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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

For the transition period from _____ to _____

Commission File Number 001-39323

VAXCYTE, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**46-4233385**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
825 Industrial Road, Suite 300	
San Carlos, California	**94070**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 837-0111

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	PCVX	The Nasdaq Stock Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of its Common Stock on the Nasdaq Global Select Market on June 30, 2025, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $3.7 billion. Shares of the Registrant's common stock held by each executive officer, director and holder of 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose.

The number of shares of Registrant's Common Stock outstanding as of February 20, 2026 was 143,920,361.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates information by reference from the registrant's definitive proxy statement to be filed with the U.S. Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in connection with the registrant's 2025 annual meeting of stockholders.

Table of Contents

All references in this Annual Report on Form 10-K to "we," "us," "our," "the Company" and "Vaxcyte" refer to Vaxcyte, Inc. and our wholly-owned consolidated subsidiary, or, as the context may require, Vaxcyte, Inc. only.

"Vaxcyte," "eCRM," and other trademarks of ours appearing in this Annual Report on Form 10-K are our property. This Annual Report on Form 10-K contains additional trade names and trademarks of other companies. We do not intend our use or display of other companies' trade names or trademarks to imply an endorsement or sponsorship of us by such companies, or any relationship with any of these companies.

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K 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 Annual Report on Form 10-K, including statements regarding our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, 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," "seek," "should," "target," "will," or "would," or the negative of these words or other similar terms or expressions. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our expectations regarding the potential benefits, spectrum of coverage and immunogenicity of our vaccine candidates;
- our expectations regarding our preclinical study results and prior clinical study results potentially being predictive of future clinical study results;
- the timing of the initiation, progress and potential 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 future 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 and our third-party manufacturers' manufacturing capabilities and the scalable nature of our manufacturing process;
- potential effects of extensive or changes in government regulation;
- the pricing, coverage and reimbursement of our vaccine candidates, if approved;
- our ability and the ability of our third-party contract manufacturers to operate and continue operations;
- our ability to hire and retain key personnel;
- our ability to obtain additional financing; and
- the volatility of the trading price of our common stock.

Actual events or results may differ from those expressed in forward-looking statements. You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report on Form 10-K 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 titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

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 Annual Report on Form 10-K. 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 Annual Report on Form 10-K. 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K to reflect events or circumstances after the date of this Annual Report on Form 10-K 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.

Summary of Risks Affecting Our Business

Our business is subject to numerous risks and uncertainties, including those discussed more fully in the section titled "Risk Factors" in this Annual Report on Form 10-K. These risks include, but are not limited to, the following:

- We are in the clinical or preclinical stages of vaccine development and have a 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. We currently have no source of product revenue and may never achieve profitability. Our stock is a highly speculative investment.
- We will require substantial additional funding to finance our operations, which may not be available to us on acceptable terms, or at all. 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, require us to modify processes, and make it difficult to predict the time and cost of vaccine candidate development and the timing to apply for and obtain regulatory approvals.
- Our vaccine candidates are in clinical or 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.

- The U.S. Food and Drug Administration ("FDA") may disagree with our regulatory plan, and we may fail to obtain regulatory approval of our vaccine candidates.
- Our business is highly dependent on the success of our pneumococcal conjugate vaccine ("PCV") candidates. If we are unable to successfully develop, obtain approval for and effectively commercialize our PCV candidates, 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 and commercialize 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 products.
- We currently rely on third-party manufacturing and supply partners to supply raw materials and components for, and the manufacture of, our preclinical and clinical supplies as well as our vaccine candidates. Our inability to procure necessary raw materials or to have sufficient quantities of preclinical and clinical supplies or the inability to have our vaccine candidates manufactured, including delays or interruptions at our third-party manufacturers, 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.
- The development, review and approval of our product candidates are subject to the operational capacity, processes and resource levels of regulatory authorities, which may fluctuate over time and could delay or adversely affect our business.
- 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.

PART I

Item 1. Business.

Overview

We are a clinical-stage vaccine innovation company engineering high-fidelity vaccines to protect humankind from the consequences of bacterial diseases. We are re-engineering the way highly complex vaccines are made through the XpressCF™ cell-free protein synthesis platform. Unlike conventional cell-based approaches, our system for producing difficult-to-make proteins and antigens is intended to develop and deliver high-fidelity vaccines with enhanced immunological benefits that are beyond the capabilities of conventional approaches.

Vaccines are one of the most successful and cost-effective global health interventions and prevent millions of deaths worldwide each year. Routine pediatric vaccinations in the United States are estimated to prevent approximately 17 million cases of disease over the lifetimes of each annual birth cohort, and it is estimated that every $1 spent on childhood vaccination results in savings of approximately $11. Adult vaccination has increased with the introduction of new vaccines along with expanded age recommendations and growing international adoption, which is contributing to the growth of the overall vaccine market. Given the critical role vaccines play in preventing disease from childhood through adulthood, the global vaccine market is large, durable and growing. There are areas of significant unmet medical need, including vaccines that can provide broader protection, against both currently circulating and historically prevalent strains, than currently marketed vaccines and novel vaccines that target pathogens for which there are no currently approved vaccines. We are driven to eradicate or treat invasive bacterial infections, which have serious and costly health consequences when left unchecked.

We carefully select our target disease areas and vaccine candidates based on the following criteria: areas of significant unmet medical need, clear commercial opportunity and efficient market adoption, acceptable biological risk and established or acceptable 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 these criteria.

Our pipeline includes:

- PCV candidates that we believe are among the broadest-spectrum PCV candidates currently in development, targeting the approximately $8 billion global pneumococcal vaccine market. Pneumococcal disease ("PD") is an infection caused by *Streptococcus pneumoniae* bacteria. It can result in invasive pneumococcal disease (“IPD”), including meningitis and bacteremia, and non-invasive PD, including pneumonia, otitis media and sinusitis. Our broad-spectrum, carrier-sparing PCV candidates, VAX-31, VAX-24 and VAX-XL, are designed to improve upon standard-of-care PCVs for both adults and children by covering the serotypes that are responsible for increasing portions of IPD in circulation and are associated with high case-fatality rates, antibiotic resistance and meningitis, while maintaining coverage of previously circulating strains that are currently contained through continued vaccination.
    - PCV Franchise Adult Indication:
        - VAX-31 is a 31-valent, broad-spectrum, carrier-sparing investigational PCV being developed for the prevention of IPD and pneumonia. VAX-31 is the broadest-

spectrum PCV in the clinic, and has the potential to provide protection against both currently circulating and historically prevalent serotypes. VAX-31 was designed to increase coverage, in a single vaccine, to approximately 95% of IPD and approximately 88% of pneumococcal pneumonia circulating in adults in the United States aged 50 and older, with the potential to provide an incremental 14-34% of coverage for IPD and an incremental 19-31% of coverage for pneumococcal pneumonia over current standard-of-care adult PCVs.

- In September 2024, we announced positive topline results from a Phase 1/2 study of VAX-31 in adults. The VAX-31 Phase 1/2 clinical study was a randomized, observer-blind, active-controlled, dose-finding clinical study designed to evaluate the safety, tolerability and immunogenicity of a single injection of VAX-31 at three dose levels (Low, Middle and High) and compared to Prevnar 20® ("PCV20") in 1,015 healthy adults aged 50 and older. In the Low, Middle and High Doses, all serotypes were dosed at 1.1mcg, 2.2mcg and 3.3mcg, respectively, except serotypes 1, 5 and 22F, which were dosed at 1.65mcg, 3.3mcg, and 4.4mcg, respectively. The Phase 1 portion of the study included 64 healthy adults 50 to 64 years of age and the Phase 2 portion included 951 healthy adults 50 years of age and older. The immunogenicity objectives of the study included an assessment of the induction of antibody responses at Month 1, based on opsonophagocytic activity (“OPA”) and immunoglobulin G ("IgG"), at each of the three VAX-31 doses and compared to PCV20 for the 20 serotypes in common, as well as for the additional 11 serotypes contained in VAX-31, but not in PCV20.

  In the Phase 1/2 study, VAX-31 was observed to be well tolerated and demonstrated a safety profile at all doses studied through the full six-month evaluation period similar to PCV20. VAX-31 showed robust OPA immune responses for all 31 serotypes at all doses studied. At the Middle and High Doses, VAX-31 met or exceeded the regulatory immunogenicity criteria for all 31 serotypes and, at the Low Dose, for 29 of 31 serotypes. At the VAX-31 High Dose, average OPA immune responses were greater for 18 of 20 serotypes compared to PCV20 (geometric mean ratio (“GMR”) greater than 1.0), with seven of these serotypes achieving statistically higher immune responses compared to PCV20. At the Middle Dose, 13 of 20 serotypes had a GMR greater than 1.0 and five serotypes achieved statistically higher immune responses compared to PCV20. At the Low Dose, 18 of 20 serotypes met the OPA response non-inferiority criteria, 8 of 20 serotypes had a GMR greater than 1.0 and three serotypes achieved statistically higher immune responses. For all 11 incremental serotypes unique to VAX-31, and not in PCV20, all three doses met the superiority criteria.

  Based on these positive results, we selected the High Dose of VAX-31 to advance to an adult Phase 3 program.

- In November 2024, we announced that the FDA granted breakthrough therapy designation ("BTD") for VAX-31 for the prevention of IPD in adults and, in August 2025, we announced that the FDA expanded the BTD

for VAX-31 to include the prevention of pneumonia caused by *Streptococcus pneumoniae*.

- In December 2025, following an FDA End-of-Phase 2 meeting, we announced that the first participants were dosed in a Phase 3 pivotal, non-inferiority trial evaluating VAX-31 for the prevention of IPD and pneumonia in adults compared to standard-of-care PCVs ("OPUS-1"). We expect to announce topline safety, tolerability and immunogenicity data from this study in the fourth quarter of 2026.

- In January 2026, we announced the initiation of an additional Phase 3 trial evaluating VAX-31 when administered concomitantly with a licensed, high-dose seasonal influenza vaccine in pneumococcal-naïve adults aged 50 years and older ("OPUS-2"). In February 2026, we announced the initiation of a separate Phase 3 study evaluating VAX-31 in adults previously vaccinated with a lower-valency pneumococcal vaccine ("OPUS-3"). We expect to report safety, tolerability and immunogenicity data from the OPUS-2 and OPUS-3 studies in the first half of 2027. We are also planning for a manufacturing consistency study (e.g., a lot-to-lot study).

◦ PCV Franchise Pediatric Indication:

- VAX-31 is a 31-valent, broad-spectrum, carrier-sparing investigational PCV also being developed for the prevention of IPD in children. VAX-31 is the broadest-spectrum PCV in the clinic designed to cover approximately 92% of IPD in U.S. children under five years of age and approximately 96% of otitis media due to *Streptococcus pneumoniae* in U.S. children five years of age or under.

  - In December 2024, we announced that the first participants were dosed in the first stage of a Phase 2, randomized, dose-finding study of VAX-31 in infants. Stage 1 of the study evaluated the safety and tolerability of VAX-31 at three dose levels (Low, Middle and High) and compared to PCV20 in 48 infants in a dose-escalation approach. In the Low, Middle and High Doses, all serotypes were dosed at 1.1mcg, 2.2mcg and 3.3mcg, respectively, except serotypes 1, 5 and 22F, which were dosed at 1.65mcg, 3.3mcg, and 4.4mcg, respectively. Participants who received VAX-31 in Stage 1 continued the standard dosing regimen as part of Stage 2.

  - In February 2025, we announced that the Phase 2, randomized, dose-finding study of VAX-31 in healthy infants had advanced to the second stage of the study. Stage 2 of the study is evaluating the safety, tolerability and immunogenicity of VAX-31 at the same three dose levels evaluated in Stage 1 and compared to PCV20. In line with recommendations from the ACIP, the study design includes a primary immunization series consisting of three doses given at two months, four months and six months of age, followed by a subsequent booster dose at 12-15 months of age.

  - In September 2025, we announced advancement of the VAX-31 infant Phase 2 randomized, dose-finding study to the third and final stage following modifications to the protocol to add a new dose arm to evaluate a

VAX-31 Optimized Dose (majority of serotypes dosed at 4.4mcg and the balance dosed at 3.3mcg) and discontinue enrollment in the Low Dose arm. The Middle and High Dose arms continued as planned.

- The modified study is evaluating the safety, tolerability and immunogenicity of VAX-31 and compared to PCV20 in 900 participants, including the 100 participants previously enrolled in the Low Dose arm.

- In January 2026, we announced that we completed enrollment of this study. We expect to announce topline safety, tolerability and immunogenicity data from the primary three-dose immunization series and booster dose either sequentially or together by the end of the first half of 2027.

- Pending the VAX-31 Phase 2 infant study readout, we plan to initiate a Phase 3 program in infants with an Optimized Dose formulation of VAX-24 or VAX-31.

- VAX-24 is a 24-valent, broad-spectrum, carrier-sparing investigational PCV being developed for the prevention of IPD in infants, and it covers more serotypes than any pneumococcal infant vaccine on the market today.

  - In March 2025, we announced positive topline, interim data from the VAX-24 infant Phase 2 study, a randomized, observer-blind, dose-finding two-stage clinical study evaluating the safety, tolerability and immunogenicity of VAX-24 in healthy infants that enrolled 803 participants.

  - In November 2025, we announced final safety, tolerability, and immunogenicity results from the VAX-24 infant Phase 2 study that were consistent with the positive interim data reported in March 2025 and showed that VAX-24 elicited robust, dose-dependent immune responses, with little to no evidence of carrier suppression observed. The final data analysis included full 6-month safety results and complete post-dose 3 (primary immunization series) and post-dose 4 (booster dose) IgG and OPA results. The key immunogenicity endpoints included an assessment of immune responses for each of the VAX-24 dose levels (Low, Mid, Mixed) in comparison with PCV20 for the 20 common and 4 unique serotypes in VAX-24. At 1-month post-dose 3 and post-dose 4, immune responses were assessed based on serotype-specific IgG seroconversion rates (IgG threshold value of ≥0.35mcg/mL). IgG GMRs were also assessed at 1-month post-dose 3 and post-dose 4, along with other key immunogenicity endpoints, including OPA.

    In this study, VAX-24 was well-tolerated and demonstrated a safety profile similar to PCV20 across all doses studied. Post-dose 3 and post-dose 4, all VAX-24 doses evaluated demonstrated robust IgG and OPA immunogenicity responses.

    - Post-dose 3, all VAX-24 doses met target precedent Phase 2 non-inferiority criteria on relative seroconversion rates (lower limit of

the 95% confidence interval for the difference between the proportion of participants achieving the pre-defined seroconversion rate (IgG concentration ≥0.35 mcg/mL) is > -15% for each serotype) for the highest circulating serotypes, as defined by the percentage of IPD caused in individuals <5 yrs of age in the U.S. in 2023 based on the U.S. Center for Disease Control ("CDC") active bacterial core ("ABC") surveillance data, contained in VAX-24. The Low and Mid doses met the seroconversion rate criteria for 20 of 24 serotypes overall and the Mixed Dose met such criteria for 19 of 24 serotypes. The Mid and Mixed Doses met the target Phase 2 IgG GMR point estimate of >0.6 for 21 of 24 serotypes.

- Post-dose 4, all VAX-24 doses met our target Phase 2 IgG GMR point estimate of >0.6 for the three highest circulating serotypes contained in VAX-24. The Mixed Dose met this target for 19 of 24 serotypes overall and the Mid dose met this target for 18 of 24 serotypes. Post-dose 4, VAX-24 elicited robust memory responses across all doses for all serotypes.

- Additionally, the four incremental serotypes unique to VAX-24 that provide expanded serotype coverage relative to PCV20 elicited robust immune responses and met all target criteria across all endpoints at all doses evaluated.

- The final positive data from the VAX-24 infant Phase 2 dose-finding study further validated our rationale for exploring higher doses in the ongoing VAX-31 infant Phase 2 study.

  - VAX-XL is a third-generation PCV candidate designed to provide the broadest coverage of any PCV currently in development.

- VAX-A1, a novel conjugate vaccine candidate designed to prevent disease caused by Group A Streptococcus (“Group A Strep”). Group A Strep is pervasive globally and causes an estimated 800 million cases of illness annually, including pharyngitis, or strep throat, and certain severe invasive infections and sequelae. There is currently no vaccine against Group A Strep, which is one of the leading infectious disease-related causes of death and disability worldwide and a significant contributor to the prescription of antibiotics in children. We believe we have demonstrated preclinical proof of concept for VAX-A1, the data for which were published in December 2020. We plan to initiate a Phase 1 adult study for VAX-A1 in 2026, with the primary objective of assessing safety and tolerability.

- VAX-GI, a novel preclinical vaccine candidate being developed as a preventative treatment for dysentery and shigellosis, which is caused by Shigella bacteria. Shigella is a bacterial illness estimated to cause 80 million to 165 million cases of disease and 600,000 deaths annually, mostly among children. The central antigen in VAX-GI is IpaB, a well-appreciated antigen that other developers have been unable to produce in an amount sufficient to enable a commercial product. With our cell-free technology, we believe we can produce this antigen at substantially improved yields, allowing for

commercial-scale production. VAX-GI is being developed in collaboration with the University of Maryland, Baltimore as well as with partial funding from two research grants awarded by the National Institutes of Health ("NIH"). As part of our continued focus on strategic capital deployment and in order to prioritize our resources towards our PCV franchise, we announced in August 2025 that we had paused the advancement, beyond preclinical development, of VAX-GI while remaining confident in its potential and preserving the option to advance the program in the future.

- Other discovery-stage programs that leverage our cell-free protein synthesis platform, which, if proven successful in preclinical studies, could also be advanced into IND-enabling activities and clinical studies.

Our Approach

To address areas of significant unmet medical need, we carefully select the disease areas we target and are developing vaccine candidates based on the following criteria:

- *Clear commercial opportunity and efficient market adoption:* We select vaccine targets that are characterized by an established patient population and significant unmet medical need. Our PCV candidates are designed to improve upon the standard-of-care for both adults and children by covering the serotypes that are responsible for a significant portion of IPD in circulation and are associated with high case-fatality rates, antibiotic resistance and meningitis, while maintaining coverage of previously circulating strains that are currently contained through continued vaccination practice. We believe that by providing the broadest coverage of serotypes for PCVs, as well as providing novel vaccines for diseases for which there are no currently approved vaccines, we can leverage the U.S. Centers for Disease Control ("CDC"), ACIP and similar international advisory body recommendations to drive rapid and significant market adoption.

- *Acceptable biological risk:* We choose vaccine targets with well-understood mechanisms of action and strong precedents for positive preclinical study results that we believe will translate to positive clinical trial results. For example, conjugate vaccines have demonstrated effectiveness in both preclinical and clinical trials against a range of bacteria, including *Streptococcus pneumoniae*, meningococcus and haemophilus influenza B. There is consistent evidence that antibodies directed against these bacteria are protective against their respective diseases.

- *Established or acceptable clinical pathways:* We pursue vaccine targets that we believe have established or acceptable clinical development pathways in order to accelerate the potential time to market. For example, we believe that our PCVs would receive regulatory approval based on successful completion of clinical studies utilizing well-defined surrogate immune endpoints, consistent with how other PCVs have obtained regulatory approval in the past, rather than requiring clinical field efficacy studies. For our novel vaccine candidates, for which 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.

Our Platform

Our modern synthetic techniques, including advanced chemistry and the XpressCF™ cell-free protein synthesis platform, offer several advantages over conventional cell-based protein expression methods, which we believe enable us to generate superior, novel, broader-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, which dampens the immune response and may lead to 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 using conventional technologies to address diseases for which there are no available vaccines. In addition, our platform enables us to rapidly screen vaccine candidates, requiring less effort than conventional chemistry which allows us to produce and iterate conjugate candidates, thereby dramatically accelerating the development cycle of designing, producing and testing vaccine candidates.

We are re-engineering the way highly complex vaccines are made 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.

Our Strategy

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

- *Advance our PCV candidates through clinical development and regulatory approval.* Our PCV candidates, VAX-31,VAX-24 and VAX-XL, target the pneumococcal vaccine market. We are advancing these PCV candidates along a well-understood clinical development pathway in an effort to obtain regulatory approval in adults and infants based on successful completion of clinical studies using previously established surrogate immune endpoints, without the need to conduct clinical field efficacy studies, consistent with how other conjugate vaccines have obtained approval.

- *Establish scalable production of our PCV candidates.* 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 have scaled to supply clinical volumes and believe can scale to supply initial volumes of VAX-31 needed to support commercial launch. We have access to substantial manufacturing resources through our contract manufacturer, Lonza, that we believe can facilitate an independent path to market. For the adult indication, we are conducting scale-up activities to support potential regulatory approval and commercial launch of VAX-31 in this population using existing Lonza infrastructure. In October 2023, to complement this plan, we entered into a new commercial manufacturing agreement with Lonza to support the potential global commercialization of our PCV candidates in both the adult and pediatric populations. In November 2023, we entered into a manufacturing rights agreement with Sutro Biopharma, Inc ("Sutro Biopharma") to obtain control over the development and manufacture of cell-free extract, a key component of our PCV franchise. Pursuant to the manufacturing rights agreement, we obtained exclusive rights to independently, or through certain third parties, develop, improve and manufacture cell-free extract for use in connection with our vaccine candidates. In addition, in September 2025, we announced a new agreement with Patheon Manufacturing Services, LLC, part of Thermo Fisher Scientific (collectively, "Thermo Fisher") to provide custom commercial fill-finish capacity for our broad-spectrum PCVs at Thermo Fisher's Greenville, North Carolina facility. The initiative, which includes both manufacturing and related services, represents a long-term U.S. commercial manufacturing commitment of up to $1 billion.

- *Create a long-lasting PCV franchise by offering the broadest-spectrum PCV available.* The two leading pneumococcal vaccine franchises to date, Prevnar and Pneumovax 23 (“PPSV23”), have been administered well over a billion times, generating over $100 billion in combined sales over 20 and 40 years, respectively, and can attribute their success to having been the broadest-spectrum vaccines on the market. In addition, the recently approved PCV, Capvaxive® ("PCV21"), is now commercially available for the adult market. If approved, we believe VAX-31 and/or VAX-24 may potentially replace the standard-of-care PCVs currently available because of their coverage against both currently circulating and historically prevalent strains. We designed VAX-24 to address the 24 pneumococcal strains covered by Prevnar and PPSV23 that drive a significant portion of pneumococcal disease today with the durable, boostable immune response of a conjugate vaccine. Further, we have designed VAX-31 to address these 24 strains plus seven additional epidemiologically significant emerging strains that are causing increasing pneumococcal disease and antibiotic resistance, which collectively drive most pneumococcal disease today. With these broad-spectrum vaccine candidates, we believe we are well-

positioned to obtain ACIP recommendations and potentially replace the current standard-of-care for pneumococcal disease prevention in both adult and pediatric populations, thereby creating a long-lasting PCV franchise.

- *Develop novel vaccine candidates and leverage our platform to expand our pipeline.*

    - *VAX-A1:* We believe our data published in December 2020 demonstrated preclinical proof of concept for VAX-A1. We nominated the final vaccine candidate and initiated IND-enabling activities for VAX-A1 in 2021. We plan to initiate a Phase 1 adult clinical study in 2026, with the primary objective of assessing safety and tolerability.

    - *VAX-GI:* VAX-GI is being developed in collaboration with the University of Maryland, Baltimore as well as with partial funding from two research grants awarded by the NIH. We are in the process of identifying additional antigens to include with IpaB and engaged in early-stage process development activities. As part of our continued focus on strategic capital deployment and in order to prioritize our resources towards our PCV franchise, we announced in August 2025 that we had paused the advancement, beyond preclinical development, of VAX-GI while remaining confident in its potential and preserving the option to advance the program in the future.

    - *Leverage our platform for other discovery stage programs.* 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, and we have other discovery-stage programs which leverage this platform.

- *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 have rights to a robust portfolio of patents and patent applications related to the XpressCF platform through our exclusive license from Sutro Biopharma. We currently have four issued U.S. patents, two issued European patents and multiple issued patents internationally, and multiple pending patent applications in the United States and internationally that cover our vaccine candidates including vaccine formulations, protein-antigen conjugates, methods of making conjugate vaccines with various protein-antigen conjugates and other processes related to vaccine production, enhancements of immunogenicity and methods of use.

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:

Global Vaccine Market

The global vaccine market size is projected to reach $115.77 billion by 2033 from an estimated $72.75 billion in 2025, growing at a compounded annual growth rate of 5.78% from 2026 to 2033. The Prevnar franchise from Pfizer Inc. (“Pfizer”), comprised of Prevnar 13 (“PCV13”) and PCV20, was among the highest selling vaccine products in the world in 2025, accounting for an estimated 9% of global vaccine sales.

The pediatric vaccine market is large and well-established in the United States, European Union and many other countries around the world. The annual new birth cohort, which in North America and Europe approached approximately 10 million in 2024, drives ongoing sales year after year due to the recommended immunization schedules. 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 vaccine classes that receive a recommendation from ACIP and/or government health and professional medical organizations are widely 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%. It is estimated that vaccination in children born between 1994 and 2023 in the United States will result in net savings of $540 billion in direct costs and $2.7 trillion in societal costs, making them one of the most cost-effective public health interventions.
In addition, the adult vaccine market is undergoing rapid growth. Vaccination rates among adults have historically been lower relative to infants and vary by disease, though strong initiatives are underway to increase awareness and utilization. Excluding the impact of the COVID-19 pandemic, studies estimate that tens of thousands of adults in the United States die annually of vaccine-preventable diseases, and hundreds of thousands more are hospitalized. Vaccine-preventable diseases among adults cost the U.S. economy an estimated $27 billion annually in direct and indirect expenses. In recent years, manufacturers have started developing more vaccines for the adult market, including Pfizer’s PCV13 and PCV20, Merck & Co., Inc.'s

("Merck") PCV15 and PCV21, GSK plc's ("GSK") Shingrix and multiple vaccines to prevent respiratory syncytial virus ("RSV"). The U.S. adult pneumococcal market generated estimated annual sales of more than $1.5 billion in 2025, and Shingrix, a vaccine for shingles (herpes zoster), 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 $4.8 billion in global sales in 2025. The vaccines to prevent RSV from Pfizer and GSK that were approved by the FDA in May 2023, and from Moderna that was approved by the FDA in May 2024, generated approximately $1.8 billion in global sales in 2025.

