock (convertible into 6,222,912 shares of common stock) in December 2019 to 12 accredited investors at a price of \$6.8296 per share for aggregate consideration of approximately \$42.5 million.
- (5) We issued an aggregate of 6,222,912 shares of Series C convertible preferred stock (convertible into 6,222,912 shares of common stock) in May 2018 to 13 accredited investors at a price of \$6.8296 per share for aggregate consideration of approximately \$42.5 million.
- (6) We issued an aggregate of 11,449,510 shares of Series B convertible preferred stock (convertible into 11,449,510 shares of common stock) between March 2017 and May 2018 to nine accredited investors at a price of \$5.2535 per share for aggregate consideration of approximately \$60.1 million.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

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

(a) Exhibits.

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
1.1*	Form of Underwriting Agreement.
3.1#	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.
3.2#	Amended and Restated Bylaws of the Registrant, as currently in effect.
3.3*	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect prior to the closing of this offering.
3.4*	Form of Amended and Restated Bylaws of the Registrant, to be in effect prior to the closing of this offering.
4.1*	Form of common stock certificate of the Registrant.
5.1*	Opinion of Cooley LLP.

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<u>Exhibit Number</u>	<u>Description of Exhibit</u>
10.1*	Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated May 29, 2018.
10.2#	SutroVax, Inc. Amended and Restated 2014 Equity Incentive Plan and forms of agreements thereunder.
10.3*	SutroVax, Inc. 2020 Equity Incentive Plan and forms of agreements thereunder.
10.4*	SutroVax, Inc. 2020 Employee Stock Purchase Plan and forms of agreements thereunder.
10.5*	Form of Indemnification Agreement entered into by and between the Registrant and each director and executive officer.
10.6*	Amended and Restated Executive Employment Agreement entered into by and between the Registrant and Grant Pickering, dated , 20 .
10.7*	Amended and Restated Executive Employment Agreement entered into by and between the Registrant and Jeff Fairman, dated , 20 .
10.8*	Amended and Restated Executive Employment Agreement entered into by and between the Registrant and Paul Sauer, dated 20 .
10.9*	Executive Employment Agreement entered into by and between the Registrant and Elaine Sun, dated January 1, 2017.
10.10*	Separation Agreement and Release entered into by and between the Registrant and Elaine Sun, dated December 17, 2019.
10.11*	Executive Employment Agreement entered into by and between the Registrant and Jim Wassil, dated November 15, 2019.
10.12*	Amended and Restated Executive Employment Agreement entered into by and between the Registrant and Jane Wright-Mitchell, dated , 20 .
10.13*	Amended and Restated Executive Employment Agreement entered into by and between the Registrant and Jim Wassil, dated 20 .
10.14+#	Development and Manufacturing Services Agreement by and between the Registrant and Lonza Ltd, dated October 29, 2018.
10.15+#	Development and Manufacturing Services Agreement by and between the Registrant and Lonza Ltd, dated October 21, 2016, as amended.
10.16+#	Letter Agreement by and between the Registrant and Lonza Ltd, dated June 19, 2018.
10.17+#	Amended and Restated SutroVax Agreement by and between the Registrant and Sutro Biopharma, Inc., dated October 12, 2015, as amended.
10.18+#	Supply Agreement by and between the Registrant and Sutro Biopharma, Inc., dated May 29, 2018.
10.19+#	License Agreement by and between the Registrant and The Regents of the University of California, represented by its San Diego campus, dated February 4, 2019.
10.20#	Lease Agreement by and among the Registrant, Grey Peak Fork, LLC and Grey Peak Fork, Series A, LLC, dated July 22, 2016.
10.21#	Assignment and Assumption of Lease and Consent of Lessor by and among the Registrant, Orchard Therapeutics North America and Rakesh Kumar and Premila Kumar Revocable Family Trust, dated July 1, 2019.
10.22#	Third Addendum to Standard Multi-Tenant Office Lease by and between the Registrant and Rakesh Kumar and Premila Kumar Revocable Family Trust, dated July 1, 2019.



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<u>Exhibit Number</u>	<u>Description of Exhibit</u>
23.1*	Consent of Deloitte & Touche LLP, 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.  
# Previously filed.  
+ Certain portions of this agreement have been omitted because the omitted portions are both not material and would likely cause competitive harm if publicly disclosed.

(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.**

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.

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 SEC 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.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant under Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Foster City, State of California, on \_\_\_\_\_, 2020.

### SUTROVAX, INC.

By: \_\_\_\_\_  
Grant E. Pickering  
President and Chief Executive Officer

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Grant E. Pickering and Jane Wright-Mitchell, 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 or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, 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>
_____ Grant E. Pickering	President, Chief Executive Officer and Director <i>(Principal Executive and Principal Financial Officer)</i>	, 2020
_____ Mandy Wong	Controller <i>(Principal Accounting Officer)</i>	, 2020
_____ Moncef Slaoui, Ph.D.	Director	, 2020
_____ Kurt von Emster	Director	, 2020
_____ Patrick Enright	Director	, 2020
_____ Patrick Heron	Director	, 2020
_____ Peter Hirth, Ph.D.	Director	, 2020

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<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Rob Hopfner, Ph.D.	Director	, 2020
_____ Heath Lukatch, Ph.D.	Director	, 2020
_____ William J. Newell	Director	, 2020