In October 2024, the ACIP voted to recommend expanding the age-based pneumococcal vaccination guidelines for pneumococcal vaccination in adults to begin at 50 years of age and older from the prior recommendation beginning at 65 years of age and older, which expanded the market by adding approximately 62 million additional eligible Americans for the universal recommendation.

Pneumococcal Disease

Pneumococcal disease is an infection caused by *Streptococcus pneumoniae* bacteria. It can result in IPD, including meningitis and bacteremia, and non-invasive pneumococcal disease, including pneumonia, otitis media and sinusitis. Global pneumococcal disease in children is driven by emerging serotypes not covered by currently available vaccines and in adults by not only emerging serotypes, but also fragmented coverage of today's standard-of-care vaccines. In the United States, pneumococcal pneumonia is estimated to result in approximately 225,000 U.S. adult hospitalizations each year. *Streptococcus pneumoniae* is among the WHO's top antibiotic-resistant pathogens to be urgently addressed, and the United States CDC lists drug-resistant Streptococcus pneumoniae as a "serious threat." In children under five, *Streptococcus pneumoniae* is the leading cause of vaccine-preventable deaths globally, resulting in approximately 300,000 deaths annually. It is estimated that acute otitis media affects approximately 5 million children and results in greater than 10 million antibiotic prescriptions annually in the United States. Pneumococci also cause over 50% of all cases of bacterial meningitis in the United States. 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 significant, particularly for young children and older adults, underscoring the need for a broader-spectrum vaccine.

Evolution of Pneumococcal Vaccines

There are currently two types of vaccines targeting pneumococcal disease—polysaccharide-only vaccines and PCVs. 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.

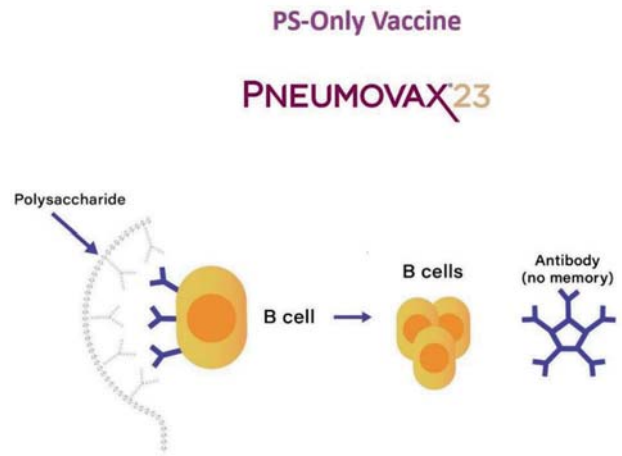
Pneumococcal Polysaccharide-Only Vaccines

PPSV23, manufactured and marketed by Merck is the only pneumococcal polysaccharide vaccine widely available. PPSV23 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. PPSV23 is routinely administered to adults to provide protection against bacteremia and at its peak in 2020 generated sales of over $1.1 billion. After the

ACIP recommendation of PCV20 in late 2021 eliminated the need for PPSV23 in a large part of the covered population, PPSV23 has declined from more than 50% of the U.S. adult market share to less than 3%.

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 ("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 PPSV23 are only thought to protect against blood-borne infections, such as bacteremia. Figure 1 below illustrates polysaccharide-induced T-cell independent antibody responses.

Figure 1.



Graphics adapted from Strugnell et al, *Understanding Modern Vaccines*, Vol 1, Issue 1, 61-88.

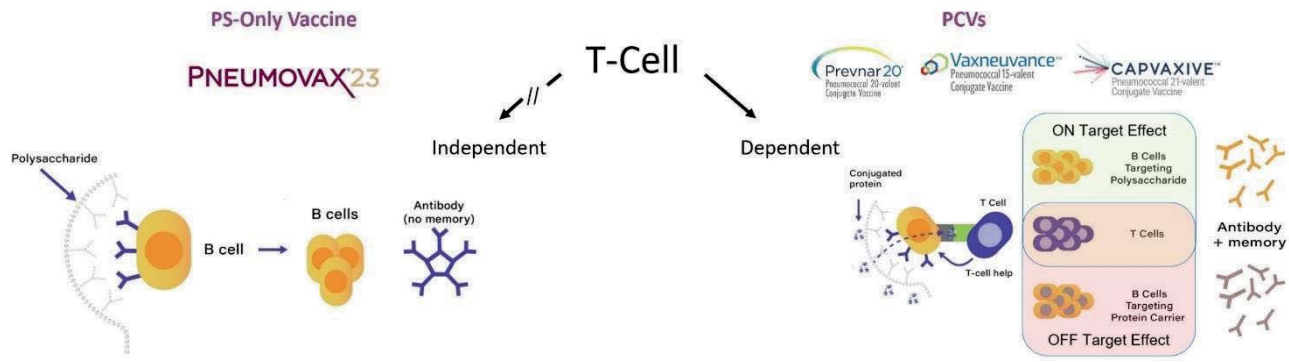
Polysaccharide vaccines also interfere with optimal use of PCVs, as they create a hyporesponsive immune effect. In particular, absent T-cell inducement, polysaccharide vaccines actually clear the memory B-cells that are formed following primary immunization with a PCV, thereby eliminating the ability to boost with subsequent vaccination. This historically has been a significant drawback of vaccination in older adults, which consisted of the administration of a limited spectrum PCV followed by the administration of a polysaccharide vaccine. Despite these shortcomings, PPSV23 historically has been widely used primarily to provide protection against circulating strains not contained in the currently available PCVs. The current routine standard-of-care in adults, which consists of the administration of either PCV20 or PCV21 alone or PCV15 followed by the administration of PPSV23, continues to include the alternative of a polysaccharide vaccine.

Pneumococcal Conjugate Vaccines

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 $CD4^+$ 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 leading to a more robust and durable immune response and enabling the use of PCVs in young children. Figure 2 below illustrates this immune response:

Figure 2.



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 *Streptococcus 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_{197} to produce seven separate conjugates. 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 GSK, and PCV13, a 13-valent PCV from Wyeth (subsequently acquired by Pfizer). Based on its broader coverage of then-emerging strains, PCV13 was adopted as the standard-of-care in the United States and Europe. Synflorix's use has been limited primarily to emerging countries.

PCV13 contains the seven serotypes originally included in Prevnar plus six more serotypes of *Streptococcus pneumoniae* (1, 3, 5, 6A, 7F and 19A) and was approved and launched in the United States in 2010. Each polysaccharide is conjugated to CRM_{197} to produce 13 individual conjugates, which are mixed into a final vaccine formulation and then adsorbed to alum. In 2010, PCV13 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 PCV13 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 recommendation, PCV13 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 PCV13.

In an effort to develop even broader-spectrum PCVs than PCV13, two vaccines were successfully developed for the adult and infant populations: PCV20, a 20-valent PCV from Pfizer, and PCV15, a 15-valent PCV from Merck.

PCV20 contains the 13 serotypes included in PCV13 plus seven more serotypes of *Streptococcus pneumoniae* (8, 10A, 11A, 12F, 15B, 22F and 33F) and was granted regulatory approval and launched in the United States in 2021 for the prevention of IPD and pneumonia in adults based on non-inferior OPA responses relative to PCV13 without the need for a field efficacy study. PCV20's indication for the prevention of pneumonia caused by *Streptococcus pneumoniae* serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F in adults is approved under accelerated approval based on immune responses as measured by OPA assay. While PCV20 failed to achieve non-inferiority on serotype 8 relative to PPSV23, it was still granted approval across all 20 strains. In 2023, the FDA approved PCV20 for use in infants for the prevention of IPD, and for the prevention of otitis media caused by *Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F without the need for a field efficacy study. While PCV20 failed to achieve non-inferiority for five of the 13 common (1, 3, 4, 9V and 23F) and one of the seven unique (12F) serotypes for the co-primary endpoint following the three-dose primary immunization series in the U.S. study, it was still granted FDA approval across all 20 strains for IPD.

PCV15 contains the 13 serotypes included in PCV13 plus two more serotypes of *Streptococcus pneumoniae* (22F and 33F) and was granted regulatory approval and launched in the United States in 2021 for the prevention of IPD in adults based on non-inferior OPA responses relative to PCV13 without the need for a field efficacy study. In 2022, the FDA approved PCV15 for use in infants for the prevention of IPD based on non-inferior IgG responses relative to PCV13 without the need for a field efficacy study.

In October 2021, the ACIP voted to recommend universal vaccination for the use of either PCV20 alone or PCV15 with PPSV23 for routine use in adults aged 65 years and older as well as for those between the ages of 19 and 64 years with certain underlying medical conditions or other risk factors who had not previously received a PCV or whose previous vaccination history was unknown. In June 2022, the ACIP voted to recommend that PCV15 may be used as an option to the then recommended PCV13 for children aged under 19 years according to then recommended PCV13 dosing and schedules. In October 2022, the ACIP voted to recommend a dose of PCV20 for adults aged 65 years and older at least five years after the last pneumococcal vaccine dose for those who haven't previously received PCV20. In June 2023, the ACIP voted to recommend the use of PCV20 as an option to PCV15 for routine use in children under the age of two, and as a "catch up" vaccination for healthy children between the ages of 24 and 59 months with incomplete PCV vaccination status and children between the ages of 24 and 71 months with certain underlying conditions and an incomplete PCV vaccination status. Further, the ACIP voted to recommend that children between the ages of two and 18 years with any risk condition who have received all recommended PCV doses before the age of six do not need additional doses if they have received at least one dose of PCV20. If children between the ages of two and 18 years with any risk condition received PCV13 or PCV15, but not PCV20, the ACIP recommended that they should receive a dose of PCV20 or PPSV23. The ACIP also voted to recommend that children between the ages of six and 18 years with any risk condition who have not received any dose of PCV13, PCV15 or PCV20 should receive a single dose of PCV15 or PCV20. When PCV15 is used in this instance, the ACIP recommended that it should be followed by a dose of PPSV23 at least eight weeks later if not previously given. In June 2023, the ACIP also recommended shared clinical decision-making regarding PCV20 use for adults aged 65 years and older who have completed the recommended vaccine series with both PCV13 and PPSV23.

As a further example of the need for broader-protection vaccines to prevent IPD highlighted by the public health community, another vaccine was successfully developed for the adult population: PCV21, a 21-valent

PCV from Merck. Unlike predecessor PCVs, PCV21 does not contain each of the historically circulating serotypes covered in previously approved PCVs. PCV21 contains 11 of the 20 serotypes included in PCV20 (serotypes 3, 6A, 7F, 8, 10A, 11A, 12F, 15B, 19A, 22F and 33F) plus 10 more serotypes of *Streptococcus pneumoniae* (serotypes 9N, 15A, 16F, 17F, 20, 23A, 23B, 24F, 31 and 35B). PCV21 was granted regulatory approval and launched in the United States in 2024 for the prevention of IPD and pneumonia (serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B) in adults based on non-inferior OPA responses relative to PCV20 without the need for a field efficacy study. PCV21's indication for the prevention of pneumonia is approved under accelerated approval based on immune responses as measured by OPA.

In June 2024, the ACIP voted to recommend PCV21 as an option to either PCV20, or PCV15 with PPSV23, for (i) adults aged 65 years and older who have not previously received a PCV or whose previous vaccination history is unknown, (ii) adults between the ages of 19 and 64 with certain underlying medical conditions or other risk factors who have not previously received a PCV or whose previous vaccination history is unknown and (iii) adults aged 19 years and older who have received PCV13 but not all recommended doses of PPSV23. Additionally, the ACIP recommended shared clinical decision-making regarding a supplemental dose of PCV21 for adults aged 65 and older who have completed their vaccine series with both PCV13 and PPSV23.

In October 2024, the ACIP expanded its recommendation by lowering the age-based pneumococcal vaccination guidelines for pneumococcal vaccination in adults from 65 years and older to 50 years and older. In line with this recommendation, the ACIP recommends either a dose of PCV20 or PCV21, or PCV15 with PPSV23, for (i) adults aged 50 and older who have not previously received a PCV or whose previous vaccination history is unknown and (ii) adults between the ages of 19 and 49 with certain underlying medical conditions or other risk factors who have not previously received a PCV or whose previous vaccination history is unknown.

Drawbacks of Current PCVs

Routine immunization with PCVs has been effective in dramatically lowering the incidence of 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. As published in 2022, 35% and 37% of IPD incidence in 2018 for children under the age of five and adults aged 65 years and older, respectively, were caused by strains beyond the 20 strains covered by PCV20. Efforts to improve upon 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 notwithstanding the recent approvals of PCV21 in adults, PCV20 and PCV15, there remains a significant need for broader-spectrum PCVs that address both currently circulating and historically prevalent serotypes, as evidenced by the fact that despite the coverage of PCV21 and PCV20, the combination of PCV15 and PPSV23 remains universally recommended when adults turn 50 in the United States, as an alternative to either PCV21 or PCV20 alone, given the broader-spectrum coverage of these two vaccines combined compared to PCV21 or PCV20. Although PCV21 covers more incidence of disease, it does not address several of the serotypes historically covered, many of which continue to circulate today.

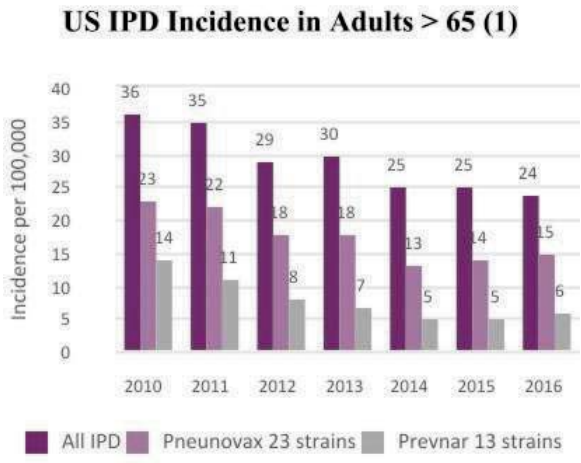
While vaccination with current PCVs has been effective in dramatically lowering the incidence of IPD in both adults and children in the United States and other industrialized nations, current PCVs suffer from the following drawbacks.

Serotype Replacement

Since the introduction of PCV13, there has been a decrease in incidence of disease attributable to the serotypes included in the vaccine. However there has been a phenomenon called serotype replacement, whereby a void is created when serotypes are taken out of circulation after widespread vaccination. As a result, serotypes not covered by PCV13 now cause residual pneumococcal disease. Broader-spectrum PCVs were historically required to maintain protection against historically pathogenic strains while expanding coverage to address current circulating and emerging strains. This serotype replacement has led to the development of a third generation of conventional PCVs, inclusive of PCV15 and PCV20. Although PCV21 was approved despite lacking protection against certain historically pathogenic strains, it is only approved in the adult population and did not receive a preferred recommendation despite its disease coverage, and is recommended solely as an alternative to PCV20 alone or PCV15 and PPSV23. VAX-31, if approved, would increase coverage to more than 95% of IPD currently circulating in the U.S. adult population aged 50 and over. In the pediatric population, VAX-31 is designed to cover approximately 92% of IPD in U.S. children under five years of age and approximately 96% of otitis media due to *Streptococcus pneumoniae* in U.S. children five years of age or under.

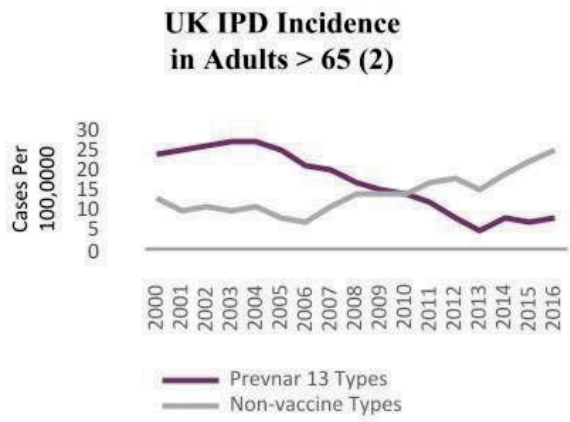
Pneumococcal disease surveillance has been conducted by the CDC in the United States and by the UK Health Security Agency. As shown in Figure 3, IPD cases in adults in the United States initially declined after the introduction of PCV13 but have since plateaued. The rate of serotype replacement has been more pronounced in the United Kingdom. Figure 4 shows the approximate IPD incidence rates in the United Kingdom caused by the incremental strains over and above those in PCV13, which increased over the last three years of surveillance.

Figure 3.



[1] U.S. CDC Active Bacterial Core Surveillance Annual Reports

Figure 4.



[2] Ladhani et al, *Lancet Infectious Disease*, 2018 Apr.; 18(4):441-45 inclusive of unpublished raw data

While some of these strains are covered by PPSV23, that vaccine only protects against blood-borne infections and not pneumonia, leaving patients vulnerable to infection. Although PCV21, PCV20 and PCV15 address more disease-causing strains than PCV13, we believe there remains a significant need for even broader-spectrum vaccines to address a greater number of currently circulating and emerging strains.

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 all versions of Prevnar is CRM_{197}, a diphtheria toxin with a single point mutation rendering it non-toxic. The CRM_{197} 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 helps diminish 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 PCV20 was compared to PCV13 in a well-controlled Phase 3 study in infants, the IgG antibody responses directed against the polysaccharides of interest for all thirteen of the common strains in each vaccine were lower for PCV20 (Figure 5). In 2020, Pfizer presented results of a well-controlled Phase 3 study in adults, aged 60 and over, where they compared PCV20 to PCV13. In that study, the OPA responses directed against the polysaccharides of interest for all thirteen of the common strains were lower for PCV20 (Figure 6).

Figure 5.

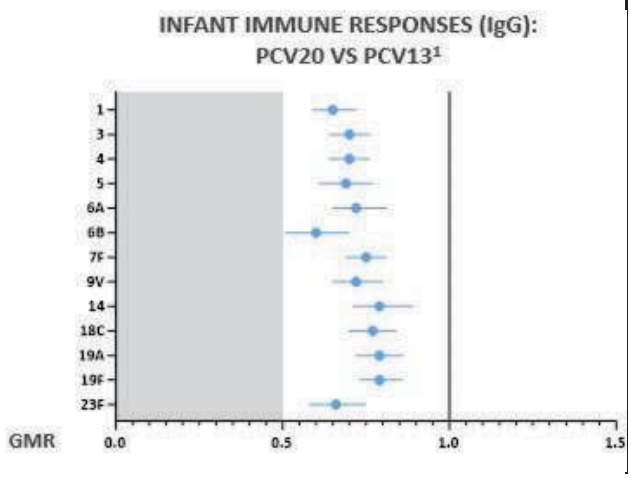
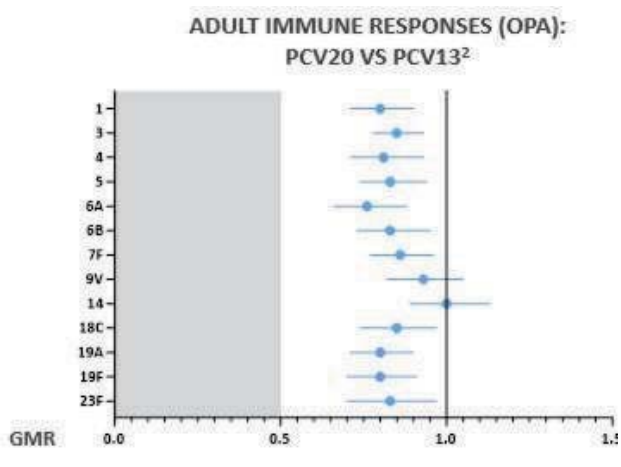


Figure 6.



[1] IgG Geometric Mean Concentrations post-dose 4 – Prevnar 20 Biologics License Application ("BLA") Clinical Review Memorandum by FDA (STN: 125731/189). April 27, 2023.

[2] PCV20 BLA Clinical Review Memorandum. STN: 125731/0 June 8, 2021.

Conventional Chemistry

The problem of carrier suppression is compounded by conventional conjugation chemistry used to make current PCVs, including PCV15, PCV20 and PCV21, which requires a higher amount of CRM_{197} protein carrier than polysaccharide antigen to complete the conjugation reaction, as well as long 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 PCV20 formulation, there are 51 micrograms of the protein carrier, CRM_{197}, relative to 2.2 micrograms of each polysaccharide (except serotype 6B at 4.4 micrograms), and in the marketed PCV21 formulation, there are 65 micrograms of CRM_{197}, relative to 4.0 micrograms of each polysaccharide. With substantially more protein carrier in the vaccines 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

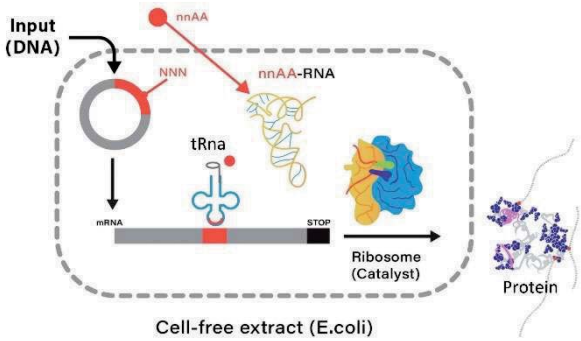
Using our cell-free protein synthesis platform, we are developing superior, novel carrier-sparing PCVs designed to have broader-spectrum coverage in an effort to address historic, current and future residual disease in ways that conventional technologies cannot. We are able to design our investigational 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 minimize carrier suppression while maintaining protective immunogenicity.

Synthesizing proteins outside of a living host cell 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 *Escherichia coli* ("*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 ("nnAAs") for native amino acids at specific sites. These inserted nnAAs serve as conjugation anchors that permit the attachment of antigens, including polysaccharides, at a specific site 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 7 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 site-specific conjugation.

Figure 7.



Most conjugate vaccines available today use a non-disease-specific protein carrier, CRM_{197}, 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 ("eCRM") with pre-determined conjugation sites. Our method produces more 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 8 shows site-specific conjugation of the polysaccharide to the protein carrier, avoiding the T-cell epitopes. Figure 9 shows the inter-strand cross-linked matrix, which is the structure of each monovalent conjugate included in the final vaccine.

Figure 8.

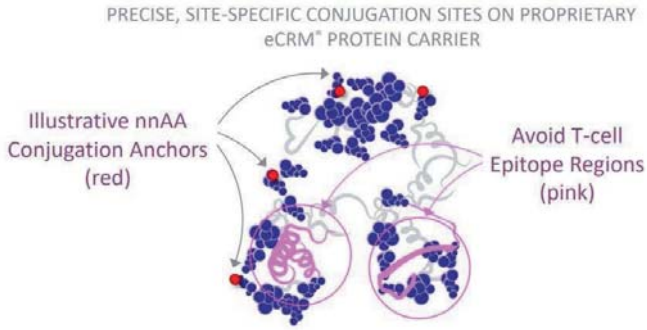


Figure 9.

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 conventional PCVs. Our clinical studies to date validated our carrier-sparing approach to develop broader-spectrum PCVs. 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.

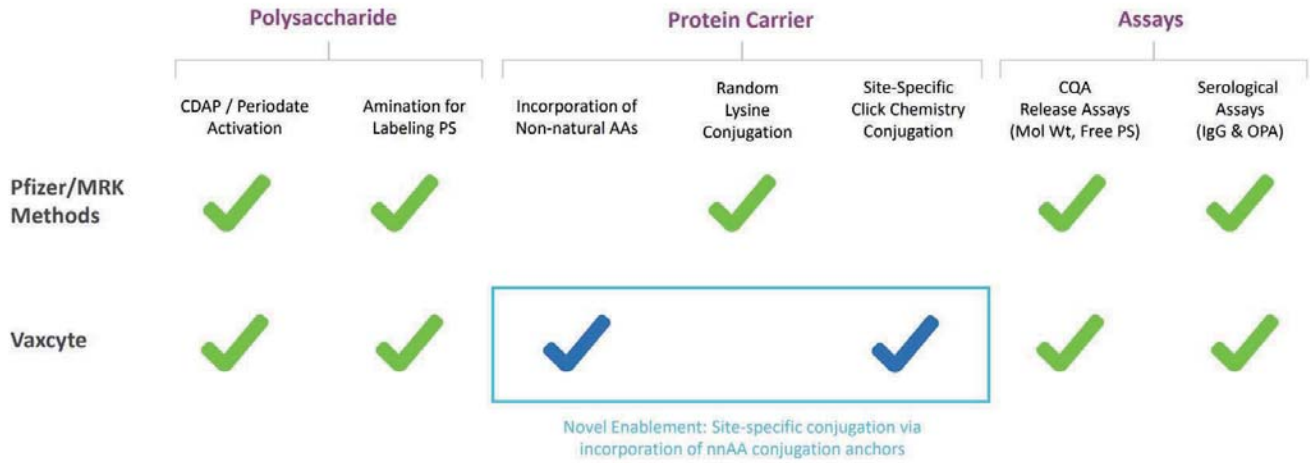
Our PCV Franchise

We are developing broad-spectrum investigational PCVs designed to improve serotype coverage compared to current standard-of-care PCVs and minimize carrier suppression. We currently have three PCV candidates in our differentiated PCV franchise: VAX-31, a 31-valent, broad-spectrum, carrier-sparing investigational PCV, which we are developing for both the infant and adult populations, VAX-24, a 24-valent, broad-spectrum, carrier-sparing investigational PCV for which we have completed a Phase 2 trial in both the adult and infant populations, and VAX-XL, a third-generation PCV candidate designed to provide the broadest coverage of any PCV currently in development. VAX-31, the broadest-spectrum PCV in the clinic, is designed to provide protection against both currently circulating and historically prevalent serotypes and cover approximately 95% and 92% of IPD circulating in the U.S. adult (ages 50 and older) and infant (under the age of five) populations, respectively. The 31 serotypes included in VAX-31 are associated with high case-fatality rates, antibiotic resistance and meningitis. VAX-24 covers more serotypes than any pneumococcal infant vaccine on the market today.

As shown in Figure 10 below, there are critical differences between VAX-31 and VAX-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 nnAAs, 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 10.



Furthermore, VAX-31 and VAX-24 improve upon the serotype spectrum of coverage relative to PCV15 and PCV20 in both the adult and infant populations, and VAX-31 improves on the same in the adult population relative to PVC21, and use less protein carrier per conjugate than these conventional chemistry PCVs. In aggregate, VAX-31 contains more protein carrier, and VAX-24 contains a similar amount of protein carrier, relative to PCV15 and PCV20. We believe the resulting decreased carrier burden per conjugate of VAX-31 and VAX-24 are critical for minimizing carrier suppression and producing broader-spectrum pneumococcal vaccines without sacrificing immunogenicity.

Where appropriate, we capitalize on the efficiencies of well-established clinical, manufacturing and regulatory precedents by leveraging conventional methods for the development of our PCV candidates. 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 PCV13, PCV15, PCV20 and PCV21.

We are pursuing a well-characterized clinical development path for our PCV candidates, consistent with other PCV developers. We have been able to conduct smaller and shorter clinical trials that target immune endpoints (e.g., OPA and IgG responses) previously recognized by regulatory authorities, and anticipate that we will be able to conduct such studies going forward. Pfizer applied this approach to the development of PCV13 and PCV20 and Merck applied it to the development of PCV15 and PCV21. Based on this standard, as a prerequisite for regulatory approval, we believe that any investigational PCV will have to be compared to the standard-of-care at the time a clinical trial is initiated. Currently, the standard-of-care for routine use is either PCV20 or PCV21 alone or PCV15 followed by PPSV23 in adults and PCV20 or PCV15 in infants.

Clinical Development Overview

We are pursuing clinical development for adults with VAX-31 and, for the pediatric population, have completed a Phase 2 study with VAX-24 and are currently conducting a Phase 2 study with VAX-31.

Adult Indication

We have selected VAX-31 to advance to an adult Phase 3 program, which was initiated in December 2025.

For VAX-31, we achieved clinical proof of concept in September 2024 when we announced positive topline results from a Phase 1/2 study evaluating the safety, tolerability and immunogenicity of VAX-31 in healthy adults aged 50 and older. Based on these positive results, we selected the High Dose of VAX-31 to advance to an adult Phase 3 program. Following an FDA End-of-Phase 2 meeting, we initiated a Phase 3 pivotal, non-inferiority study in December 2025 and expect to announce topline safety, tolerability and immunogenicity data in the fourth quarter of 2026. In January 2026, we announced the initiation of an additional Phase 3 trial evaluating VAX-31 when administered concomitantly with a licensed, high-dose seasonal influenza vaccine in pneumococcal-naïve adults aged 50 years and older ("OPUS-2"). In February 2026, we announced the initiation of a separate Phase 3 study evaluating VAX-31 in adults previously vaccinated with lower-valency pneumococcal vaccines ("OPUS-3"). We expect to report safety, tolerability and immunogenicity data from the OPUS-2 and OPUS-3 studies in the first half of 2027. We are also planning for a manufacturing consistency study (e.g. a lot-to-lot study). Subject to the results of the adult Phase 3 studies, we would expect to submit a BLA shortly following the completion of the last Phase 3 study.

For adults, the FDA has granted VAX-31 BTD for the prevention of IPD as well as pneumonia caused by *Streptococcus pneumoniae*. A BTD is designed to expedite the development and review of drugs that are intended to treat serious or life-threatening conditions and is based upon preliminary clinical evidence indicating that the drug or vaccine may demonstrate substantial improvement over available therapies on one or more clinically significant endpoints.

Infant Indication

We have completed a Phase 2 study with VAX-24 and and are currently conducting a Phase 2 study with VAX-31 for the prevention of IPD in infants.

In March 2025, we announced positive topline, interim data from the VAX-24 infant Phase 2 study, a randomized, observer-blind, dose-finding two-stage clinical study evaluating the safety, tolerability and immunogenicity of VAX-24 in healthy infants that enrolled 803 participants.

In November 2025, we announced final safety, tolerability, and immunogenicity results from the VAX-24 infant Phase 2 study that were consistent with the positive interim data reported in March 2025 and showed that VAX-24 elicited robust, dose-dependent immune responses, with little to no evidence of carrier suppression observed.

In this study, VAX-24 was well-tolerated and demonstrated a safety profile similar to PCV20 across all doses studied. The results from this study informed advancement of our modified VAX-31 infant Phase 2 dose-finding study. The final positive data from the VAX-24 infant Phase 2 dose-finding study further validated our rationale for exploring higher doses in the ongoing VAX-31 infant Phase 2 study.

For VAX-31, in December 2024 we announced that the first participants were dosed in the first stage of a Phase 2 randomized, dose-finding study of VAX-31 in healthy infants, and in February 2025, we announced that the ongoing study had advanced to the second stage of the study and that the first participants had been dosed. In

September 2025, we announced advancement of the modified VAX-31 infant Phase 2 randomized, dose-finding study to the third and final stage. The study advanced to the third and final stage following modifications to the protocol to add a new dose arm to evaluate the VAX-31 Optimized Dose (majority of serotypes dosed at 4.4mcg and the balance dosed at 3.3mcg) and discontinue enrollment in the Low Dose arm. The Middle and High Dose arms are continuing as planned. In January 2026, we announced that we had completed enrollment of this study.

Clinical Data: Adult Indication

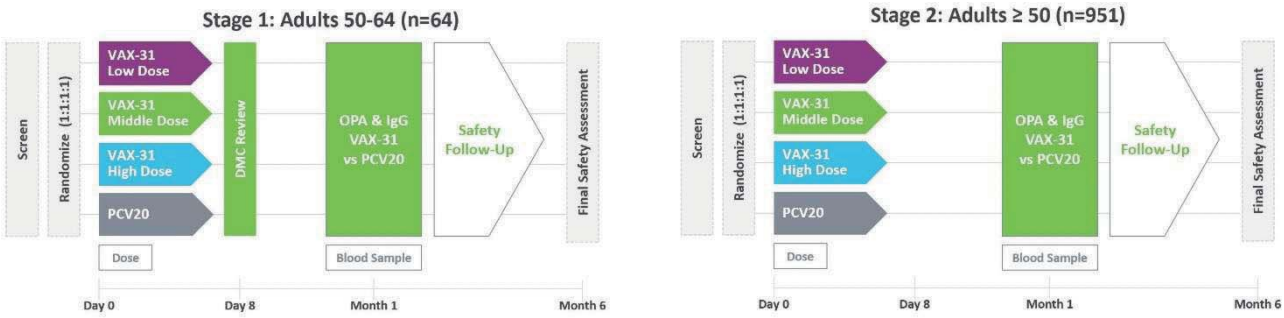
We are using OPA titers as the primary immunogenicity endpoint for the VAX-31 program in adults. OPA is believed to be the primary protective mechanism against pneumococcal disease. In addition, we are measuring IgG responses as a secondary endpoint, as such responses may serve as supportive evidence of immunogenicity for comparison. We believe that these endpoints, if met in a Phase 3 trial, will be sufficient to obtain regulatory approval of VAX-31 and that we will not need a clinical field efficacy study.

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, PCV13 was approved based on the establishment of non-inferiority of OPA responses relative to PPSV23, 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. PCV20 was approved based on the same non-inferiority criterion but compared with PCV13 and PPSV23, while PCV15 was approved based on the same non-inferiority for the common serotypes, but a different non-inferiority criterion for the incremental strains compared to PCV13. PCV21 was approved based on the same non-inferiority criterion as PCV15, but compared to PCV20.

The VAX-31 Phase 1/2 clinical study was a randomized, observer-blind, active-controlled, dose-finding clinical study designed to evaluate the safety, tolerability and immunogenicity of VAX-31 at three dose levels (Low, Middle and High) and compared to PCV20 in 1,015 healthy adults aged 50 and older. In the Low, Middle and High Doses, all serotypes were dosed at 1.1mcg, 2.2mcg and 3.3mcg, respectively, except serotypes 1, 5 and 22F, which were dosed at 1.65mcg, 3.3mcg, and 4.4mcg, respectively. The Phase 1 portion of the study evaluated the safety and tolerability of a single injection of VAX-31 at three dose levels and compared to PCV20 in 64 healthy adults 50 to 64 years of age. In January 2024, we announced that the first participants were dosed in the Phase 2 portion of the Phase 1/2 study of VAX-31 in healthy adults. The initiation of the Phase 2 portion occurred after an independent Data Monitoring Committee conducted an assessment of the Phase 1 safety and tolerability results and recommended that the study proceed as planned to Phase 2. Phase 1 participants were evaluated for immunogenicity, and the Phase 1 safety, tolerability and immunogenicity data was pooled with the participants in the Phase 2 portion of the study. The Phase 2 portion of the study evaluated the safety, tolerability and immunogenicity of a single injection of VAX-31 at the same three dose levels and compared to PCV20, in 951 healthy adults 50 years of age and older. Participants were randomized equally in four separate arms and, 30 days after dosing, serology samples were collected to assess immunogenicity. The immunogenicity objectives of the study included an assessment of the induction of antibody responses, using OPA and IgG at each of the three VAX-31 doses and compared to PCV20, for the 20 serotypes in common, as well as for the additional 11 serotypes contained in VAX-31, but not in PCV20. Participants in the study were evaluated for safety through six months after vaccination. The study was conducted at approximately 25 sites in the United States. In January 2024, we announced the completion of enrollment in the Phase 1/2 clinical study evaluating VAX-31 in healthy adults aged 50 and older.

Figure 12 is a schematic of the overall study design of our VAX-31 adult Phase 1/2 study:

Figure 12.



In September 2024, we announced positive topline results from the study.

Safety and Tolerability Findings:

As shown in Figure 13, based on the full six-month safety data, VAX-31 was observed to be well tolerated and demonstrated a safety profile at all doses studied through the full six-month evaluation period similar to PCV20. As shown in Figure 14 and Figure 15, frequently reported local and systemic reactions were generally mild-to-moderate, resolving within several days of vaccination, with no meaningful differences observed across the cohorts. No serious adverse events were considered to be related to study vaccines.

Figure 13.

	VAX-31 Low Dose	VAX-31 Middle Dose	VAX-31 High Dose	PCV20
NUMBER OF SUBJECTS WITH:	255	254	253	253
Unsolicited TEAE, n (%)	42 (16.5)	43 (16.9)	47 (18.6)	42 (16.6)
Related Unsolicited TEAE, n (%)	7 (2.7)	11 (4.3)	17 (6.7)	12 (4.7)
MAAE, n (%)	45 (17.6)	42 (16.5)	35 (13.8)	31 (12.3)
Related MAAE, n (%)	1 (0.4)	4 (1.6)	0	0
NOCI, n (%)	2 (0.8)	6 (2.4)	5 (2.0)	5 (2.0)
Related NOCI, n (%)	1 (0.4)	0	0	0
SAE, n (%)	2 (0.8)	3 (1.2)	5 (2.0)	3 (1.2)
Related SAE, n (%)	0	0	0	0
Death, n (%)	0	0	0	0
Related Death, n (%)	0	0	0	0

Figure 14.

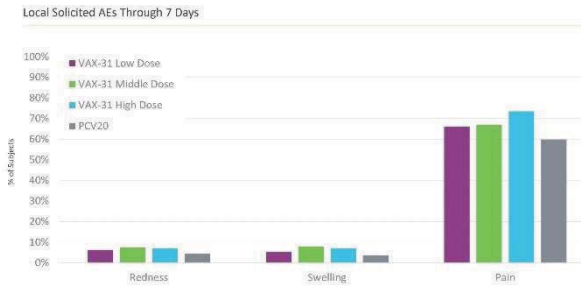
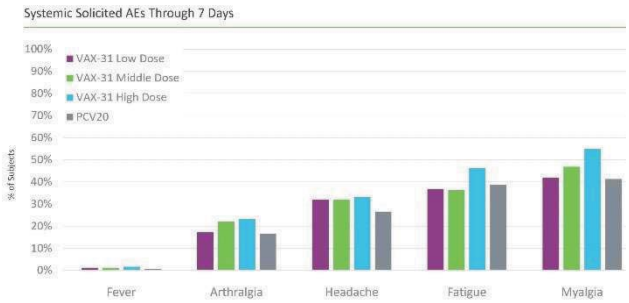


Figure 15.

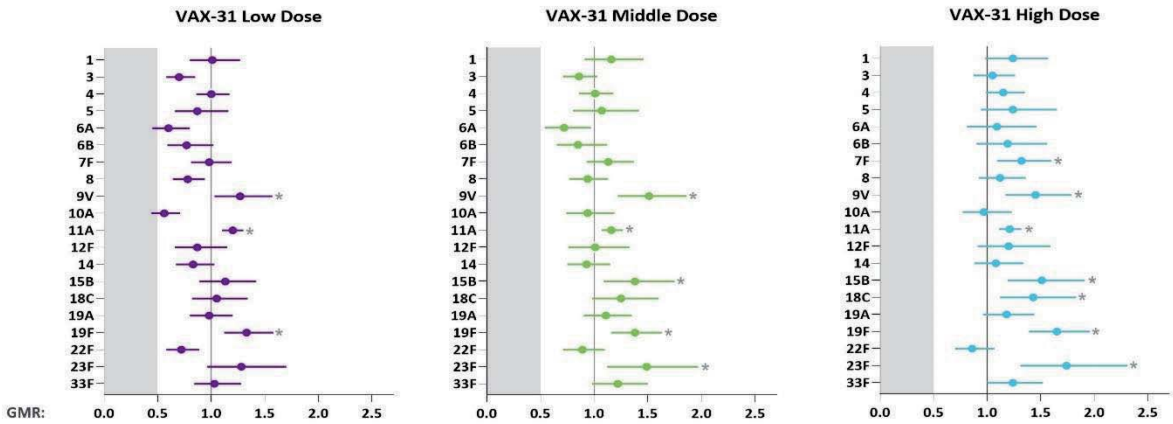


Immunogenicity Findings:

As shown in Figures 16 and 17, VAX-31 showed robust OPA immune responses for all 31 serotypes at all doses studied. At the Middle and High Doses, VAX-31 met or exceeded the regulatory immunogenicity criteria for all 31 serotypes and, at the Low Dose, for 29 of 31 serotypes.

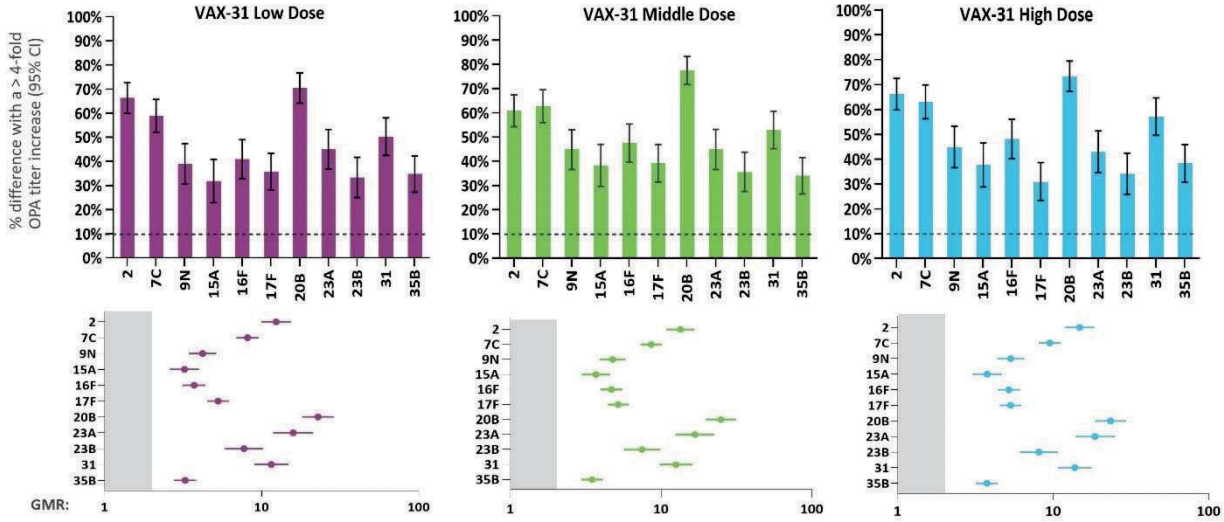
As shown in Figure 16, at the Middle and High doses, VAX-31 met or exceeded the OPA response non-inferiority criteria (lower bound of the 2-sided 95% confidence interval of the OPA GMR is greater than 0.5) for all 20 serotypes common with PCV20. At the VAX-31 High Dose, average OPA immune responses were greater for 18 of 20 serotypes compared to PCV20 (GMR greater than 1.0), with seven of these serotypes achieving statistically higher immune responses compared to PCV20 (lower bound of the 2-sided 95% confidence interval of the OPA GMR is greater than 1.0). At the Middle Dose, 13 of 20 serotypes had a GMR greater than 1.0 and five serotypes achieved statistically higher immune responses compared to PCV20. At the Low Dose, 18 of 20 serotypes met the OPA response non-inferiority criteria, 8 of 20 serotypes had a GMR greater than 1.0 and three serotypes achieved statistically higher immune responses.

Figure 16.



As shown in Figure 17, for all 11 incremental serotypes unique to VAX-31, and not in PCV20, all three doses met the superiority criteria (lower bound of the 2-sided 95% confidence interval of the difference in the proportions of participants with a ≥4-fold increase from day 1 to month 1 is greater than 10%, and lower bound of the 2-sided 95% confidence interval of the OPA GMR is greater than 2.0).

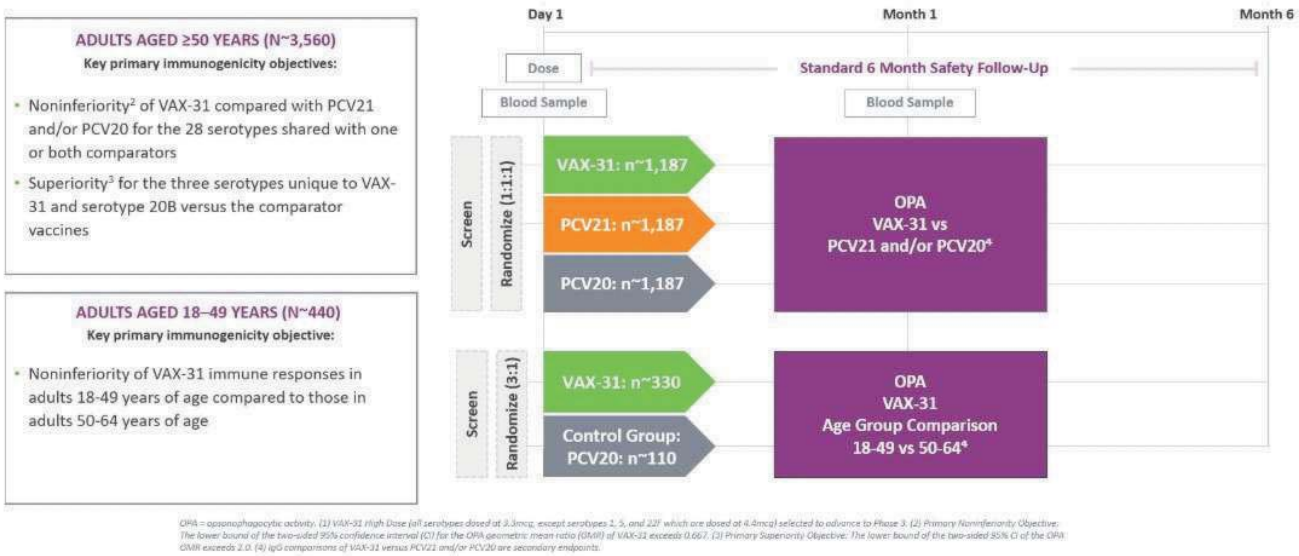
Figure 17.



Based on these positive results, we selected the High Dose of VAX-31 to advance to an adult Phase 3 program. Following an FDA End-of-Phase 2 meeting, we are advancing a comprehensive Phase 3 adult clinical program for VAX-31 to support a planned BLA submission. The announced Phase 3 clinical studies, which were finalized in consultation and alignment with the FDA, include the pivotal, noninferiority trial evaluating VAX-31 for the prevention of IPD and pneumonia in adults (OPUS-1); a trial evaluating VAX-31 when administered concomitantly with a licensed, high-dose seasonal influenza vaccine in pneumococcal-naïve adults (OPUS-2); and a trial in adults who have previously received a pneumococcal vaccine (OPUS-3), all of which are currently enrolling participants. Across these three studies, approximately 6,000 adults are expected to be enrolled in total, of whom approximately 3,400 will receive VAX-31, with the intent to generate a broad and robust safety, tolerability and immunogenicity dataset. We are also planning for a manufacturing consistency study (e.g., a lot-to-lot study).

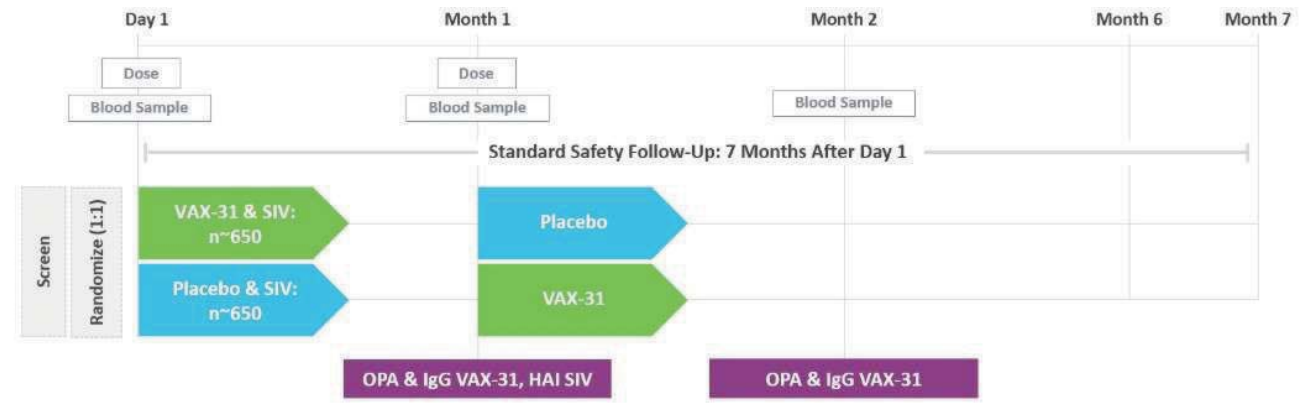
OPUS-1 is evaluating the safety, tolerability and immune responses of VAX-31 in approximately 3,560 adults aged 50 and older through direct, head-to-head comparisons with both PCV21 and PCV20, the current standard-of-care PCVs, with the objective of establishing a best-in-class profile for VAX-31. The trial is also evaluating the safety, tolerability and immune responses of VAX-31 in approximately 440 adults aged 18-49. OPUS-1 is being conducted at approximately 50 sites in the United States.

The key primary immunogenicity objectives of this trial are to demonstrate (i) noninferiority if the lower bound of the two-sided 95% confidence interval for the OPA GMR of VAX-31 exceeds 0.667 compared with PCV21 and/or PCV20 for the 28 serotypes shared with one or both comparators and (ii) superiority if the lower bound of the two-sided 95% confidence interval of the OPA GMR exceeds 2.0 for the three serotypes unique to VAX-31 and serotype 20B versus the comparator vaccines. The trial is also evaluating the safety, tolerability and immune responses of VAX-31 in adults aged 18-49. Key secondary immunogenicity objectives are included to evaluate VAX-31 based on additional measures of non-inferiority, superiority and statistically greater immune responses.



OPA = opsonophagocytic activity. (1) VAX-31 High Dose (all serotypes dosed at 8.3mcg, except serotypes 1, 5, and 22F which are dosed at 4.4mcg) selected to advance to Phase 3. (2) Primary Noninferiority Objective: The lower bound of the two-sided 95% confidence interval (CI) for the OPA geometric mean ratio (GMR) of VAX-31 exceeds 0.667. (3) Primary Superiority Objective: The lower bound of the two-sided 95% CI of the OPA GMR exceeds 2.0. (4) IgG comparisons of VAX-31 versus PCV21 and/or PCV20 are secondary endpoints.

OPUS-2 is a randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety, tolerability and immunogenicity of VAX-31 when administered either concomitantly with or one month following administration of a licensed, high-dose seasonal influenza vaccine in pneumococcal-naïve, healthy U.S. adults aged 50 years and older. The study is expected to enroll approximately 1,300 participants at approximately 25 sites in the United States. The results of this descriptive study are intended to inform the design of a potential post-licensure outcomes study that further evaluates VAX-31 in concomitant use with an influenza vaccine and to provide supportive evidence as part of the broader Phase 3 dataset.



OPA = opsonophagocytic activity, IgG = immunoglobulin G, HAI = hemagglutination inhibition, SIV = seasonal influenza vaccine.

OPUS-3 is a randomized, double-blind, active-controlled, descriptive clinical trial designed to evaluate the safety, tolerability and immunogenicity of a single dose of VAX-31 in approximately 720 healthy U.S. adults

aged 50 years and older with a history of prior pneumococcal vaccination at least six months prior. The study will be conducted at approximately 30 sites in the United States.

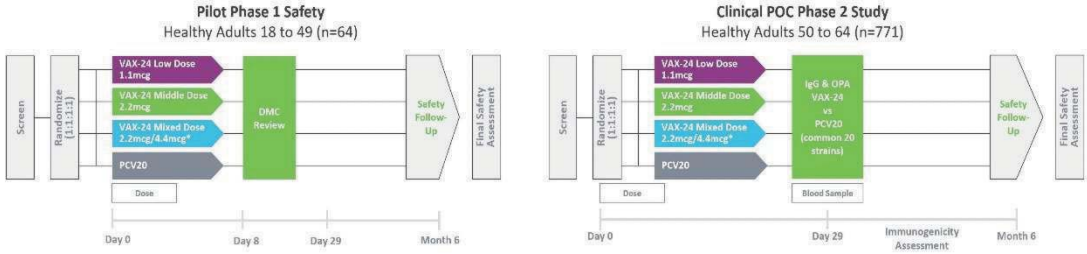
Contextual Information: VAX-24 Adult Indication

Phase 1/2 Clinical Proof-of-Concept Study in Adults Aged 18 to 64

Our first-in-human study was a randomized, double-blind, dose-finding, controlled Phase 1/2 clinical proof-of-concept study designed to evaluate the safety, tolerability and immunogenicity of VAX-24 in healthy adults aged 18 to 64. The Phase 1 portion of the study evaluated the safety and tolerability of a single injection of VAX-24 at three dose levels, 1.1mcg, 2.2mcg and 2.2mcg/4.4mcg, and compared to PCV20 in 64 healthy adults aged 18 to 49. Participants were randomized equally in four separate arms and were evaluated for safety 8 and 29 days after dosing. The Phase 2 portion evaluated the safety, tolerability and immunogenicity of a single injection of VAX-24 at the same three dose levels and compared to a single injection of PCV20 in 771 healthy adults 50 to 64 years of age. Participants were randomized equally in four separate arms and approximately 28 days after participants were dosed, samples were collected to assess immunogenicity. The immunogenicity objectives of the Phase 2 portion of the study included an assessment of the induction of antibody responses, using OPA and IgG, at each of the three VAX-24 doses and compared to PCV20, and for the additional four serotypes contained in VAX-24 (and PPSV23), but not in PCV20, the percentage of subjects that experienced a four-fold rise in antibody titers. Participants in the study were evaluated for safety through six months after vaccination.

Figure 18 is a schematic of the overall study design of our Phase 1/2 study:

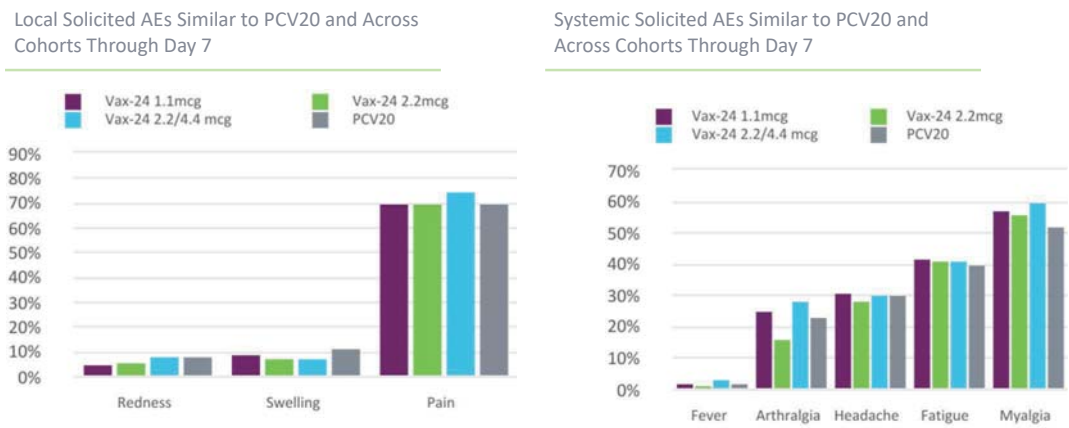
Figure 18.



In October 2022, we announced positive topline results from both the Phase 1 and Phase 2 portions of the study.

VAX-24 met the primary safety and tolerability objectives, demonstrating a safety profile similar to PCV20 for all doses studied. Frequently reported local and systemic reactions were generally mild-to-moderate, resolving within several days of vaccination, with no difference observed across the cohorts. No serious adverse events or new onset chronic illnesses were considered to be related to study vaccines.

Figure 19.



In this study, VAX-24 demonstrated robust OPA and IgG immune responses for all 24 serotypes at all doses studied (1.1mcg, 2.2mcg, 2.2mcg/4.4mcg). At the conventional 2.2mcg dose, which we plan to advance to a potential Phase 3 program, VAX-24 met or exceeded the established regulatory immunogenicity standards for all 24 serotypes. At this dose, VAX-24 met the standard OPA response non-inferiority criteria for all 20 serotypes common with PCV20, of which 16 serotypes (3, 4, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 23F and 33F) achieved higher immune responses and four serotypes (9V, 18C, 19F and 33F) reached statistical significance. Additionally, at all three doses, VAX-24 met the standard superiority criteria for all four serotypes (2, 9N, 17F and 20B) unique to VAX-24.

Figure 20.

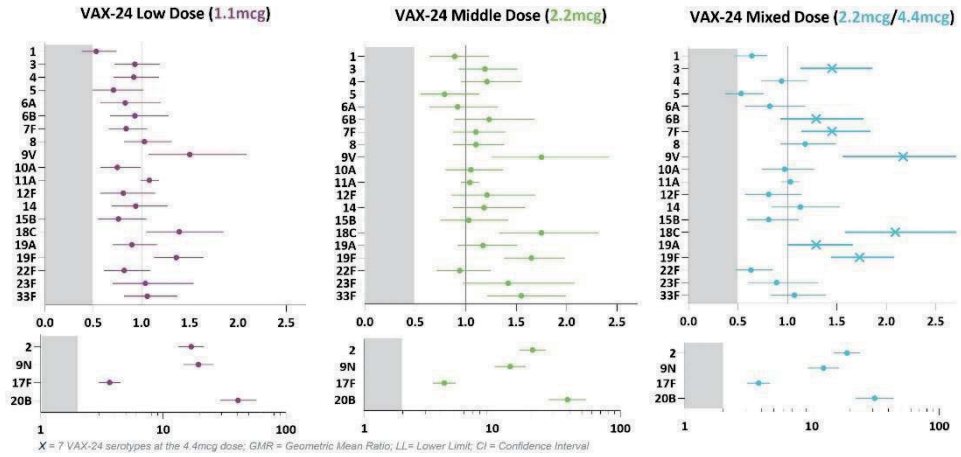
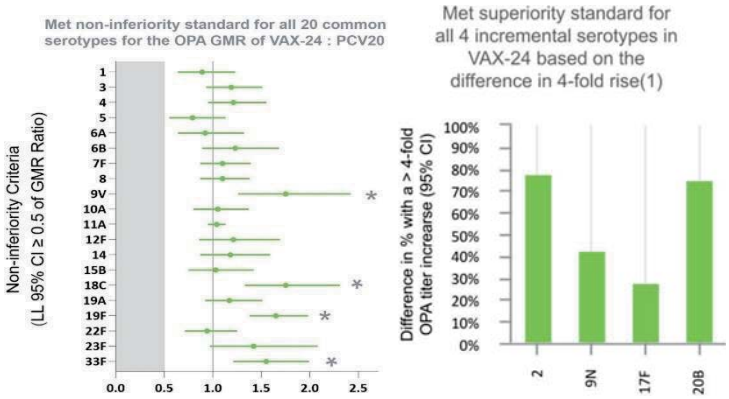


Figure 21.



Regulatory Threshold for Superiority (LL95%CI > 10%)

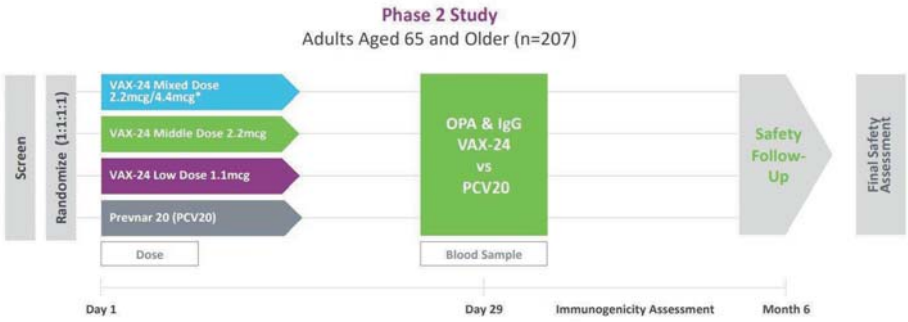
Based on the results of this study, the FDA granted a BTD for VAX-24 for the prevention of IPD in adults.

Phase 2 Clinical Study in Adults 65 and Older

To add to the body of data in adults, we conducted a separate Phase 2 study in adults aged 65 and older. This study was a randomized, double-blind, dose-finding, controlled Phase 2 study designed to evaluate the safety, tolerability and immunogenicity of a single injection of VAX-24 at the same three dose levels evaluated in the Phase 1/2 study, 1.1mcg, 2.2mcg and 2.2mcg/4.4mcg, and compared to a single injection of PCV20 in 207 healthy adults aged 65 and older. Participants were randomized equally in four separate arms and approximately 28 days after participants were dosed, samples were collected to assess immunogenicity. The immunogenicity objectives of the study include an assessment of the induction of antibody responses, using OPA and IgG, at each of the three VAX-24 doses and compared to PCV20, and for the additional four serotypes contained in VAX-24 (and PPSV23), but not in PCV20, the percentage of subjects that experience a four-fold rise in antibody titers. This study was designed to inform the powering of a Phase 3 study and was not powered to demonstrate non-inferiority. Participants in the study also were evaluated for safety through six months after vaccination.

Figure 22 is a schematic of the overall study design of our Phase 2 study in adults aged 65 and older:

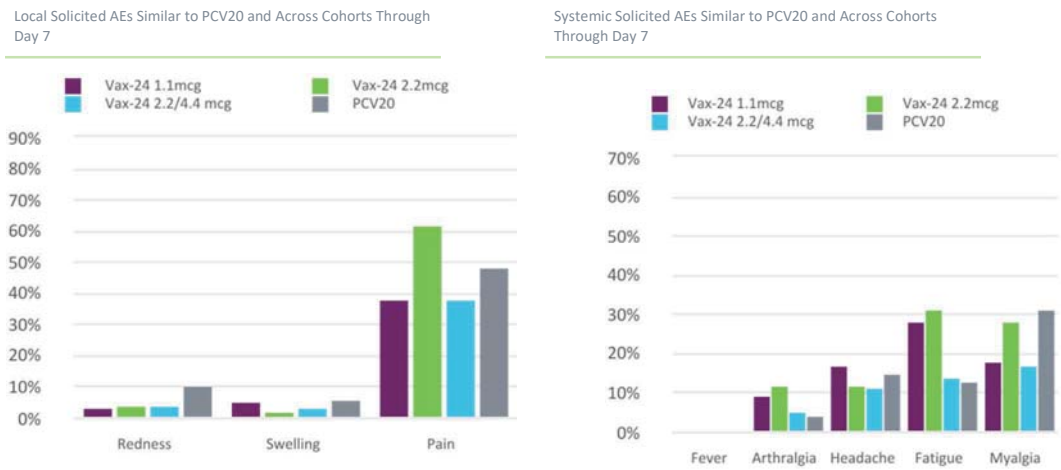
Figure 22.



On April 17, 2023, we announced positive results from this Phase 2 study of VAX-24 in adults aged 65 and older, as well as data from the full six-month safety assessment and prespecified pooled immunogenicity analyses from both the Phase 2 study in adults aged 65 and older and the prior Phase 1/2 study in adults aged 18-64.

In this Phase 2 study, VAX-24 demonstrated robust OPA immune responses across all 24 serotypes at all doses studied (1.1mcg, 2.2mcg, and 2.2mcg/4.4mcg), confirming the prior Phase 2 adult study results. The VAX-24 2.2mcg dose, which we had planned to advance to a potential Phase 3 program prior to our decision to advance exclusively VAX-31, showed an overall improvement in immune responses compared to PCV20 relative to the results from the prior Phase 2 study in adults aged 50-64. The six-month safety data from both adult studies showed safety and tolerability results for VAX-24 similar to PCV20 at all doses studied.

Figure 23.



Consistent with prior Phase 2 study, the 2.2mcg dose demonstrated higher OPA GMR for 16 out of the 20 shared serotypes. The 2.2mcg dose showed robust immune responses for all 24 serotypes.

Figure 24.

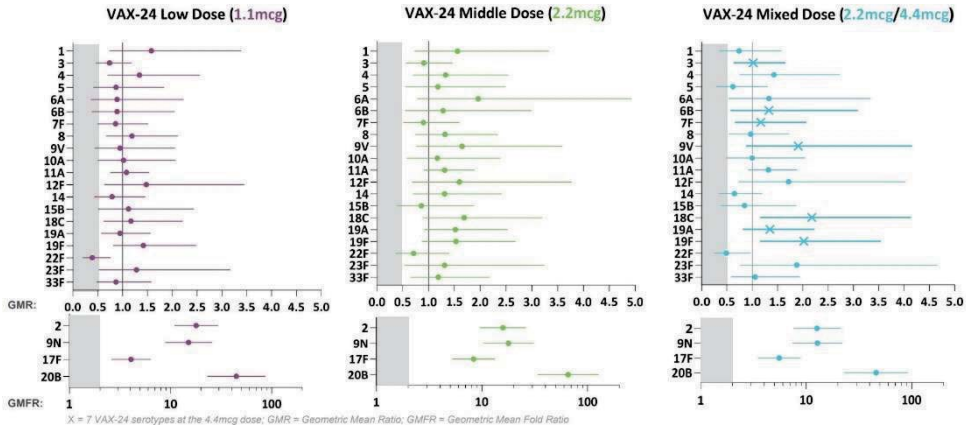
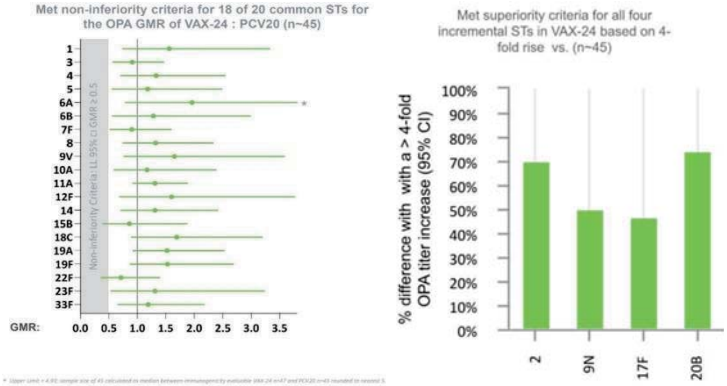


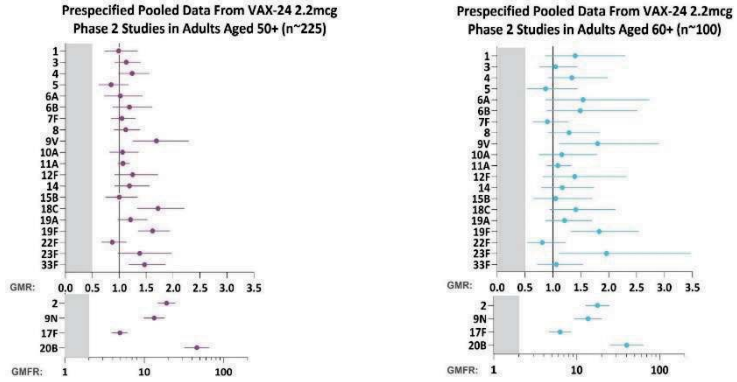
Figure 25.



Prespecified Pooled Immunogenicity Analyses of Data from VAX-24 Adult Phase 2 Studies

Additionally, we conducted prespecified pooled analyses of data from both adult Phase 2 studies to evaluate the immunogenicity of VAX-24 in participants aged 50 and older and aged 60 and older, which are representative populations for the potential VAX-24 Phase 3 pivotal study. The prespecified pooled immunogenicity analyses of data from both adult Phase 2 studies showed the VAX-24 2.2mcg dose met the OPA non-inferiority criteria for all 20 serotypes common with PCV20 and met the superiority criteria for the four additional serotypes unique to VAX-24. In the pooled group with participants aged 50 and older, VAX-24 met the OPA response non-inferiority criteria for all 20 serotypes common with PCV20, of which 16 achieved higher immune responses and four reached statistical significance. In the pooled group with participants aged 60 and older, VAX-24 met the OPA response non-inferiority criteria for all 20 serotypes common with PCV20, of which 17 achieved higher immune responses and three reached statistical significance.

Figure 26.



Combined Six-Month Safety Data from Both Adult VAX-24 Studies

In April 2023, we also reported the full six-month safety results from the VAX-24 Phase 2 study in adults aged 65 and older and the VAX-24 Phase 1/2 study in adults aged 18-64. Through six months, VAX-24 demonstrated safety and tolerability results similar to PCV20 across all ages and doses studied. Frequently reported local and systemic reactions were generally mild-to-moderate, resolving within several days of vaccination, with no meaningful difference observed across the cohorts. Further, no serious adverse events or new onset chronic illnesses were considered to be related to study vaccines. In a VAX-24 arm of the Phase 2 study in adults aged 65 and older, one participant with multiple pre-existing risk factors suffered a sudden cardiac death six months post-vaccination, which the Principal Investigator determined was not related to study vaccine due to the participant's history of hypertensive cardiovascular disease.

Figure 27.

	VAX-24 — Low Dose (1.1mcg)	VAX-24-Middle Dose (2.2mcg)	VAX-24 - Mixed Dose (2.2mcg/4.4mcg)	PCV20
Number of Subjects with	261	258	260	262
Unsolicited TEAE, n (%)	38 (14.6)	28 (10.9)	30 (11.5)	42 (16.0)
Related Unsolicited TEAE, n (%)	5 (1.9)	13 (5.0)	7 (2.7)	13 (5.0)
MAAE, n (%)	32 (12.2)	29 (11.2)	27 (10.4)	37(14.1)
Related MAAE, n (%)	0	0	1 (0.4)	0
NOCI, n (%)	4 (1.5)	4 (1.6)	7 (2.7)	5 (1.9)
Related NOCI, n (%)	0	0	0	0
SAE, n (%)	3 (1.1)	4 (1.6)	2 (0.77)	4 (1.5)
Related SAE, n (%)	0	0	0	0
Death, n (%)	0	1 (0.39)[1]	0	0
Related Death, n (%)	0	0	0	0

(1) 66-year-old white, obese male (BMI: 47.4) with hypertension. No solicited AEs were reported after vaccination. Participant suffered sudden cardiac death six months post-vaccination determined by Principal Investigator to be not related to study product due to participant's history of hypertensive cardiovascular disease.

TEAE = Treatment emergent adverse events

Excludes Solicited AEs

Clinical Programs: Infant Indication

We expect the clinical development of VAX-24 and VAX-31 in infants to follow similar approaches utilized for PCV13, PCV15 and PCV20, where vaccine effectiveness against IPD was inferred from immunologic correlates, and approvals are based on non-inferiority comparisons of IgG responses and totality of data, whereas in the adult population approvals have been based on non-inferiority comparisons of OPA responses. Consistent with the approval processes for PCV13, PCV15 and PCV20 in infants, we do not anticipate that clinical field efficacy trials will be required for VAX-24 or VAX-31 in the pediatric population.

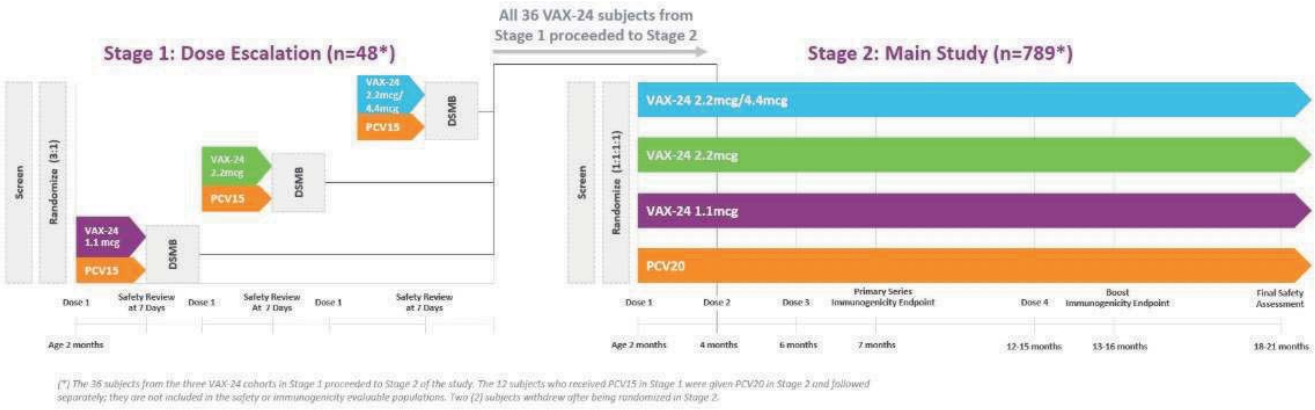
Our Phase 3 and commercial strategy for VAX-24 or VAX-31 for the infant indication will depend on several factors, including the results from our ongoing Phase 2 study for VAX-31. Pending the outcome of our Phase 2 VAX-31 study, we plan to initiate a Phase 3 program with an Optimized Dose formulation of VAX-24 or VAX-31. We expect our Phase 3 program in the pediatric population to focus on evaluating non-inferiority to PCV20, the current standard of care in infants, for immunogenicity and seroconversion or antibody concentration threshold; assessing U.S. routine vaccination responses following concomitant administration with our vaccine candidate; and generating a sufficient safety database in infants. The Phase 3 non-inferiority results would then be used to seek approval in the pediatric population. This approach is similar to the approach utilized to develop PCV13, where the immunogenicity of PCV13 was compared to the original 7-valent Prevnar product, which was the standard of care at the time, as well as the approaches for PCV15 and PCV20, which were compared to PCV13.

VAX-24

The VAX-24 Phase 2 infant study was a randomized, observer-blind, dose-finding two-stage clinical study evaluating the safety, tolerability and immunogenicity of VAX-24 at three dose levels, 1.1mcg, 2.2mcg, and 2.2mcg/ 4.4mcg, and compared to PCV15 and PCV20 in healthy infants. The Stage 1 portion of the study evaluated the safety and tolerability of a single injection of VAX-24 at three dose levels compared to PCV15 in 48 infants in a dose-escalation approach. The Stage 2 portion evaluated the safety, tolerability and immunogenicity of VAX-24 at three dose levels and compared to PCV20 in 789 healthy infants. In line with recommendations from the ACIP, the study design included a primary immunization series consisting of three doses given at two months, four months and six months of age, followed by a subsequent booster dose at 12-15 months of age. The key prespecified immunogenicity study endpoints included an assessment of immune responses for all three VAX-24 doses and compared to PCV20 on the shared serotypes measured at 30 days post-dose three ("PD3") and post-dose four ("PD4"). Immune responses were assessed based on anti-pneumococcal polysaccharide serotype-specific IgG responses (proportion of participants achieving the accepted IgG threshold value of ≥0.35mcg/ml) at 30 days PD3 and IgG geometric mean titer ratios at 30 days PD4. All participants in the study were evaluated for safety through six months following the booster dose.

Figure 28 is a schematic of the overall study design of our VAX-24 infant Phase 2 study:

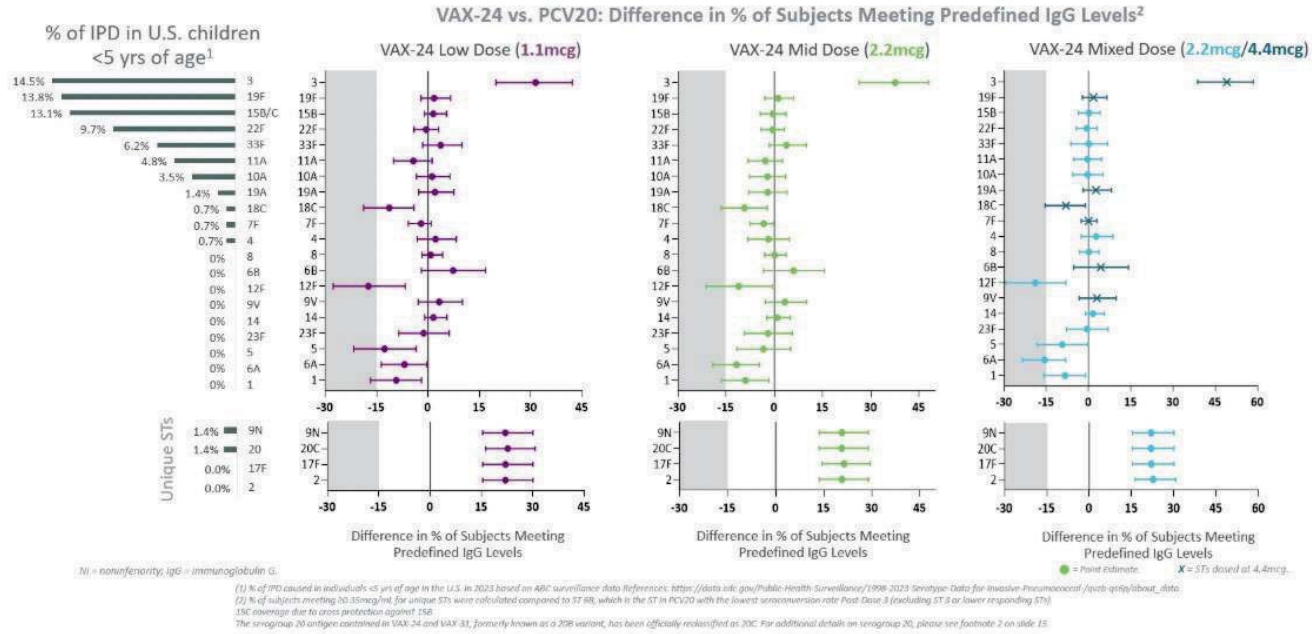
Figure 28.



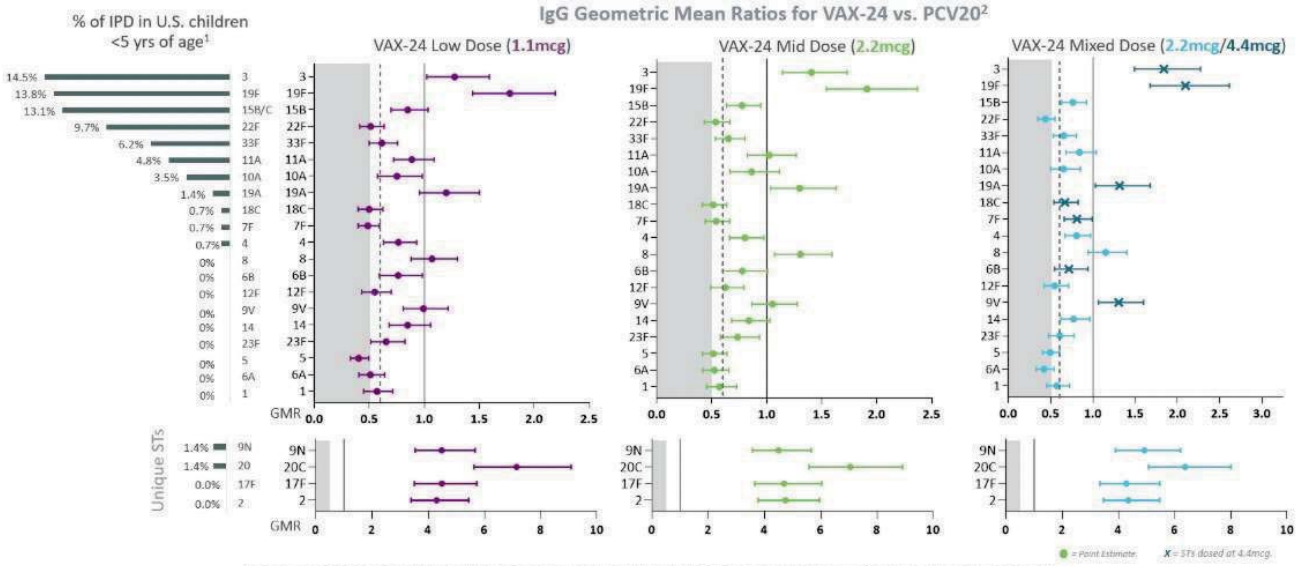
(*) The 36 subjects from the three VAX-24 cohorts in Stage 1 proceeded to Stage 2 of the study. The 12 subjects who received PCV15 in Stage 1 were given PCV20 in Stage 2 and followed separately; they are not included in the safety or immunogenicity evaluable populations. Two (2) subjects withdrew after being randomized in Stage 2.

In March 2025, we announced positive topline, interim data from the VAX-24 infant Phase 2 study and, in November 2025, we announced final safety, tolerability, and immunogenicity results that were consistent with the positive interim data reported in March 2025 and showed that VAX -24 elicited robust, dose-dependent immune responses, with little to no evidence of carrier suppression observed. The final data analysis included full 6-month safety results and complete post-dose 3 (primary immunization series) and post-dose 4 (booster dose) IgG and OPA results. The key immunogenicity endpoints included an assessment of immune responses for each of the VAX-24 dose levels (Low, Mid, Mixed) in comparison with PCV20 for the 20 common and 4 unique serotypes in VAX-24. At 1-month post-dose 3 and post-dose 4, immune responses were assessed based on serotype-specific IgG seroconversion rates (IgG threshold value of ≥0.35mcg/mL). IgG GMRs were also assessed at 1-month post-dose 3 and post-dose 4, along with other key immunogenicity endpoints, including OPA.

Post-dose 3, all VAX-24 doses met target precedent Phase 2 non-inferiority (NI) criteria on relative seroconversion rates (lower limit of the 95% confidence interval for the difference between the proportion of participants achieving the pre-defined seroconversion rate (IgG concentration ≥0.35 mcg/mL) for the highest circulating serotypes, as defined by the percentage of IPD caused in individuals <5 yrs of age in the U.S. in 2023 based on ABC surveillance data, contained in VAX-24. The Low and Mid doses met the seroconversion rate criteria for 20 of 24 serotypes overall and the Mixed Dose met such criteria for 19 of 24 serotypes. The Mid and Mixed Doses met the target Phase 2 IgG GMR point estimate of >0.6 for 21 of 24 serotypes.



Post-dose 4, all VAX-24 doses met our target Phase 2 IgG GMR point estimate of >0.6 for the three highest circulating serotypes contained in VAX-24. The Mixed Dose met this target for 19 of 24 serotypes overall and the Mid dose met this target for 18 of 24 serotypes. Post-dose 4, VAX-24 elicited robust memory responses across all doses for all serotypes.



Additionally, the four incremental serotypes unique to VAX-24 that provide expanded serotype coverage relative to PCV20 elicited robust immune responses and met all target criteria across all endpoints at all doses evaluated.

In this study, VAX-24 was well-tolerated and demonstrated a safety profile similar to PCV20 across all doses studied. Frequently reported local and systemic reactions were generally mild-to-moderate, resolving within several days of vaccination, with no meaningful differences observed across the cohorts. No serious adverse events were considered to be related to study vaccines.

	VAX-24 Low Dose	VAX-24 Mid Dose	VAX-24 Mixed Dose	PCV20
NUMBER OF SUBJECTS	195	186	191	185
Unsolicited TEAE, n (%)	167 (85.6)	161 (86.6)	163 (85.3)	169 (91.4)
Related Unsolicited TEAE, n (%)	6 (3.1)	13 (7.0)	13 (6.8)	6 (3.2)
MAAE, n (%)	172 (88.2)	155 (83.3)	167 (87.4)	161 (87.0)
Related MAAE, n (%)	3 (1.5)	3 (1.6)	3 (1.6)	1 (0.5)
NOCI, n (%)	12 (6.2)	12 (6.5)	15 (7.9)	10 (5.4)
Related NOCI, n (%)	0	1 (0.5)[1]	0	0
SAE, n (%)	10 (5.1)	7 (3.8)	11 (5.8)	11 (5.9)
Related SAE, n (%)	0	0	0	0
Death, n (%)	0	0	0	1 (0.5)[2]
Related Death, n (%)	0	0	0	0

TEAE = treatment emergent adverse events, NOCI = new onset of chronic illnesses, MAAE = medically attended adverse events, SAE = serious adverse events.
(1) Related NOCI = mild nasal congestion.
(2) One sudden infant death syndrome (SIDS) case occurred in the PCV20 cohort 7 weeks after the first and only dose was administered; following a thorough investigation, case was found to be unrelated to study vaccine.

The final positive data from the VAX-24 infant Phase 2 dose-finding study further validated our rationale for exploring higher doses in the ongoing VAX-31 infant Phase 2 study.

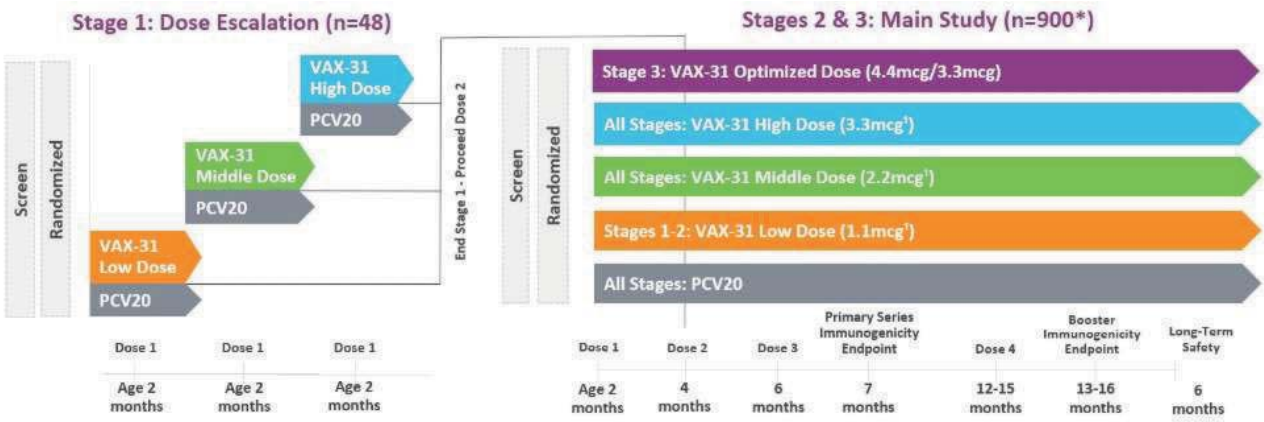
VAX-31

The VAX-31 Phase 2 infant study is a randomized, double-blind, active controlled, dose-finding, three-stage clinical study evaluating the safety, tolerability and immunogenicity of VAX-31 compared to PCV20 in healthy infants. Stage 1 of the study evaluated the safety and tolerability of VAX-31 at three dose levels (Low, Middle and High) and compared to PCV20 in 48 infants in a dose-escalation approach. In the Low, Middle and High Doses, all serotypes were dosed at 1.1mcg, 2.2mcg and 3.3mcg, respectively, except serotypes 1, 5 and 22F, which were dosed at 1.65mcg, 3.3mcg, and 4.4mcg, respectively. Participants who received VAX-31 in Stage 1 continued the standard dosing regimen as part of Stage 2. Stage 2 is evaluating the safety, tolerability and immunogenicity of VAX-31 at the same three dose levels and compared to PCV20. In line with recommendations from the ACIP, the study includes a primary immunization series consisting of three doses given at two, four and six months of age, followed by a subsequent booster dose at 12-15 months of age. On September 2025, we announced advancement of the VAX-31 infant Phase 2 randomized, dose-finding study to the third and final stage following modifications to the protocol to add a new dose arm to evaluate the VAX-31 Optimized Dose (majority of serotypes dosed at 4.4mcg and the balance dosed at 3.3mcg) and discontinue enrollment in the Low Dose arm. The Middle and High Dose arms are continuing as planned.The key

prespecified immunogenicity study endpoints include an assessment of immune responses for each of the VAX-31 dose levels in comparison with PCV20 for the 20 common and 11 unique serotypes in VAX-31. Post-primary series PD3 immune responses will be assessed based on serotype-specific IgG seroconversion rates (proportion of participants achieving the accepted IgG threshold value of ≥0.35mcg/mL) at 30 days PD3. IgG geometric mean titers will be assessed at 30 days PD3 and PD4, along with other key immunogenicity endpoints. All participants in the study will be evaluated for safety through six months following the booster dose.

Figure 29 is a schematic of the overall study design of our VAX-31 infant Phase 2 study:

Figure 29



We expect to announce topline safety, tolerability and immunogenicity data for the Phase 2 randomized, dose-finding study from the primary three-dose immunization series and booster dose either sequentially or together by the end of the first half of 2027.

Pending the VAX-31 infant study readout, we plan to initiate a Phase 3 program with an Optimized Dose formulation of VAX-24 or VAX-31.

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) bacteria cause a wide spectrum of both acute and chronic clinical conditions that lead to considerable disease burden globally. Group A Strep causes an estimated 800 million cases of illness each year and is one of the leading infectious disease-related causes of death and disability worldwide. It is estimated that over 600,000 deaths globally result from Group A Strep, and, even in

countries where antibiotic treatment is readily available, Group A Strep has a considerable disease burden contributing more than 600 million cases of pharyngitis per year along with substantial morbidity from cellulitis, invasive disease, and skin infections. The total annual market for a Group A Strep vaccine is estimated at approximately $3 billion to $4 billion globally. The annual economic burden of Group A Strep disease in the U.S. population is estimated to exceed $6 billion resulting from invasive disease and non-severe acute upper respiratory infections. In addition, Group A Strep drives significant antibiotic use, especially among children, and as such contributes towards increased antimicrobial resistance. Among older adults (≥ 65 years) in the United States, rates of invasive disease and deaths caused by Group A Strep have been increasing over the last decade. Some of the most serious consequences of Group A Strep include invasive diseases such as flesh-eating disease (necrotizing fasciitis), sepsis and sequelae such as rheumatic heart disease ("RHD"). An estimated 55 million people are affected by RHD each year worldwide. Importantly, the majority of Group A Strep infections lead to pharyngitis, commonly known as strep throat, which is highly prevalent in school-age children. In the United States, an estimated 17% of outpatient antibiotic prescriptions dispensed to children aged 3 to 9 years are for the treatment of suspected Group A Strep infections. Studies have indicated that antibiotic resistance to Group A Strep has significantly increased over the past decade, leading the CDC to categorize Group A Strep as a concerning threat. Additionally, the development of vaccines against Group A Strep has become a priority for the WHO amid recognition of the rising disease incidence globally, as well as the need to combat avoidable antibiotic consumption.

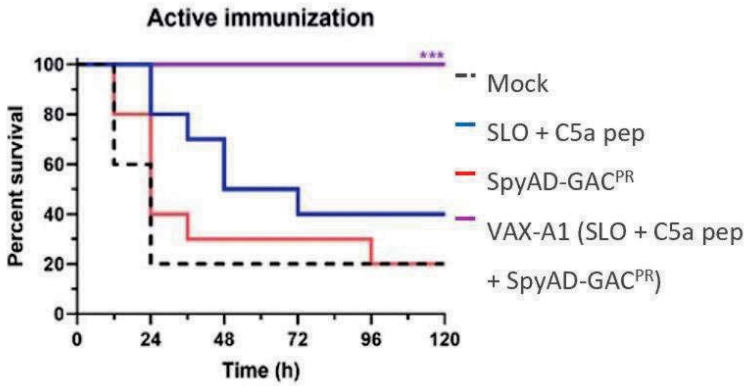
It has been established that the repeated natural infection of children with Group A Strep results in immune responses that are protective against subsequent Group A Strep infection. We believe this observation justifies the development of a rationally designed vaccine for Group A Strep that is focused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

VAX-A1

We have developed a conjugate vaccine candidate, VAX-A1, 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 protein-polysaccharide conjugate along with two additional conserved surface proteins.

Our initial preclinical proof-of-concept study was published in the journal *Infectious Microbes & Diseases* in December 2020. In the study, a novel protein and polysaccharide conjugate of the Group A Strep polysaccharide was constructed for inclusion in a universal subunit vaccine against infections by the pathogen. The VAX-A1 vaccine candidate, based on SpyAD-conjugated to a modified polyrhamnose backbone (lacking N-acetyl glucosamine) and including SLO and C5a peptidase, demonstrated protection from subcutaneous and systemic challenge in mice, antibody binding and opsonophagocytic killing for multiple Group A Strep M Protein Gene types and no evidence of cross-reactivity to human heart and brain tissue antigens (Figure 30), which is a key leading indicator of vaccine safety. The study was carried out in collaboration with researchers at the Division of Host-Microbe Systems and Therapeutics, Department of Pediatrics, University of California School of Medicine and the Skaggs School of Pharmacy and Pharmaceutical Sciences at the University of California, San Diego.

Figure 30.



Our VAX-A1 vaccine development program has been funded in part by a grant obtained from Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator ("CARB-X"), a global non-profit partnership dedicated to accelerating antibacterial innovation to tackle the rising global threat of drug-resistant bacteria.

We nominated the final vaccine candidate for our VAX-A1 program and initiated IND-enabling activities in 2021 and plan to initiate a Phase 1 adult clinical study in 2026, with the primary objective of assessing safety and tolerability.

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.

VAX-GI

VAX-GI is a novel preclinical vaccine candidate being developed as a preventative treatment for dysentery and shigellosis, which is caused by Shigella bacteria. Shigella is a bacterial illness that causes dysentery with symptoms, including bloody diarrhea, fever, and stomach cramps. Currently there are no prophylactics and treatment is primarily oral rehydration therapy, with antibiotics (mainly ciprofloxacin and azithromycin) used to shorten the duration of infection. However, the growing incidence of antibiotic resistance has complicated this approach with an increasing rate of extensively drug resistant. Shigella is estimated to cause 80 million to 165 million cases of disease and 600,000 deaths annually, mostly among children. Further, in young children Shigella can cause malnutrition and induce or exacerbate stunting, leading to a long-term impact on both physical and cognitive development. This has resulted in the WHO including Shigella vaccine development as a priority goal.

VAX-GI, which includes cell-free produced IpaB conjugated to Shigella flexneri 2a polysaccharide was used to vaccinate mice which were evaluated for generation of a productive immune response and protection. All groups were challenged i.n. (pulmonary infection model) with virulent S. flexneri 2a 2457T or S. sonnei Moseley on day 57 postvaccination. Immunization with S. flexneri 2a OPS-IpaB conjugate vaccine afforded 78% protection against homologous S. flexneri 2a challenge ($P < 0.0001$) whereas S. flexneri 2a OPS-CRM provided only 50% protection ($P = 0.0014$) (Figure 33A). IpaB alone conferred 67% protection against S. flexneri 2a ($P = 0.0003$) (Figure 33A). The trend of higher protective efficacy of OPS-IpaB than of OPS-CRM or IpaB alone suggests that both OPS and IpaB contribute to the observed protective immunity. IpaB- and OPS-specific IgG titers in mice that were protected were significantly higher than titers in those that succumbed to infection (Figure 33C). Importantly, S. flexneri 2a OPS-IpaB exhibited 56% protection against heterologous S. sonnei challenge ($P < 0.0001$) (Figure 33B). Because Shigella O-polysaccharide immunity is serotype specific, this cross protection is attributable to IpaB. This is consistent with the lack of protection in the OPS-CRM group (11% survival). IpaB alone afforded 44% protection against S. sonnei ($P = 0.0003$) (Figure 33B), which was not significantly different from the protection elicited by S. flexneri 2a OPS-IpaB. IpaB-specific serum IgG was again significantly higher in mice that were protected against S. sonnei infection (Figure 33D). S. flexneri 2a and S. sonnei IpaBs share >98% homology; therefore, cross protection was expected. The slight difference in IpaB efficacy in the two experiments is likely due to the higher severity of S. sonnei infection (mice succumbed sooner). Unvaccinated control mice had very low to no survival. We plan to pursue conjugate and protein-only approaches simultaneously, as shown in Figure 34.

Figure 33.

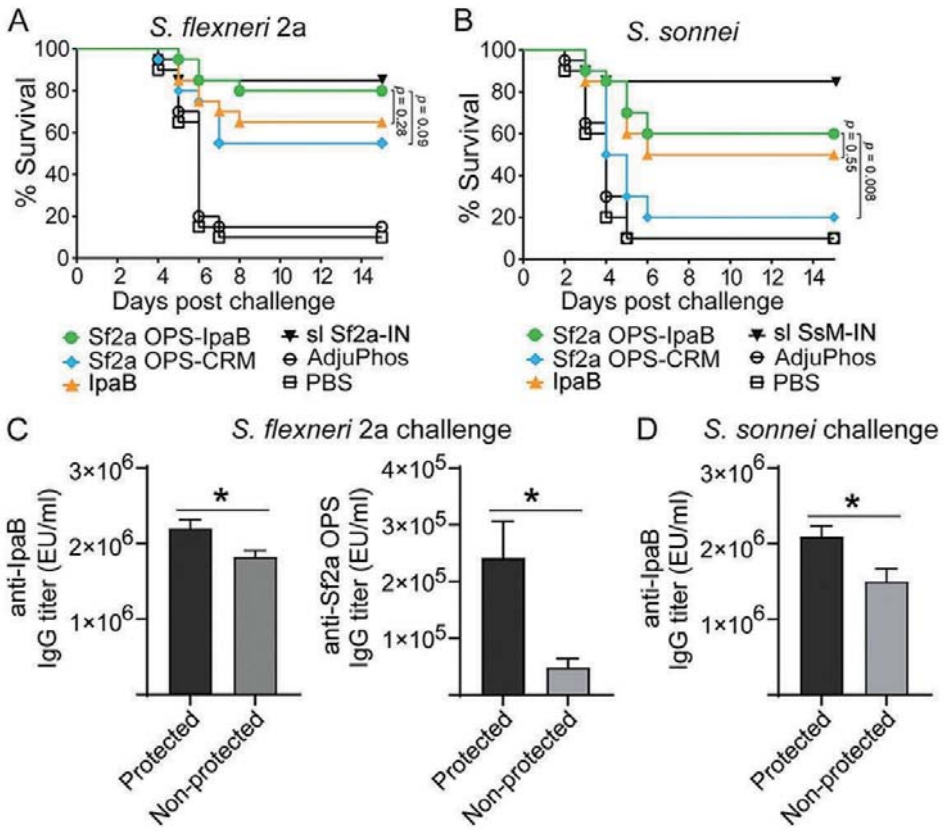
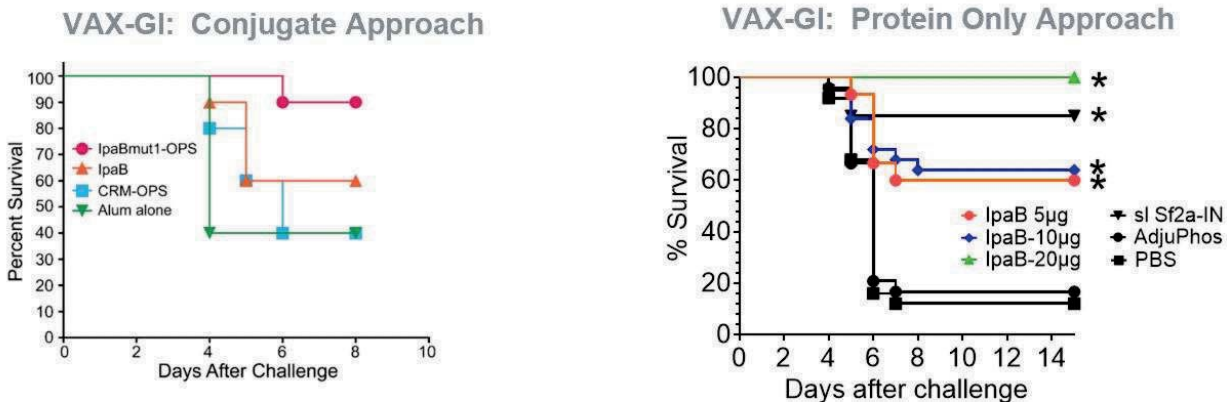


Figure 34.



VAX-GI is being developed in collaboration with the University of Maryland, Baltimore as well as with partial funding from two research grants awarded by the NIH. As part of our continued focus on strategic capital deployment and in order to prioritize our resources towards our PCV franchise, we announced in August 2025 that we had paused the advancement, beyond preclinical development, of VAX-GI while remaining confident in its potential and preserving the option to advance the program in the future.

Manufacturing and Supply

We have designed and developed a proprietary, scalable and portable manufacturing process for VAX-31 and VAX-24 that we believe can scale to address clinical and commercial vaccine supply needed to serve both adult and pediatric populations.

VAX-31 and VAX-24 Process

The manufacturing process for our VAX-31 and VAX-24 vaccine candidates consists of four key components: (i) our proprietary eCRM protein carrier; (ii) the 31 or 24 pneumococcal polysaccharides; (iii) the 31 or 24 conjugate drug substances; and (iv) the mixture of these 31 or 24 drug substances into the final drug product.

eCRM

Our proprietary eCRM protein carrier is produced using our cell-free protein synthesis platform, which is exclusively licensed from Sutro Biopharma for the Vaccine Field (as defined in the Sutro Biopharma License Agreement (as defined below)). eCRM, contains multiple copies of non-native para azido-methyl-phenylalanine ("pAMF") amino acid. 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 31 or 24 pneumococcal polysaccharides is individually isolated from *Streptococcus pneumoniae* bacterial strains. Each individual *Streptococcus pneumoniae* strain is cultured in a bioreactor using an improved single standardized fed-batch bioreactor process and a single standardized downstream purification process. Overall, this standardized upstream and downstream process is simple and streamlined, 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 31 or 24 conjugate drug substances is manufactured individually, as monovalent conjugates, by conjugating each of the 31 or 24 activated 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 largely standardized across the various polysaccharides. Through statistical design of experiment studies, we have gained a significant understanding of which variables to adjust to maximize product quality and, accordingly, immunogenicity in rabbit models.

Drug Product

All 31 or 24 conjugate drug substances are mixed, formulated with appropriate excipients and adsorbed onto alum. Clinical doses are filled in vials and stored refrigerated.

Key Agreements

We currently do not own or operate any manufacturing facilities, but our strategic partnerships with Lonza and other contract manufacturing organizations ("CMOs") provide us with access to substantial resources to facilitate an independent supply path to the market. We have entered into agreements with Lonza, 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, to secure capacity, technical expertise and resources to support the production of eCRM, polysaccharides and drug substance for our PCV programs. We have also entered into a commercial manufacturing agreement with Lonza to support the potential global commercialization of our PCV candidates in both the adult and pediatric populations. This agreement complements our plans to utilize existing Lonza infrastructure to advance clinical development and the anticipated initial U.S. launch of VAX-31 for the adult population. We have relationships with other leading CMOs for the production of the final drug product for our PCV candidates, for the extract and lysates that we use to manufacture eCRM and for certain raw materials. We have an agreement with Sutro Biopharma pursuant to which Sutro Biopharma supplies us with extract and custom reagents for use in manufacturing preclinical and certain clinical supply of vaccine compositions. In December 2019, we exercised our right to require Sutro Biopharma to establish a second supplier for extract and custom reagents to support future clinical and commercial needs and thereafter initiated a tech transfer to a CMO as a second supplier of extract. In December 2022, we entered into a separate agreement with Sutro Biopharma pursuant to which we enhanced our rights with the second supplier of extract and acquired an option to access expanded rights to develop and manufacture extract, among other rights. In

November 2023, we exercised this option and entered in a manufacturing rights agreement to obtain control over manufacturing and development of cell-free extract for our vaccine candidates. In September 2025, we announced a new agreement with Patheon Manufacturing Services, LLC, part of Thermo Fisher Scientific (collectively, "Thermo Fisher") to provide custom commercial fill-finish capacity for our broad-spectrum PCVs at Thermo Fisher's Greenville, North Carolina facility.

Lonza Agreements

Development and Manufacturing Services Agreements

In April 2022, we entered into a non-exclusive development and manufacturing services agreement with Lonza effective as of March 22, 2022, which was subsequently amended on May 12, 2022, November 21, 2022 and October 31, 2023 (as amended, the "2022 Lonza DMSA"). Pursuant to the 2022 Lonza DMSA, Lonza is obligated to perform services, including manufacturing process development and clinical manufacture and supply of our proprietary PCV candidates. Subject to the terms and conditions set forth in the 2022 Lonza DMSA, Lonza has granted to us a non-exclusive, worldwide, fully paid-up, irrevocable, transferable license, including the right to grant sublicenses, under the New General Application Intellectual Property, to research, develop, make, have made, use, sell and import the Product. Unless earlier terminated, the 2022 Lonza DMSA shall remain in place for a period of five years. Either party may terminate the 2022 Lonza DMSA for any reason on prior written notice to the other party, provided that Lonza may not exercise such right until a specified future date. In addition, either party may terminate the 2022 Lonza DMSA (i) within a given time period upon any material breach that is left uncured by the other party, or (ii) immediately if the other party becomes insolvent. We may also terminate the 2022 Lonza DMSA upon an extended force majeure event. Upon expiration and/or termination of the 2022 Lonza DMSA and/or any purchase order, we will pay Lonza for all service rendered, all costs incurred, all unreimbursed capital equipment and any cancellation fees (each term as defined in the 2022 Lonza DMSA).

In February 2023, we entered into another non-exclusive development and manufacturing services agreement with Lonza effective as of March 1, 2023 (the "2023 Lonza DMSA"). Pursuant to the 2023 Lonza DMSA, Lonza will perform manufacturing process development and the manufacture of components for our PCV candidates, including the polysaccharide antigens, our proprietary eCRM protein carrier and conjugated drug substances. Subject to the terms and conditions set forth in the 2023 Lonza DMSA, Lonza has granted to us a non-exclusive, worldwide, fully paid-up, transferable license, including the right to grant sublicenses (subject to the prior written consent of Lonza), under the New General Application Intellectual Property, to use, sell and import the Product manufactured under the 2023 Lonza DMSA (but no other products). Unless earlier terminated, the 2023 Lonza DMSA shall remain in place for a period of five years and shall automatically renew for one additional two-year period unless either party provides written notice of non-renewal at least two years prior to the fifth anniversary of the effective date. We may terminate the 2023 Lonza DMSA for any reason on prior written notice to the other party on a Project Plan-by-Project Plan basis. Either party may terminate the 2023 Lonza DMSA (i) within a given time period upon any material breach that is left uncured by the other party, (ii) immediately if the other party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, or files or has filed against it, a petition in bankruptcy or has a receiver appointed for a substantial part of its assets, (iii) upon an extended force majeure event, or (iv) if it becomes apparent to either party at any stage in the provision of the Services that it will be impossible to complete the Services for scientific or technical reasons despite exercise of best commercial efforts by both parties. Pursuant to the reason for termination and the party initiating the termination, we will pay Lonza for some combination of services rendered, costs incurred, unreimbursed capital equipment and/or any cancellation

fees. Upon an extended force majeure event, neither party shall have any further liability to the other party (each term as defined in the 2023 Lonza DMSA).

Under each of the 2022 Lonza DMSA and 2023 Lonza DMSA (collectively, the "Lonza Agreements"), we pay Lonza agreed-upon fees for their performance of development and manufacturing services and pass-through expenses incurred by Lonza for raw materials, as well as customary procurement and handling fees. Under each Lonza Agreement, we own all rights, title and interest in and to any and all New Customer Intellectual Property (as defined in each Lonza Agreement), and Lonza owns all rights, title and interest in New General Application Intellectual Property (as defined in each Lonza Agreement).

Commercial Manufacturing and Supply Agreement

On October 13, 2023, we entered into a pre-commercial services and commercial manufacturing supply agreement with Lonza (the "Lonza Commercial Manufacturing and Supply Agreement").

Pursuant to the Commercial Manufacturing and Supply Agreement, Lonza will (i) construct and build out a dedicated suite (the "Suite") at Lonza's facilities in Visp, Switzerland to manufacture certain key components (including drug substance) for our proprietary PCV franchise and any other products or intermediates we may choose (collectively, the "Products") and (ii) maintain and operate the Suite (utilizing Lonza's employees) to manufacture the Products as a service provided to us, including conducting related quality control and quality assurance operations. Lonza will be a preferred, non-exclusive, supplier of the Products to us, and we retain the right to procure the Products from one or more alternate and/or backup manufacturers of the Products (including at our own facilities).

Under the Lonza Commercial Manufacturing and Supply Agreement, prior to completion of construction and certification of the Suite for commercial operation, we will contribute to the capital expenditure costs to construct the Suite (and will own certain equipment in the Suite to be purchased or otherwise acquired by us), and will pay Lonza a fixed-rate monthly service fee for Lonza's pre-commercial services prior to commencement of commercial operations (which monthly service fee amount is subject to increases in subsequent years). Following commencement of commercial operations of the Suite to manufacture the Products, we will pay Lonza (i) Suite fees based on allocations of certain of Lonza's costs to maintain the facility in which the Suite is located and to provide shared services to us and Lonza's other customers in such facility, (ii) service fees based upon Lonza's actual full-time equivalent employee ("FTE") costs to operate the Suite to manufacture the Products, and (iii) certain other pass-through costs, including for raw materials. In addition, we may be obligated to pay or reimburse Lonza for certain other fees and expenses under the Lonza Commercial Manufacturing and Supply Agreement. Lonza will be eligible for certain financial bonuses, and subject to certain financial penalties, as incentives for the timely completion of certain scale-up activities, receipt of certain regulatory approvals for the Suite and manufacture of the Products in accordance with our commercial requirements.

Unless earlier terminated, the Lonza Commercial Manufacturing and Supply Agreement will remain in effect until December 31, 2038, subject to automatic renewal for up to three additional renewal periods of five years each, unless we elect not to renew (with 24 months advanced notice to Lonza). We are permitted to terminate the Lonza Commercial Manufacturing and Supply Agreement for convenience or for Lonza's uncured material breach, in each case subject to certain notice obligations. Lonza is permitted to terminate the Commercial Manufacturing and Supply Agreement in the event that we commit certain specified material breaches, including uncured failure to pay material, undisputed amounts of money due to Lonza, subject to certain notice obligations. Either party may terminate the Commercial Manufacturing and Supply Agreement in certain

circumstances in the event of the other party's bankruptcy. In the event that we terminate the agreement for convenience, or Lonza terminates the agreement in the event that we commit certain specified material breaches, then certain termination consequences may be triggered, including that (i) we would forfeit any outstanding entitlement to credit from Lonza of the Repurposing Fee (as defined below), and (ii) we would be obligated to pay Lonza a termination penalty equal to the greater of (a) CHF 70.0 million, or (b) a prespecified number of months' FTE fees for the actual FTEs assigned to us as of the date of termination. Within 30 days of the Effective Date, we paid Lonza a repurposing fee (the "Repurposing Fee") of CHF 27.0 million that will be credited back to us over a 10-year period starting upon commencement of commercial production. In the event of termination under certain circumstances, Lonza shall be obligated to provide certain wind-down and transition services to us for up to 12 and 24 months, respectively.

2026 Development and Manufacturing Services Agreement

On February 18, 2026, we entered into a development and manufacturing services agreement with Lonza, effective as of January 1, 2026, pursuant to which Lonza will perform manufacturing process development and commercial manufacture and supply of certain key components for our proprietary PCV franchise. Under the agreement, we will pay Lonza for development and manufacturing services, in addition to paying for certain raw material and other costs. We will be required to purchase, and Lonza will be required to supply, the components pursuant to the relevant purchase orders under the agreement. In consideration of the commercial supply services and Lonza's other obligations under the agreement, we will pay Lonza a daily fee for Lonza's operation of the facility solely to actively manufacture the components. With respect to such commercial supply, and subject to termination rights, we and Lonza have agreed to a mutually binding percentage of annual facility capacity that shall be utilized by Lonza fully and exclusively for Lonza's performance of services thereunder, which percentages may be adjusted under certain circumstances.

Unless earlier terminated, the agreement will remain in effect until December 31, 2038, subject to automatic renewal for up to three additional renewal periods of five years each, unless we elect not to renew. We may terminate the agreement for convenience, and the agreement contains customary for-cause termination rights for each party. If the Agreement is terminated (i) by us for convenience, or (ii) by Lonza for our uncured failure to pay material, undisputed amounts of money due to Lonza, then we shall pay Lonza certain cancellation fees as specified in the agreement.

Sutro Biopharma Agreements

Amended and Restated License Agreement

We are party to an amended and restated license agreement with Sutro Biopharma, dated October 12, 2015, which was subsequently amended on May 9, 2018, May 29, 2018, September 28, 2023 and November 21, 2023 (as amended, the "Sutro Biopharma License Agreement"). Under the Sutro Biopharma License Agreement, we received an exclusive, worldwide, royalty-bearing, sublicensable 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 sublicensable, for the treatment or prophylaxis of infectious diseases, excluding cancer vaccines, and (ii) 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 Biopharma License Agreement, we are

obligated to pay Sutro Biopharma a 4% royalty on worldwide aggregate annual net sales of our vaccine products for human health and a 2% royalty on such net sales of vaccine products for animal health. 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 10 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.

On September 28, 2023, we and Sutro Biopharma amended certain terms of the Sutro Biopharma License Agreement, including with respect to (i) royalty reduction provisions applicable in the event of expiration of relevant patent claims, which would result in lower royalties payable by us to Sutro Biopharma under certain circumstances, (ii) the ownership, prosecution, maintenance and enforcement of certain intellectual property rights licensed or arising under the Sutro Biopharma License Agreement (including as agreed to be amended in the Option Agreement (as defined below), and (iii) the timing and form for financial reporting of royalty payment calculations.

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.

Supply Agreement

In May 2018, we entered into a supply agreement with Sutro Biopharma, which was subsequently amended on February 22, 2021 and November 21, 2023 (as amended, the "Sutro Biopharma Supply Agreement") 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 Biopharma 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. The term of the Sutro Biopharma Supply Agreement is from execution until the later of (i) July 31, 2022, or (ii) the date that we and Sutro Biopharma enter into the Phase 3/Commercial Supply Agreement and Sutro Biopharma is supplying to us each Product under the Phase 3/Commercial Supply Agreement (each term as defined in the Sutro Biopharma Supply Agreement). 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.

Option Agreement

In December 2022, we entered into an option grant agreement with Sutro Biopharma (the "Option Agreement"). Pursuant to the Option Agreement, we acquired from Sutro Biopharma (i) authorization to enter into an agreement with an independent alternate CMO to directly source Sutro Biopharma's cell-free extract, allowing us to have direct oversight over financial and operational aspects of the relationship with the CMO; and (ii) a right, but not an obligation, to obtain certain exclusive rights to internally manufacture and/or source extract from certain CMOs and the right to independently develop and make improvements to extract (including the right to make improvements to the extract manufacturing process as well as cell lines) for use in connection with the exploitation of certain vaccine compositions (the "Option"). We and Sutro Biopharma agreed to negotiate the terms and conditions of a form definitive agreement to be entered into in the event we exercise the Option, which would include the terms and conditions set forth in an executed term sheet between us (the "Term Sheet") and such terms that were necessary to give effect to each of the terms and conditions set forth in the Term Sheet (the "Form Definitive Agreement").

As consideration for the Option and other rights and authorizations granted to us under the Option Agreement, we paid Sutro Biopharma upfront consideration of $22.5 million, consisting of (i) $10.0 million in cash and $7.5 million worth of shares of our common stock (the number of shares calculated based on the arithmetic average of the daily volume weighted average price of our common stock as traded on Nasdaq in the three consecutive trading days immediately prior to the issuance thereof) in December 2022, and (ii) $5.0 million in October 2023 within five business days after we and Sutro Biopharma mutually agree in writing upon the Form Definitive Agreement on September 28, 2023. The 167,780 shares of common stock issued was recorded at fair value of $8.0 million on the date of settlement, December 22, 2022.

On November 21, 2023 (the "Option Exercise Date"), we exercised the Option by submitting written notice thereof to Sutro Biopharma and concurrently paid Sutro Biopharma $50.0 million in cash as the first of two installment payments for the Option exercise price, followed by the second and final installment of $25.0 million in cash in May 2024. Upon the occurrence of certain regulatory milestones, certain additional milestone payments may total up to $60.0 million in cash. In the event that we undergo a change of control, certain rights and payments may be accelerated.

Manufacturing Rights Agreement

Concurrent with the payment of the first installment of the Option exercise price pursuant to the Option Agreement, on November 21, 2023, the manufacturing rights agreement (in the form of the Form Definitive Agreement) between us and Sutro Biopharma (the "Manufacturing Rights Agreement") became effective. Under the Manufacturing Rights Agreement, we received an exclusive (except as to Sutro Biopharma), perpetual (subject to termination), worldwide license, for no additional royalty (i.e., royalty-free, other than any royalties due under the Sutro Biopharma License Agreement), under Sutro Biopharma's relevant patents and know-how, to manufacture or have manufactured extract and improvements to extract (in any form) solely for use in the research, development, use, production, sale, offering for sale, export, import, commercialization or other exploitation of Vaccine Compositions (as defined in the Sutro Biopharma License Agreement) (as well as certain rights with respect to certain regulatory matters related to extract and its use in connection with such Vaccine Compositions). We have the right to extend our rights and obligations under the Manufacturing Rights Agreement to our affiliates and to sublicense our rights to manufacture extract and improvements to extract to certain third-party CMOs and other contractors (for our benefit and not for such third party's independent commercial use). For clarity, we are not permitted to manufacture extract for sale to third parties for the independent use of such third parties. Under the Manufacturing Rights Agreement, we have the obligation to

protect the confidentiality of the extract manufacturing technology, and Sutro Biopharma has certain audit rights in connection therewith.

Under the Manufacturing Rights Agreement, upon our request and at our cost, Sutro Biopharma will support up to two technology transfers to us (or to an affiliate of ours or certain third-party CMOs designated by us) of certain Sutro Biopharma know-how, materials and information to enable us to manufacture or have manufactured extract. Under certain circumstances, Sutro Biopharma may source extract from us or certain third-party CMOs, subject to reimbursement for technology transfer costs.

The Manufacturing Rights Agreement contains certain terms with respect to the ownership, prosecution, maintenance and enforcement of certain intellectual property rights licensed or arising under the Manufacturing Rights Agreement, which are generally consistent with the Sutro Biopharma License Agreement.

Unless earlier terminated, the Manufacturing Rights Agreement will remain in effect in perpetuity. Sutro Biopharma may only terminate the Manufacturing Rights Agreement in the event of our (i) uncured, intentional, material breach of certain confidentiality provisions resulting in actual, material harm to Sutro Biopharma's business, (ii) uncured, intentional material breach of certain provisions relating to the use of certain of Sutro Biopharma's know-how outside of the Vaccine Field, (iii) unintentional, material breach of certain provisions relating to the use of certain of Sutro Biopharma's know-how outside of the Vaccine Field that we do not use reasonable best efforts to cease and (to the extent reasonably curable) cure in a timely fashion, or (iv) uncured failure to pay the Option exercise price or any undisputed milestone payment under the Option Agreement when due. We may terminate the Manufacturing Rights Agreement at our discretion upon 60 days' written notice, and both parties may terminate the Manufacturing Rights Agreement upon mutual written consent.

Thermo Fisher Scientific Agreement

Commercial Manufacturing and Supply Agreement

In September 2025, we entered into a master services agreement with Thermo Fisher, pursuant to which Thermo Fisher will formulate, fill, inspect, package, label, test, manufacture and supply drug product for us at Thermo Fisher's facility in Greenville, North Carolina (the "Thermo Fisher Commercial Manufacturing and Supply Agreement"). Pursuant to the Thermo Fisher Commercial Manufacturing and Supply Agreement, we have agreed to order drug product from Thermo Fisher based on certain binding forecast periods and established prices. In addition, we will also pay Thermo Fisher for technology transfer activities and reimburse Thermo Fisher for certain out-of-pocket capital expenditures under the terms of the agreement.

The Thermo Fisher Commercial Manufacturing and Supply Agreement has an initial term of 15 years and will automatically renew for additional three-year periods unless either party provides notice of non-renewal before the end of the then existing term, subject to completion of ongoing services. We are permitted to terminate the Thermo Fisher Commercial Manufacturing and Supply Agreement prior to expiration, subject to the payment of applicable termination fees, plus certain capital expenditure commitments.

University of California, San Diego License Agreement

We are party to a license agreement with the University of California, San Diego, dated February 4, 2019, which was subsequently amended on August 16, 2019 (as amended, the "UCSD License") whereby we are the exclusive licensee of an issued U.S. patent and pending U.S. patent application related to a non-cross-reactive

Group A Strep carbohydrate antigen and methods of producing the antigen. We licensed this technology for the development of our Group A Strep 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 to 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, excluding any earned royalties or reimbursements of research and development expenses, of 20% up to a maximum of $2.5 million.

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 and 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.

Competition

In recent history, the global vaccine market has been highly concentrated among a small number of multinational pharmaceutical companies. Pfizer, Merck, GSK and Sanofi have been responsible for developing and introducing most new vaccines to the world. Other pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions are also working towards new solutions given the continuing global unmet medical need.

Within the current pneumococcal vaccine market, Pfizer, Merck and GSK have comprised the significant majority of market share and sales, with Pfizer's PCV13 and PCV20, Merck's PPSV23, PCV15 and PCV21 and GSK's Synflorix totaling a combined $8.5 billion in global pneumococcal vaccine sales in 2025 (approximately 77%, 21% and 2%, of such sales for these three product families, respectively).

Existing vaccine makers, as well as new entrants, are competing to develop the next generation of pneumococcal vaccines. PCV20 was granted regulatory approval and launched in the U.S. in 2021 for the prevention of IPD and pneumonia in adults, and in 2023, the FDA approved PCV20 for use in infants for the prevention of IPD, and for the prevention of otitis media caused by *Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F. PCV15 was granted regulatory approval and launched in the U.S. in 2021 for the prevention of IPD in adults, and in 2022, the FDA approved PCV15 for use in infants for the prevention of IPD. PCV21 was granted regulatory approval and launched in the U.S. in 2024 for the prevention of IPD and

pneumonia (serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B) in adults. The indications for the prevention of pneumonia for both PCV20 and PCV21 are approved under accelerated approvals based on immune responses as measured by OPA.

The current standard-of-care in adults consists of the administration of either PCV20 or PCV21 alone or PCV15 followed by the administration of PPSV23. In infants, the current standard-of-care consists of the administration of either PCV20 or PCV15 alone.

Pfizer announced in 2024 that it is developing a 25-valent PCV candidate that is currently in adult and pediatric Phase 2 clinical trials, and that it is working on a 30-plus valent PCV candidate that is in preclinical development. Pfizer announced in November 2025 that it plans to initiate adult and pediatric pivotal trials evaluating PCV25 in 2026.

In September 2025, Merck announced positive results from its Phase 3 study evaluating PCV21 in children aged 2–17 with increased risk for pneumococcal disease. Merck is also advancing additional next-generation PCV candidates through multiple early-phase clinical studies evaluating different formulations.

GSK, which previously acquired vaccine developer Affinivax, was previously developing a 24-valent affinity-bound pneumococcal vaccine candidate in adults and infants. In October 2024, GSK announced the termination of its adult 24-valent program in favor of a preclinical 30-plus valent candidate. In October 2025, GSK announced the initiation of a Phase 1 study in Australia evaluating its 30-plus valent candidate in adults. In the fourth quarter of 2025, GSK removed its pediatric 24-valent candidate, which had previously advanced into a Phase 2 clinical trial program, from its publicly disclosed pipeline.

Sanofi and SK bioscience have partnered to develop a 21-valent PCV and, in June 2023, announced positive results from their Phase 2 clinical trials in infants. In December 2024, Sanofi and SK bioscience announced the initiation of a global pediatric Phase 3 clinical program of their 21-valent PCV candidate, as well as an expanded agreement to develop, license and commercialize "next-generation" PCVs for both pediatric and adult populations. In February 2026, SK bioscience announced that it expected topline results from this Phase 3 study to be available in 2027, and that a next-generation PCV candidate, also co-developed with Sanofi, was in preclinical development with clinical trial entry expected in 2026.

We believe success will ultimately be based on the combination of several factors, including the broadest coverage of serotypes, disease coverage, immunogenicity, boostability, safety and tolerability. Convenience and pricing may also be factors. Other vaccines in development may obtain FDA approval and commercially launch before VAX-31 or VAX-24. However, if approved, we believe, based on our clinical results to-date and our unique site-specific conjugation and carrier-sparing technology, that our PCV candidates may potentially replace the current standard-of-care vaccines for IPD prevention in both the adult population, in the case of VAX-31, and pediatric population, in the case of VAX-24 and/or VAX-31.

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, mostly in academic institutions. Based on publicly available information, a limited number of Group A Strep vaccine candidates are in development, including programs at the GSK Vaccines Institute for Global Health which is in a preclinical stage, Moderna which has a candidate in a Phase 1 study, and Griffith University which has an ongoing Phase 1/2 clinical study in healthy adults, as well as other early-stage efforts including VaxForm and BioMVis that have been described as preclinical or otherwise early

in development. We are not aware of any Group A Strep vaccine candidate in clinical development that is designed to provide broad coverage across all Group A Strep strains. Competition in this area is expected to be based on clinical profile and development progress, including potential efficacy, safety and tolerability, dosing regimen and convenience, manufacturing feasibility, and pricing and access dynamics. In addition, we are aware that some companies are developing therapeutic approaches for Group A Strep-associated diseases that may overlap with certain clinical or commercial segments targeted by Group A Strep vaccines.

Based on publicly available information, we are aware of a limited number of Shigella vaccine programs in clinical development, including candidates being advanced by Valneva and LimmaTech. In addition, we are aware that some companies are developing therapeutics for other indications that target pathogens or biological mechanisms that may overlap with the underlying pathogens associated with Shigella, which could compete in certain patient populations or clinical settings. Competition in this area is expected to be based on clinical profile and development progress, including potential efficacy, safety and tolerability, dosing regimen and convenience, manufacturing feasibility, and pricing and access dynamics.

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 VAX-31, VAX-24 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 and any other inventions that are commercially important to our business. We may 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 ("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 February 24, 2026 contains four issued U.S. patents and multiple issued international patents, multiple pending patent applications in the United States and internationally, and multiple pending patent cooperation treaty applications that are owned by us, as well as certain foreign counterparts of a subset of

these patent applications in foreign countries, including Australia, Brazil, Canada, China, India, Israel, Japan, South Korea, Taiwan, 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 patent applications are directed to vaccine formulations, protein-antigen conjugates, methods of making protein-antigen conjugates and other processes related to vaccine production, and the promotion of immunogenicity using the protein-antigen conjugates and vaccines. For our Group A Strep vaccine, these patent applications are directed to vaccine formulations, protein-antigen conjugates, vaccines and components thereof, as well as processes for their manufacture. If issued, the 20-year term expiration dates of our patents will expire between 2037 and 2043, 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 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.

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. Certain Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA") marketplace and other private payor plans are required to include coverage for certain preventative services, including vaccinations recommended by the ACIP without cost share obligations (i.e., co-payments, deductibles

or co-insurance) for plan members. Children through 18 years of age without health insurance coverage for vaccines may be eligible to receive such vaccinations free-of-charge through the CDC's Vaccines for Children program ("VFC"). 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.

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. 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 that receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 a 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 (the "PHS Act").

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 application, which must be active before human clinical trial commencement;

- approval by an institutional review board ("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 ("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;

- 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 good manufacturing practices ("cGMP") 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, and other nonclinical studies must be conducted. Preclinical toxicology studies in animals must be conducted in compliance with applicable federal regulations and requirements, including good laboratory practices and the Animal Welfare Act and its implementing 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. The FDA may also put the clinical trial on hold at any time after it commences if there are safety or effectiveness concerns with the drug or biological product being studied.

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.

- *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. Completion of these so-called Phase 4 studies as post-marketing requirements may also be made a condition to approval of the BLA. These post-market 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 DSMB may place a clinical trial on hold 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 cGMP standards designed to assure the product's continued safety, purity and potency. The FDA may also 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. Some deficiencies found during the pre-approval inspection, if significant, could result in an FDA warning letter. 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 FDA may impose limitations on the uses for which the product may be marketed, may require that warning statements or contraindications 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 ("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 (also referred to as "ETASU"), 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, purity, and potency after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. Also, product marketing may be restricted or 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 events, 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, if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market and the sponsor cannot remedy these deficiencies, the FDA may undertake a process to withdraw licensure. 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, untitled or 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.

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 will 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 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 the 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 required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. The Food and Drug Omnibus Reform Act and new FDA guidance, provide that confirmatory studies must be underway prior to approval of the BLA to gain approval under the accelerated approval pathway. 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. The 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. A BTD 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 ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") which created section 351(k) of the PHS Act, establishing 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.

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 FDA does not evaluate patent protection if another applicant submits a full BLA and not a biosimilar application, but the first license holder may choose to bring a patent infringement case, which may forestall marketing of such a competing 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.

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 August 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law, which among other things, enables the Centers for Medicare & Medicaid Services ("CMS") to assert control over the prices of certain single-source drugs and biotherapeutics reimbursed under the Medicare Drug Price Negotiation Program, subjects drug manufacturers to potential civil monetary penalties and a significant excise tax for offering a price that is not equal to or less than the government-imposed "maximum fair price" under the law; imposes Medicare rebates for certain Part B and Part D drugs where relevant pricing metrics associated with the products increase faster than inflation; and redesigns the funding and benefit structure of the Medicare Part D program, potentially increasing manufacturer liability while capping annual out-of-pocket drug expenses for Medicare beneficiaries. These provisions started taking effect incrementally in late 2022 and currently are subject to various legal challenges. Further, as of January 1, 2023, the IRA eliminates patient cost sharing for FDA-approved adult vaccines that are recommended by the ACIP and covered under Medicare Part D and mandates that all state Medicaid programs cover FDA-approved adult vaccines that are recommended by the ACIP and their administration without cost sharing as of October 1, 2023. In addition, in December 2024, CMS released revised guidance on the Part D Manufacturer Discount

Program, which requires manufacturers to take on more of the beneficiary cost previously subsidized by the federal government through the application of increased drug discounts. The IRA does not change either VFC or the related provisions added in 2010 under the ACA. VFC was established to give first-dollar coverage to children up to 18 years of age whose families could not pay for vaccinations while the ACA guaranteed coverage of vaccines without cost sharing for Americans who are either privately insured or newly covered in states that expanded Medicaid. Unless an exception applies, single-source vaccines can qualify for Medicare price negotiations 11 years after their BLA is approved and become subject to the IRA's negotiated maximum fair price ceiling two years after that. In addition, certain vaccines, including pneumococcal virus vaccines, are excluded from the Medicare Part B inflation rebate. CMS also has stated in guidance and rulemaking that it is not imposing Medicare Part D inflation rebates at this time on vaccines and other drugs and biologics that are not "covered outpatient drugs" under Medicaid or otherwise do not have an obligation to report drug pricing data to Medicaid. Additionally, the IRA contains a limited small biotech exception, which applies on a drug-specific basis, and qualifying drugs may be exempt from possible pricing negotiation through 2028 and eligible for a lower limit (i.e., a price floor) on the potential maximum fair price in 2029 and 2030, if the manufacturers of those drugs continue to qualify each year. By February 1 of each year, CMS announces the list of the next Medicare Part B and Part D drugs selected for negotiation under the IRA.

Prior to the IRA, 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: (i) 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; (ii) 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; (iii) 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; (iv) expanded the eligibility criteria for Medicaid programs; (v) 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; (vi) created a new Medicare Part D coverage gap discount program which the IRA replaced, in which manufacturers were required 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 (as discussed above, the IRA replaced this program with the Part D Manufacturer Discount Program effective January 1, 2025); and (vii) established a Center for Medicare & Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drugs.

There have been judicial and legislative challenges to certain aspects of the ACA. By way of example, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law and included 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, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. More recently, a challenge to the ACA advanced to the U.S. Supreme Court. Specifically, in Braidwood Management v. Becerra, the plaintiffs argued that the ACA's requirement that insurance cover certain preventive services without cost sharing is unconstitutional. In March 2023, the judge struck down the requirement with immediate nationwide effect by ruling, in part, that members of a panel charged under the ACA with recommending

preventative services coverage had been appointed in an unconstitutional manner. Parties on both sides of the lawsuit appealed this ruling, and in June 2024 the U.S. Court of Appeals for the Fifth Circuit (Fifth Circuit) held, among other things, that the ACA's requirement that group health plans and health insurance issuers cover certain preventative services without cost-sharing is unconstitutional. After granting the government's petition for certiorari in the case, the U.S. Supreme Court announced its decision in June 2025 upholding the constitutionality of the ACA's preventive-services mandate.

Other legislative and executive changes have been proposed or 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 Infrastructure Investment and Jobs Act, will remain in effect through the first seven months of 2032, 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.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to regulate pharmaceutical product pricing, including price or reimbursement constraints, discounts, restrictions on specific product access, marketing cost disclosure and transparency measures and, in some cases, measures designed to encourage importation from other countries and bulk purchasing.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law. The OBBBA is projected to decrease federal health care spending by approximately $1 trillion by reducing Medicaid spending and enrollment and making changes to federal Medicare spending. The law also made changes to ACA marketplace enrollment that are projected to decrease the number of individuals with marketplace coverage. It is unclear if these changes will impact the pharmaceutical industry.

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 inducing or rewarding the referral of an individual, or 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. The term "remuneration" has been broadly interpreted to include anything of value. 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.

Federal civil and criminal false claims laws, including the civil False Claims Act, which prohibits, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, using or causing to be made or used a false record or statement material to an obligation to pay or transmit money to the federal government, or knowingly concealing or improperly avoiding or decreasing an obligation to pay money 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 may share in amounts paid by the entity to the government in recovery or settlement. 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.

The federal Health Insurance Portability and Accountability Act of 1996 ("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, including private third-party payors, or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services, including those by private payors. 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 and covered subcontractors 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) 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, such as state anti-kickback and false claims laws, may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, there are 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 federal and state healthcare laws described above can result in significant penalties, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, 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.

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 ("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 ("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 ("EEA"), which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein, we must obtain a Marketing Authorization, ("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 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 payors 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 or may become subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and the protection of health-related and other personal data. Such obligations may include, without limitation, the Federal Trade Commission Act, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (the "CPRA" and collectively, the "CCPA"), the European Union's General Data Protection Regulation 2016/679 (the "EU GDPR"), and the EU GDPR as it forms part of the United Kingdom (the "UK") law by virtue of section 3 of the European Union (Withdrawal) Act 2018, or the UK GDPR, and the ePrivacy Directive. In addition, numerous U.S. states — including, but not limited to California, Colorado, Connecticut, Montana, Oregon, Utah, Texas, and Virginia — have enacted comprehensive data privacy laws in the past few years, and other U.S. states, including Washington and Nevada, have enacted consumer health data privacy laws. Certain privacy and data protection laws and regulations, including HIPAA, establish standards for the protection of certain health information and impose requirements relating to the use, disclosure, and safeguarding of individually identifiable health information by covered entities and their business associates.

Foreign data privacy and security laws (including, but not limited to, the EU GDPR and UK GDPR) may impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the EEA, and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. Failure to comply with the requirements of the EU GDPR and the applicable national data protection laws of the EU member states may result in: temporary or definite bans on processing of personal data and other corrective actions; 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; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

See the section titled "Risks Related to Government Regulation" for additional information about the laws and regulations to which we are or may become subject to and about the risks to our business associated with such laws and regulations.

Employees & Human Capital

As of December 31, 2025, we had 507 full-time employees, with most of those based in the United States. Of our full-time employees, approximately 16% have Ph.D. or M.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.

We recognize that attracting, incentivizing, retaining and promoting talented employees is vital to our success. We aim to create a supportive and empowering environment in which our employees can grow, succeed and advance their careers, with the overall goal of developing, expanding and retaining a world-class workforce aligned with our current pipeline and future business goals. Our efforts to recruit and retain a high-performing and committed workforce include providing competitive compensation and benefits, including equity incentive compensation, and supporting our employees' well-being and success.

Continuous development is essential to achieving our organization's goals. We are committed to offering both in-person and virtual training opportunities, as well as hands-on learning experiences through cross-functional exposure, such as presentations and job shadowing. In addition, we value our employees' insights and provide virtual and onsite forums where our employees can provide feedback, recognize each other's contributions and accomplishments, and offer suggestions for enhancing our work environment.

Corporate and Other Information

We are headquartered in San Carlos, California. We were incorporated in the state of Delaware on November 27, 2013 as SutroVax, Inc. and we changed our name to Vaxcyte, Inc. in May 2020. Our website is located at https://www.vaxcyte.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K including their exhibits, proxy and information statements, and amendments to those reports filed or furnished pursuant to Section 13(a), 14, and 15(d) of the Securities Exchange Act of 1934 (as amended, the "Exchange Act") are available through the "Investors & Media" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein or therein by reference. In addition, our filings with the SEC may be accessed through the SEC's website at http://www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the

statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors.

RISK FACTORS

Our business involves significant risks, some of which are described below. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and the related notes. 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. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10-K.

Risks Related to Our Financial Position and Capital Needs

We are in the clinical or preclinical stages of vaccine development and have a 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, advancing our vaccine candidates through clinical trials, enabling manufacturing activities in support of our product development efforts, 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 certain of 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.

We may encounter unforeseen expenses, difficulties, complications, delays, changes in the regulatory environment, 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. We currently have no source of product revenue and may never achieve profitability. Our stock is a highly speculative investment.

We are a clinical-stage biotechnology vaccine company. Investment in clinical-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 $766.6 million and

$463.9 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $2.2 billion.

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 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.

We will require substantial additional funding to finance our operations, which may not be available to us on acceptable terms, or at all. 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, 2025, we had cash, cash equivalents and investments of $2,442.6 million. We believe our existing cash, cash equivalents and investments will fund our current operating plans through at least 12 months from the filing date of this Annual Report on Form 10-K. 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. Furthermore, we will need to raise substantial additional capital to complete the development, manufacturing and commercialization of our drug candidates. 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 ability to raise additional capital may be adversely impacted by potential worsening global economic conditions, including higher inflation rates, changes in interest rates and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide, including the trading price of common stock, resulting from civil and political unrest in certain countries and regions. 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 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;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory authorities, which may require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the costs of establishing additional manufacturing capacity to meet potential incremental supply requirements following the initial commercial launches of VAX-31 in the adult population and VAX-31 or VAX-24 in the pediatric population, if approved;

- our ability to set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors;
- the costs of building a sales force in anticipation of any product commercialization;
- 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;
- market acceptance of our product candidates in the medical community and with third-party payors and consumers;
- any product liability or other lawsuits related to our products;
- 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
- macroeconomic factors that may exacerbate the magnitude of the factors discussed above.

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. For example, although we allocated resources for the development of VAX-24 in the adult population through a Phase 1/2 program, we made the determination to suspend further development of VAX-24 for the adult indication because we chose to advance exclusively VAX-31 for an adult Phase 3 program following the positive results of the VAX-31 adult Phase 1/2 study. Additionally, in August 2025, we announced that as part of our continued focus on strategic capital deployment and in order to prioritize our resources towards our PCV franchise, we had paused the advancement, beyond preclinical

development, of VAX-GI while remaining confident in its potential and preserving the option to advance the program in the future. We also discontinued further development of VAX-PG, a vaccine candidate we were developing for periodontal disease, which demonstrated an acceptable safety profile but not sufficient efficacy signals to warrant further investment. 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, manufacturing and commercialization rights.

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, require us to modify processes, and make it difficult to predict the time and cost of vaccine candidate development and the timing to apply for and obtain regulatory approvals.

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. ("Sutro Biopharma") and our proprietary know-how for vaccine applications against infectious disease. Our future success depends on the successful application of this approach to vaccine development. We are in the clinical or preclinical stages of developing our vaccine candidates and there can be no assurance that any development problems we may experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be overcome. For example, although we have achieved proof-of-concept for our carrier-sparing approach with VAX-31 and VAX-24, our approach may not be validated for our other vaccine candidates or subsequent trials of VAX-31 or VAX-24. 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 completed clinical development on any of our product candidates, 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. We may also encounter difficulty recruiting sufficient participants for our clinical studies, or the FDA may impose additional requirements on us regarding trial size or a long-term safety study that will significantly slow or forestall our development program.

Furthermore, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our vaccine candidates and learn more about these critical factors. Conjugate vaccine development is highly complex, and development of broad-valency pneumococcal conjugate vaccines ("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. Over the course of the development and manufacturing of VAX-24, we previously encountered process-related matters that required us to make adjustments to our processes. For example, in 2020 we encountered such process-related matters during our drug substance manufacturing campaign for VAX-24 at Lonza, Ltd. ("Lonza"). The cumulative impact of the time required to make adjustments to our

processes led to a delay of our drug substance manufacturing campaign due to scheduling conflicts and capacity constraints at Lonza. There can be no assurance that we or Lonza will be able to successfully manufacture drug substances in a timely manner in the future, or at all. Such process changes and manufacturing delays have caused a change in our Investigational New Drug ("IND") application timelines in the past and future changes or delays could impact future timelines for VAX-31, VAX-24 or for our other product candidates. In addition, if we encounter similar manufacturing issues after product approval, it will require inspection and approval of the new manufacturing site and submission of a Biologics License Application ("BLA") supplement, which may further impede or delay commercialization.

In addition, the preclinical and clinical trial requirements of the FDA, European Medicines Agency ("EMA") and other regulatory agencies and the criteria these regulators use to determine the safety and immunogenicity or efficacy of a vaccine candidate are determined according to the type, complexity, novelty and intended use and market of the potential products, taking into consideration the benefits and risks for the intended population who will receive the vaccine, as well as the disease(s) to be prevented. Regulatory agencies also evaluate a sponsor's data to determine whether the manufacturing and facility information assure product quality and consistency. Approvals by the FDA and EMA for existing pneumococcal vaccines, such as Pfizer Inc.'s ("Pfizer") Prevnar 13® ("PCV13") and Prevnar 20® ("PCV20"), and Merck & Co., Inc.'s ("Merck") VAXNEUVANCE™ ("PCV15"), Capvaxive® ("PCV21") and Pneumovax® 23 ("PPSV23"), may not be indicative of what these regulators may require for approval of our vaccine candidates. For example, in the adult population, these existing pneumococcal vaccines were previously approved based on the establishment of non-inferiority of OPA responses relative to the then current standard of care vaccine(s), 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. Following discussions with the FDA, the non-inferiority standard in our VAX-31 adult OPUS-1 Phase 3 pivotal, noninferiority trial is set at 0.667. The FDA may challenge our VAX-31 Phase 3 Chemistry, Manufacturing and Controls ("CMC") strategy, which could cause significant delays or unanticipated costs. 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. Evolving regulatory approaches to vaccine approval decisions may present additional hurdles to development that would necessitate a change to our approach to meet regulatory expectations.

Our vaccine candidates are in clinical or 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.

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, and we may never be able to obtain marketing approval for any of our product candidates. Before obtaining regulatory approval for the commercial distribution of our vaccine candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate the safety and immunogenicity or 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 studies or clinical trials or abandon a program;
- product-related adverse effects experienced by volunteers 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 IND applications or comparable foreign applications or delays or failures in obtaining necessary authorizations 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;
- challenges by the FDA to our clinical or regulatory strategies;
- changes in FDA personnel that alter the FDA's advice with respect to our development strategy;
- delays in enrolling subjects 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 CMC activities related to our clinical trials;
- harmful side effects or inability of our vaccine candidates to meet immunogenicity or 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 addition, changes to the standard-of-care or the approval standards for new vaccines have, and could again in the future, 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.

Our business is highly dependent on the success of our PCV candidates. If we are unable to successfully develop, obtain approval for and effectively commercialize our PCV candidates, our business would be significantly harmed.

Our business and future success depends on our ability to successfully develop, obtain regulatory approval of, and then commercialize our PCV candidates, which include VAX-31, our 31-valent clinical PCV candidate in development for both the adult and pediatric populations, VAX-24, our 24-valent clinical PCV candidate in development for the pediatric population, and VAX-XL, our third-generation PCV candidate designed to provide the broadest coverage of any PCV currently in development. Although VAX-31 has produced positive topline results in a Phase 1/2 clinical study in adults, it may not demonstrate the same results in the adult pivotal Phase 3 study needed to obtain marketing approval from the FDA or comparable foreign regulatory authorities or in infant clinical studies. VAX-31 and VAX-24 will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient 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 our PCV candidates through the development process.

The clinical and commercial success of VAX-31, VAX-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;
- 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 ("cGMP") and do so in a timely manner;

- 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, long-term safety 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 and immunogenicity or efficacy and acceptable risk to benefit profile of our PCV candidates and any future vaccine candidates;
- the pace and prevalence of serotype replacement following the introduction of our PCV candidates 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;
- 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 Advisory Committee on Immunization Practices ("ACIP"), comparable foreign regulatory authority, professional society, or other clinical 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;
- 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 immunogenicity or 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;
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims;
- our ability to set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors; and
- macroeconomic factors that may exacerbate the magnitude of the factors discussed above.

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 and commercialize 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; in recent history, Pfizer, Merck, GSK plc ("GSK") and Sanofi have been responsible for developing and introducing most new vaccines to the world. 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 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 studies 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 from ACIP for their products. For example, PCV13 obtained FDA approval for the prevention of invasive pneumococcal disease ("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 implemented a similar approach to the development of its 20-valent PCV vaccine candidate, PCV20, which was approved by the FDA in June 2021 for use in adults and in April 2023 for use in infants and children. Pfizer announced in 2024 that it is developing a 25-valent PCV candidate ("PCV25") that is currently in adult and pediatric Phase 2 clinical trials, and that it is working on a 30-plus valent PCV candidate that is in preclinical development. Pfizer announced in November 2025 that it plans to initiate adult and pediatric pivotal trials evaluating PCV25 in 2026. Merck received approval for PCV15, its 15-valent PCV, in July 2021 for use in adults and in June 2022 for use in infants and children. Merck announced in June 2024 that PCV21, its 21-valent PCV, received approval from the FDA for use in adults. In September 2025, Merck announced positive results from its Phase 3 study evaluating PCV21 in children aged 2–17 with increased risk for pneumococcal disease. Merck is also advancing additional next-generation PCV candidates through multiple early-phase clinical studies evaluating different formulations. In addition, Sanofi and SK bioscience have partnered to develop a 21-valent PCV and, in June 2023, announced positive results from their Phase 2 clinical trials in

infants. In December 2024, Sanofi and SK bioscience announced the initiation of a global pediatric Phase 3 clinical program of their 21-valent PCV candidate, as well as an expanded agreement to develop, license and commercialize "next-generation" PCVs for both pediatric and adult populations. In February 2026, SK bioscience announced that it expected topline results from this Phase 3 study to be available in 2027, and that a next-generation PCV candidate, also co-developed with Sanofi, was in preclinical development with clinical trial entry expected in 2026. GSK, which previously acquired Affinivax, was previously developing a 24-valent affinity-bound pneumococcal vaccine candidate in adults and infants. In October 2024, GSK announced the termination of their adult 24-valent program in favor of a preclinical 30-plus valent candidate. In October 2025, GSK announced the initiation of a Phase 1 study in Australia evaluating its 30-plus valent candidate in adults. In the fourth quarter of 2025, GSK removed its pediatric 24-valent candidate, which had previously advanced into a Phase 2 clinical trial program, from its publicly disclosed pipeline.

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, or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. 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, manufacturing 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.

We and our contract manufacturers may face difficulty satisfying CMC 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 ("CMOs") to access resources to facilitate the development and, if approved, commercialization of VAX-31 or VAX-24 and our other vaccine candidates. Advancing our vaccine candidates may create significant challenges for our CMOs, 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;
- maintaining a cGMP-compliant facility and passing a pre-approval inspection;

- 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 prior to authorization in the European Union ("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. Personnel changes at regulatory agencies could impact or delay the timing of pre-approval inspections or the issuance of required authorizations. Delays in establishing our manufacturing process and ensuring 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 necessary for commercial success.

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 the U.S. Centers for Disease Control and Prevention ("CDC"), ACIP, comparable foreign regulatory authority, professional society, or other clinical recommendation for use;
- 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 of 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 in relation to alternatives;
- the availability of coverage and adequate reimbursement and pricing by third-party payors, including government authorities;

- 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 professional societies and similar agencies around the world. To develop its recommendations, the 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. The 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 recommendation are widely adopted. Recent changes to federal vaccine policy have introduced new uncertainties regarding the regulatory, legal, and reimbursement landscape for vaccines in the United States. Such changes have resulted in the American Academy of Pediatrics and other recommending bodies or organizations to generate their own recommended pediatric vaccine schedule. We may need to engage with additional professional societies or organizations to secure access for both adults and infants.

The ACIP's composition and decisions could influence the pathway for new vaccines to receive a positive recommendation or the impact of a positive recommendation. If our vaccine candidates are approved but fail to receive CDC, ACIP, comparable foreign authority, professional society, or other clinical recommendations, or fail to 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. In addition to our PCV franchise, our pipeline includes preclinical vaccine
candidates VAX-A1 for Group A Streptococcus (“Group A Strep”) and VAX-GI for dysentery and shigellosis. 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 successful in a smaller subset of patients than expected or completely 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.

For example, we announced in August 2025 that preclinical data for VAX-PG demonstrated an acceptable safety profile

but not sufficient efficacy signals to support further investment, and we therefore discontinued further development of that
candidate.

Our potential vaccine candidates may be shown to have harmful side effects, cause allergic reactions, 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.

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, we believe current PCVs do not provide adequate coverage of the strains currently causing pneumococcal disease or those that previously caused 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 VAX-31 and VAX-24 are our most advanced vaccine candidates, and because our other vaccine candidates are also based on our cell-free protein synthesis platform, if VAX-31 or VAX-24 encounter safety or immunogenicity 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 to supply raw materials and components for, and the manufacture of, our preclinical and clinical supplies as well as our vaccine candidates. Our inability to procure necessary raw materials or to have sufficient quantities of preclinical and clinical supplies or the inability to have our vaccine candidates manufactured, including delays or interruptions at our third-party manufacturers, 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 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, manufacturing and commercial demand, in particular for our PCVs, may prove to be wrong. If we encounter substantial problems in our manufacturing processes or in our ability to scale to address commercial vaccine supply, our business would be materially adversely affected. Examples of potential issues related to our manufacturing processes or our ability to scale include difficulties with production costs, yields and quality control, including stability of the drug substance or drug product.

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. Over the course of the development and manufacturing of VAX-24, we previously encountered process-related

matters that required us to make adjustments to our processes. For example, in 2020 we encountered such process-related matters during our drug substance manufacturing campaign for VAX-24 at Lonza. The cumulative impact of the time required to make adjustments to our processes led to a delay of our drug substance manufacturing campaign due to scheduling conflicts and capacity constraints at Lonza. There can be no assurance that we or Lonza will be able to successfully manufacture drug substances in a timely manner in the future, or at all. Such process changes and manufacturing delays have caused a change in our IND timelines in the past and future changes or delays could impact future timelines for VAX-31, VAX-24, or for our other product candidates. Since we utilize third-party manufacturers, we are also subject to their scheduling commitments for their other clients. Scheduling conflicts with Lonza's other clients have contributed to manufacturing delays in the past, and there is no guarantee that future scheduling conflicts or related capacity constraints will not affect our manufacturing campaigns and related timelines. Certain aspects of our manufacturing process for our clinical trial product materials and supplies have also been adversely affected by macroeconomic factors in the past and may in the future be adversely affected by these and numerous other factors, including earthquakes and other natural or man-made disasters, economic downturns, equipment failures, labor shortages, health epidemics, power failures and significant changes in trade policies.

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 and inspections 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, or if they cannot pass a pre-approval inspection, 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 fail to comply with such requirements or to perform their 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, or such transfer may be subject to certain consent obligations and payment terms to the original manufacturer. 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 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 and submit a supplement to our application. 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 if we receive regulatory approval for any PCV or any other vaccine candidates. For example, in October 2023, we entered into a pre-commercial services and commercial manufacturing supply agreement (the "Lonza Commercial Manufacturing and Supply Agreement") with Lonza, pursuant to which Lonza will (i) construct and build out a dedicated suite ("Suite") at Lonza's facilities in Visp, Switzerland to manufacture certain key components (including drug substance) for our proprietary PCV franchise and any other products or intermediates we may choose (collectively, the "Products"), and (ii) maintain and operate the Suite (utilizing Lonza's employees) to manufacture the Products

as a service provided to us, including conducting related quality control and quality assurance operations. In September 2025, we also entered into a master services agreement with Patheon Manufacturing Services LLC, part of Thermo Fisher Scientific (collectively, "Thermo Fisher"), pursuant to which Thermo Fisher will commercially manufacture and supply drug product for our PCV candidates, if approved (the "Thermo Fisher Commercial Manufacturing and Supply Agreement").

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. In November 2023, we entered into a manufacturing rights agreement (the "Manufacturing Rights Agreement") with Sutro Biopharma pursuant to which we obtained exclusive rights to independently, or through certain third parties, develop, improve and manufacture cell-free extract for use in connection with our vaccine candidates. If the independent alternate CMO or the designated third parties are unable to provide a sufficient supply of cell-free extract, our third-party manufacturers may be delayed in their production of intermediate components, which may lead to delays of our drug substance manufacturing campaigns.

If we are unable to obtain additional 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 VAX-31, VAX-24 and our other vaccine candidates are also based on our cell-free protein synthesis platform, if our vaccine candidates encounter safety and immunogenicity 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.

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 subjects to complete the clinical trial or result in potential product liability claims. An independent data safety monitoring board ("DSMB") may also suspend or terminate a clinical trial at any time on various grounds, including a finding that the research volunteers are being exposed to an unacceptable health risk. Vaccine-related side effects could also affect 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 vaccines or 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 vaccines or 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 subjects in clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, our vaccine candidates in lieu of, or in addition to, existing, more familiar vaccines for which greater clinical data may be available.

Increases in negative perceptions of vaccines or the technologies that we rely on by regulators may result in the FDA not approving our products or, if approved, fewer physicians prescribing our products.

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

Our timing of submitting the IND applications for our product candidates is dependent on preclinical and manufacturing success, and if we experience additional delays, we may fail to meet our anticipated timelines. In addition, we cannot be sure that submission of an IND application or IND application 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 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, but are not limited to:

- 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;
- delays in reaching a consensus with regulatory agencies on study design or clinical or regulatory strategies;
- delays in reaching agreement on acceptable terms with prospective 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 ("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 raise 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 volunteers 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 ("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 subjects complete participation in a study or return for post-injection follow-up;
- subjects 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.

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 subjects 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 enrolling subjects 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 subjects who remain in the study until its conclusion. The enrollment of subjects depends on many factors, including, but not limited to:

- the eligibility and exclusion criteria defined in the protocol;
- the size of the population required for analysis of the trial's primary endpoints;
- the proximity of volunteers 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 subject consents;
- the ability to monitor volunteers adequately during and after injection;
- the risk that volunteers enrolled in clinical trials will drop out of the trials before the injection of our vaccine candidates or trial completion; and
- the risks and disruptions related to patient and physician investigator recruitment and retention and study site initiation and clinical trial activities.

Based on our VAX-31 End-of-Phase 2 meeting with the FDA, we believe there is confirmation that the planned immunogenicity analyses are sufficient to support licensure and an efficacy study is therefore not required. In the event that we are required to conduct any field efficacy studies for VAX-31 or any of our other product candidates, enrollment of a sufficient number of subjects 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 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 topline 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 topline or preliminary data from our preclinical or clinical trials. Interim topline 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 more patient data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data when we publish such data. As a result, the topline 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 topline 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. Additionally, disclosure of interim topline or preliminary data by us or by our competitors has and may continue to result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of 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 topline 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 have in the past and may in the future seek breakthrough therapy designation ("BTD") or Fast Track designation by the FDA for one or more of our vaccine candidates, but we may not receive the designations we seek, and even if we do, such designation may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our vaccine candidates will receive marketing approval.

We have in the past and may in the future seek BTD or Fast Track designation for some of our vaccine candidates. For instance, in August 2022 we announced that the FDA granted Fast Track designation to VAX-24 in adults ages 18 and older, in January 2023 we announced that the FDA granted a BTD for VAX-24 for the prevention of IPD in adults, in November 2024 we announced that the FDA granted a BTD for VAX-31 for the prevention of IPD in adults, and in August 2025 we announced that the FDA extended the BTD for VAX-31 to include the prevention of pneumonia caused by Streptococcus pneumoniae in adults. 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. For vaccines that have been designated as Breakthrough Therapies, the FDA may take actions to expedite the development and review of the application, and interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

A vaccine designated as a breakthrough therapy by the FDA may also be eligible for expedited review and approval. If a vaccine candidate is intended for the treatment of a serious or life-threatening condition and clinical or preclinical data demonstrate the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular vaccine candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it.

Even if we obtain Fast Track designation for one or more of our vaccine candidates, we may not experience a faster development process, review or approval compared to non-expedited FDA review procedures. In addition, the FDA may withdraw Fast Track designation from any of our vaccine candidates that may receive the designation in the future, if it believes that the designation is no longer supported. Fast Track designation alone does not guarantee qualification for the FDA's Priority Review procedures.

Whether to grant a BTD or Fast Track designation is within the discretion of the FDA. Accordingly, even if we believe one of our vaccine candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of either of these designations for a vaccine candidate may not result in a faster development process, review or approval compared to vaccine candidates considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even when one or more of our vaccine candidates qualify for either of these designations, the FDA may later decide that the vaccine candidate no longer meets the conditions for qualification and rescind the designations.

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 expenses, 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.

A variety of risks associated with our current and potential international operations and collaborations 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, but not limited to:

- differing regulatory requirements in foreign countries;
- significant changes in trade policies, 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;
- differing and changing data protection and privacy regimes and requirements;
- economic weakness, including inflation and interest rates, 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 geopolitical actions, including war and terrorism.

For example, our agreements with Lonza are denominated in Swiss Franc ("CHF"). Fluctuations in the exchange rate for CHF may increase our costs and affect our operating results.

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.

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 Chief Executive Officer, our President and Chief Financial Officer, our Vice President of Research and our Executive Vice President and Chief Operating Officer. 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 and restricted stock units ("RSUs") that vest over time. The value to employees of stock options and RSUs 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, manufacturing and commercialization plans and strategies develop, 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, but not limited to:

- 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, manufacturing 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, manufacturing 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, immunogenicity or efficacy. Any delays in entering into new strategic partnership agreements related to our vaccine candidates could delay the development, manufacturing 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 VAX-31 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 PPSV23 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.

If our information technology systems or those of the third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, significant fines or other liability; regulatory investigations or actions; disruptions of our development programs or business operations; harms to our reputation; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely collect, receive, use, retain, safeguard, disclose, share, transfer, make accessible, dispose of, transmit or otherwise process proprietary, confidential and sensitive information, including personal data (including, key-coded data, health information, data we collect about trial participants in connection with clinical trials and other special categories of personal data), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties, and other sensitive third-party data (collectively, "Sensitive Information").

We may use third-party service providers and subprocessors, including our CROs, to help us operate our business and engage in processing on our behalf in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email and other functions. We may also share Sensitive Information with our partners or other third parties in connection with our business. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a cybersecurity incident or other interruption, including a system outage, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Cyberattacks and cybersecurity incidents, system outages, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our Sensitive Information and our information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to increase, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers"; threat actors; "hacktivists"; organized criminal threat actors; personnel (through theft or misuse); and sophisticated nation-state and nation-state supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including, but not limited to, software bugs; malicious code (such as viruses and worms); social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as a fake, and phishing attacks); employee error, theft or misuse; denial-of-service attacks (such as credential stuffing); malware (including as a result of advanced persistent threat intrusions); natural disasters; terrorism; war; telecommunication and electrical failures; supply-chain attacks; ransomware attacks; attacks enhanced or facilitated by artificial

intelligence ("AI"); and other similar threats. In particular, severe ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of data and income, reputational harm and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. We may also be the subject of server malfunction, software or hardware failures, supply-chain cyberattacks, loss of data or other computer assets and other similar issues.

Remote and hybrid work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

While we have implemented security measures designed to protect against cybersecurity incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, be able to detect and remediate all such vulnerabilities, including on a timely basis. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Vulnerabilities could be exploited and result in a cybersecurity incident.

Any of the previously identified or similar threats could cause a cybersecurity incident or other interruption. A cybersecurity incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data and could disrupt our ability (and that of third parties upon whom we rely) to provide our products or operate our business.

We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against cybersecurity incidents or other security breaches and to mitigate, detect and remediate actual or potential vulnerabilities. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and Sensitive Information. If we (or a third party upon which we rely) experience a cybersecurity incident or are perceived to have experienced a cybersecurity incident, we may experience adverse consequences, including interruptions in our operations, which could result in a disruption of our development programs and our business operations. For example, the loss of clinical trial data from 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, manufacturing and commercialization of our vaccine candidates could be delayed. Furthermore, consequences from an actual or perceived security breach may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar

harms. Cybersecurity incidents and attendant consequences may cause customers to stop using our platform/products/services, deter new customers from using our products, and negatively impact our ability to grow and operate our business.

Additionally, applicable data privacy and security obligations, including, without limitation, laws, regulations, guidance as well as our internal and external policies and our contractual obligations, may require us to notify relevant stakeholders of cybersecurity incidents or other security breaches, including affected individuals, partners, collaborators, regulators, law enforcement agencies, credit reporting agencies and others. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to litigation or other liability, fines, harm to our reputation, significant costs, or other materially adverse effects. There can be no assurance that any limitations or exclusions of liability in our contracts would be enforceable or adequate or protect us from liability or damages.

We cannot be sure that our insurance coverage, if any, will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or other materially adverse impacts arising out of our processing activities, privacy and security practices, or security breaches we may experience. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large excess or deductible or co-insurance requirements), could result in substantial cost increase or prevent us from obtaining insurance on acceptable terms. Additionally, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations.

In addition to experiencing a cybersecurity incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, Sensitive Information of ours, our vendors, or our partners could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

Use of artificial intelligence in our operations could result in reputational or competitive harm and legal or regulatory liability.

We have incorporated, and may continue to incorporate, certain AI solutions into our operations, and the use of AI involves various risks and challenges that could adversely affect our business. The development and deployment of AI systems involve inherent technical complexities and uncertainties, and our AI systems may encounter unexpected technical difficulties, limitations or errors, including inaccuracies in data processing or flawed algorithms. In addition, our competitors or other third parties may incorporate AI into their operations and products more quickly or more successfully than us, which could impair our ability to compete effectively.

The use of AI applications, including large language models, may in the future result in cybersecurity incidents that implicate the personal data of end users of such applications. Any such cybersecurity incidents related to our use of AI applications could adversely affect our business and reputation. AI also presents emerging ethical issues, and if our use of AI becomes controversial, we may experience brand or reputational harm, competitive harm, regulatory scrutiny or legal liability. In addition, use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations.

Governments have passed and are likely to pass additional laws regulating generative AI. The introduction of AI technologies into our operations may result in new or enhanced governmental or regulatory scrutiny,

litigation, confidentiality or security risks or other complications that could adversely affect our business. The regulatory landscape governing AI technologies is evolving rapidly, and changes in laws, regulations or enforcement practices may impose new compliance requirements, restrict certain AI applications or increase our regulatory obligations, which could negatively impact our business.

Natural or man-made disasters or 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 impact of climate change may increase these risks due to changes in weather patterns, such as increases in storm intensity, sea-level rise, melting of permafrost and temperature extremes on facilities or operations. 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.

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 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.

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 violate (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.

Changes in tax laws or tax rulings could affect our financial position.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law in the United States, and contains a wide range of tax reform provisions, including extending and modifying certain key Tax Act provisions, such as 100% bonus depreciation and the business interest expense limitation. Additionally, the OBBBA repealed mandatory capitalization and amortization of domestic R&D expenses, reverting to the immediate expensing of R&D expenditures for tax years beginning in 2025. Further, the OBBBA provided for an election to deduct the remaining unamortized domestic R&D expense as of December 31, 2024, either entirely in 2025 or over two years, in 2025 and 2026.

The American Rescue Plan Act ("ARPA") was signed on March 11, 2021. One of the provisions of the ARPA included a modification to the provision limiting the deductibility of executive compensation expense, expanding the definition of covered employees to include the top five highest compensated employees beyond the CEO, CFO and three highest paid officers. The provision was further modified by the OBBBA, which made the provision applicable to publicly traded companies and all members of their controlled group (as opposed to members of the affiliated group, as prescribed under prior law). All changes are effective for tax years beginning after December 31, 2025. While we do not believe that these modifications will have a material impact on our income tax provision currently, we will continue to monitor this provision.

We are unable to predict what tax changes may be enacted in the future or what effect such changes would have on our business, but such changes could affect our effective tax rate and could have an adverse effect on our overall tax position in the future, along with increasing the complexity, burden, and cost of tax compliance.

Our ability to utilize our net operating loss ("NOL") 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, 2025, we had federal and state NOL carryforwards of $796.1 million and $1,907.7 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, 2025, we also had federal and state research credit carryforwards of $40.3 million and $12.3 million, respectively. The federal research and development tax credit carryforwards expire beginning in 2039 unless previously utilized, and the state research and development tax credits can be carried forward indefinitely. In general, 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. There were no ownership changes identified in 2025, as such we have determined that no federal research credits will expire unutilized or are excluded from our research carryforwards as of December 31, 2025. Subsequent ownership changes may affect the limitation in future years. 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.

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 subjects. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of subjects 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.

If any of our relationships with trial sites or any CRO that we may use in the future terminate, 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 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 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. Pursuant to the Manufacturing Rights Agreement with Sutro Biopharma, we obtained exclusive rights to independently, or through certain third parties, develop, improve and manufacture cell-free extract for use in connection with our vaccine candidates. We have engaged Lonza to perform manufacturing process development and clinical manufacture and supply of components for our PCV candidates. Lonza is currently in the process of manufacturing certain components of our vaccine candidates on a clinical scale. In addition, we entered into the Lonza Commercial Manufacturing and Supply Agreement pursuant to which Lonza will (i) construct and build out a Suite at Lonza's facilities in Visp, Switzerland to manufacture the Products, and (ii) maintain and operate the Suite (utilizing Lonza's employees) to manufacture the Products as a service provided to us. In September 2025, we also entered into the Thermo Fisher Commercial Manufacturing and Supply Agreement, pursuant to which Thermo Fisher will commercially manufacture and supply drug product for our PCV candidates, if approved.

We have not yet caused our vaccine candidates to be manufactured on a 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, among others:

- 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. For example, if the independent alternate CMO or the designated third parties under the Manufacturing Rights Agreement are unable to provide a sufficient supply of cell-free extract, our third-party manufacturers may be delayed in their production of intermediate components, which may lead to delays of our drug substance manufacturing campaigns. Additionally, if Lonza is unable to identify a timely or manageable solution for handling cell-free extract during our clinical studies, such studies may be delayed, and we will incur additional costs;
- 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;
- 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; and
- 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 BLA from the FDA. We have not previously submitted a BLA to the FDA, or similar requests for marketing authorization to comparable foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the vaccine candidate's safety, purity, and potency for each desired indication. 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 and various comparability assessments. The FDA's review of our BLA may be significantly delayed if the FDA views that the CMC information included in our submission is not adequate or requests additional CMC information or data.

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 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 indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety and immunogenicity 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 immunogenicity or 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 immunogenicity or 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 volunteers to participate in and complete a trial;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- addressing any 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 for use in clinical trials.

We could also experience 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 immunogenicity or 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 DSMB. 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.

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 thousands of patients, have significant costs and are time consuming. While we are still in the process of having discussions with the FDA regarding our Phase 3 regulatory plans, including discussions regarding our CMC strategy, the FDA may ultimately disagree with our regulatory strategy or we may be unable to successfully complete development to the FDA's satisfaction. We believe our previously reported topline results for VAX-31 support clinical non-inferiority to PCV20, but there can be no assurance that this approach in pivotal studies will be sufficient for regulatory approval.

The FDA has recently indicated consideration of additional evidentiary standards for certain vaccine approvals, including potential requirements for expanded clinical trials, additional safety data, and additional post-marketing surveillance. If applied, these changes may increase the time, cost, and complexity of developing and commercializing our vaccine candidates, and may delay or prevent the approval of new vaccines or updates to existing products.

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 endpoints. If the results from such post-marketing studies are not positive or otherwise fail to show the predicted effect, our vaccine candidate 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;
- 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;
- 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;
- exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid;
- 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. For example, on June 28, 2024, the U.S. Supreme Court, in *Loper Bright Enterprises v. Raimondo*, overturned long-standing precedent regarding the deference courts owe to agencies' interpretation of ambiguous statutes in their rulemaking. While the impact of the *Loper Bright* decision on our business and regulatory strategy is unknown, the decision generally may, among other things, increase the frequency of challenges to decisions and rulemaking of health regulators, including FDA determinations of drug approval and market exclusivity and the Centers for Medicare & Medicaid Services ("CMS") rules regarding reimbursement, and also impact the speed at which such health regulators make decisions and issue regulations.

Changes to federal vaccine recommendations could lower utilization, change reimbursement for our products, and create access challenges because vaccine coverage requirements, including limits on cost-sharing, for nearly all insurers are linked to ACIP and CDC recommendations.These changes may affect the scope of liability protections under the National Vaccine Injury Compensation Program, insurance coverage and reimbursement for certain vaccines, and the requirements for state-level vaccine mandates. Ongoing and potential reforms to the federal vaccine injury compensation system, as well as increased state-level divergence from federal recommendations, may further impact our business, operations, and financial condition.

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. 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 (the "BPCIA") established 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 12 years after the reference product was approved under a BLA and the FDA will not accept an application for a biosimilar product based on the reference biological product until four years after the date of first licensure of the reference product, and will not approve a biosimilar until 12 years after the date of first licensure. These periods of exclusivity can be extended by six months by obtaining pediatric exclusivity. In addition, if the reference product is protected by patents, the biosimilar manufacturer and reference product manufacturer must engage in a complex process called the "patent dance." The FDA has not yet approved a biosimilar vaccine.

In addition, there is a risk that any exclusivity period we receive for any of the vaccine candidates we develop that is approved in the United States as a biological product under a BLA 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 biosimilar competition sooner than anticipated. In October 2025, the FDA announced that it will no longer require comparative efficacy studies to establish biosimilarity. In addition, although it has not announced a formal policy, the FDA is no longer requiring switching studies for interchangeable products. In addition, the FDA's updated guidance no longer requires an interchangeability statement on labeling. The FDA's more expansive view of interchangeability may allow more biosimilars to be automatically substituted for the reference product upon approval.

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, including 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 interactions and arrangements with healthcare professionals, principal investigators, consultants, customers, third-party payors, and patients 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. The term "remuneration" has been broadly interpreted to include anything of value.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 prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of government funds, including Medicare and Medicaid, that are false or fraudulent, or 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. Actions under the civil False Claims Act may be brought by the federal government or as a qui tam or whistleblower action by a private individual in the name of the government. Pharmaceutical manufacturers have been investigated and have reached substantial financial settlements under the civil False Claims Act for causing 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 ("HIPAA") which , among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, regardless of the payor (e.g., public or private), 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 (the "HITECH") 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, and their business associates that perform certain services involving the use or disclosure of individually identifiable health information for or on their behalf, as well as their covered subcontractors. HITECH also created tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the Federal Food Drug, and Cosmetic Act and its implementing regulations, which prohibit, 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 CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding 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 that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs; 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;
- 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 EU GDPR, and the CCPA, which impose obligations and restrictions on the collection, use and disclosure of personal data (including health data) relating to individuals located in the European Economic Area ("EEA") and California, respectively.

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, injunctions, 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 associated costs. 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.

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. 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.

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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, 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: (i) 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; (ii) 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; (iii) 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; (iv) expanded the eligibility criteria for Medicaid programs; (v) 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; (vi) created a Medicare Part D coverage gap discount program (now replaced by the IRA); and (vii) established a Center for Medicare & Medicaid Innovation ("CMMI") at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drugs.

There have been executive, judicial and Congressional efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA, some of which have been successful. For example, the Tax Act included 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." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress.

Other legislative changes also have been proposed and adopted in the United States since the ACA was enacted. These have, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers.

Another notable Medicare healthcare reform initiative, under the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), established a quality payment incentive program through which reimbursement is adjusted up or down based on various performance data collected each performance year. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

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. For example, the IRA, among other things, (i) enables the Department of Health and Human Services ("HHS") to assert control over the prices of certain single-source drugs and biologics covered under Medicare, (ii) subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, (iii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation, and (iv) redesigns the funding and benefit structure of the Medicare Part D program, potentially increasing manufacturer liability while capping annual out-of-pocket drug expenses for Medicare beneficiaries. The IRA also eliminates patient cost sharing for FDA-approved adult vaccines that are recommended by the ACIP and covered under Medicare Part D, and mandates that all state Medicaid programs cover FDA-approved adult vaccines that are recommended by the ACIP and their administration without cost sharing. In addition, in January 2026, the HHS announced the list of 15 drugs that will be subject to the third round of price negotiations.

The IRA is currently subject to legal challenges, and it is unclear how the IRA will be effectuated or changed in the future. However, the IRA does not change either the CDC's Vaccines for Children program ("VFC") or the provisions added in 2010 under the ACA. The VFC was established to give first-dollar coverage to children up to 18 years of age whose families could not pay for vaccinations while the ACA guaranteed coverage of

vaccines without cost sharing for Americans who are either privately insured or newly covered in states that expanded Medicaid. Further, many vaccines are excluded from Medicare Part B rebate requirements.

Additional action has been taken to change healthcare policies. For example, the federal government has shown substantial interest in taking a variety of measures aimed at lowering U.S. prescription drug prices to align with the lowest prices available for the same drugs in comparable developed nations (so called "most favored nation" pricing), including through CMMI models.

At the state level, legislatures and regulatory agencies have increasingly passed legislation and implemented regulations designed to control drug pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, advance notices of price increases, marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. The OBBBA will also reduce funds for Medicaid programs, which are administered by the states.

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, or additional pricing pressures on, any of our vaccine candidates approved in the future. 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 rely on 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, any current or future vaccine candidates we develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

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 may receive for any product approved in the future, 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 adoption of cost containment measures or other healthcare reforms, and our associated compliance obligations, may prevent us from being able to generate revenue, attain profitability or commercialize any product candidates, if approved.

The development, review and approval of our product candidates are subject to the operational capacity, processes and resource levels of regulatory authorities, which may fluctuate over time and could delay or adversely affect our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including budget and funding levels for critical departments, payment of user fees and reauthorization of user fee programs, staffing levels, retention of key personnel, as well as statutory, regulatory and policy changes. In addition, funding of other government agencies that support research and development activities relevant to FDA review, such as research to understand new technologies or establish new standards, may also fluctuate over time.

Changes in policies or actions that impact the funding, staffing, or operations of regulatory agencies, including changes to the user fee reauthorization process or a failure to reauthorize user fee programs in a timely manner, could lead to changes in review periods or response times. This, in turn, could affect the development and

regulatory timelines for approval of new products and related services and have a material adverse effect on our business.

We are subject to stringent and rapidly changing laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. The obligations and restrictions imposed by these requirements can lead to substantial related implementation costs. In addition, our actual or perceived failure to comply with applicable laws and other obligations related to privacy and data security could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; reputational harm; fines and penalties; loss or revenue or profits; and other adverse business consequences.

In the ordinary course of business, we process personal data and other Sensitive Information. We are subject to or affected by numerous evolving federal, state and foreign laws and regulations, as well as policies, contracts and other obligations governing the collection, use, disclosure, retention, and security of personal data. The global data privacy and protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.

For example, HIPAA, as amended by HITECH, imposes requirements relating to the privacy and security of individually identifiable health information used, stored, or transmitted by health plans, healthcare clearinghouses and certain healthcare providers, as well as their respective contractors and their covered subcontractors that perform services for them involving individually identifiable health information. Additionally, certain states have adopted healthcare privacy and security laws and regulations that impose restrictions and obligations comparable to those listed under HIPAA, some of which can be more stringent than HIPAA. In the event we fail to properly maintain the privacy and security of individually identifiable health information governed by HIPAA or comparable state laws, or we are responsible for an unauthorized disclosure or security breach of such information, we could be subject to enforcement action under HIPAA or comparable state laws, and significant civil and criminal penalties, and fines.

In the United States, federal, state, and local governments have enacted numerous data privacy and data security laws beyond HIPAA and other healthcare privacy laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the CCPA imposes obligations on covered businesses, including, but not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. In addition, the CPRA expanded the CCPA's requirements, including by adding new rights allowing individuals to opt out of the sharing (as defined under the CCPA) of and correct their personal data and limit the use and disclosure of their sensitive personal data, as well as by establishing a new California Privacy Protection Agency to implement and enforce, alongside the California Attorney General, the CCPA. Other U.S. states have also recently enacted comprehensive data privacy laws —including Virginia, Connecticut, Utah, Colorado, Delaware, Indiana, Iowa, Kentucky, Maryland, Minnesota, Montana, New Hampshire, New Jersey, Nebraska, Oregon, Rhode Island, Tennessee, and Texas — and other local, state, and federal laws are currently under consideration. Certain states also impose stricter requirements, such as conducting data privacy impact assessments, for processing certain personal data, including sensitive information. These state laws allow for statutory fines for noncompliance. For example, the CCPA allows for fines of up to $7,500 per intentional violation and allows for private litigants affected by certain data breaches to recover significant statutory damages. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon which we rely. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject

to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors).

We are and may also additionally become subject to a growing body of privacy, data security and data protection laws outside of the United States as we expand our business and clinical trial activities. For example, the EU GDPR and the UK GDPR impose strict requirements for processing the personal data of individuals located, respectively within the EEA and the United Kingdom (the "UK"). Under either law, companies may face temporary or definitive bans on data processing and other corrective actions, fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, many jurisdictions have enacted data localization laws and cross-border personal data transfer laws. These laws may make it more difficult for companies to transfer personal data across jurisdictions, which could impede our business. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If we need but cannot implement a valid compliance mechanism for cross-border privacy and security transfers, or if the requirements for a legally compliant transfer are too onerous, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or elsewhere. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to European and other data privacy and security laws; or requiring us to increase our personal data processing capabilities in Europe and/or elsewhere at significant expense.

Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources), which may necessitate changes to our information technologies, systems, and practices and to those of any third parties upon which we rely. In addition, these obligations may require us to change our business model.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon

which we rely may fail (or be perceived to have failed) to comply with such obligations, which could negatively impact our business operations and compliance posture. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims) and mass arbitration demands; consent decrees that impose additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including, but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

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 our PCV candidates 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 United States 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 our PCV candidates 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 our PCV candidates 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 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 our PCV candidates 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 ("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, a patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment ("PTA")) or extended to account for the 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, components of our PCV candidates, and methods of making components of our PCV candidates from Sutro Biopharma and University

of Georgia Research Foundation, Inc. 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 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 our PCV candidates 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, manufacturing and commercialization of our PCV candidates 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 these 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, written description, or lack of patentable 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 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. For example, recent decisions raise questions regarding the award of PTA for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in future and whether patent expiration dates may be impacted. 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. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications may, upon grant of a patent, become a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC may be opted

out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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 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.

The ongoing conflict in Ukraine and related sanctions could significantly devalue our Eurasian patents validated in Russia, and Eurasian patent applications. Russian decrees may also significantly limit our ability to enforce Russian patents. We cannot predict when or how this situation will change.

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 rely on third parties to manufacture VAX-31, VAX-24 and potentially future vaccine candidates, and we collaborate with third parties on the development of VAX-31, VAX-24 and potentially future vaccine candidates, we must, at times, share trade secrets with them. We also conduct joint research and development 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 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. Further, disputes may arise under these agreements regarding inventorship or ownership of proprietary information generated during research and development.

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 Ownership of Our Common Stock

The price of our stock has been and may continue to be volatile, and the value of our common stock has and may continue to decline, any of which could result in substantial losses for investors.

The market price of our common stock has been and may continue 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 Annual Report on Form 10-K, these factors include, but are not limited to:

- 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, recommending body 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 our 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, including high inflation rates, bank failures, changes in interest rates, government tapering policies and the conflicts in Ukraine and the Middle East, significant changes in trade policies, 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 Select 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. 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.

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.

Expectations relating to environmental, social and governance programs may impose additional costs and expose us to new risks.

The focus of certain investors and other key stakeholders concerning corporate responsibility, specifically related to environmental, social and governance ("ESG") factors has been changing, and ESG laws and regulations regarding disclosure, reporting and diligence requirements continue to evolve. Some parties have placed an increased emphasis on corporate responsibility ratings and a number of third parties provide reports on companies in order to measure and assess corporate responsibility performance. In addition, the ESG factors

by which companies' corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. On the other hand, state attorneys general and other governmental authorities may take action against certain ESG policies or practices. We risk damage to our brand and reputation if our corporate responsibility procedures or standards do not meet the standards set by various constituencies or comply with new laws and regulations or changes to legal or regulatory requirements concerning ESG. We may be required to make investments to comply with various ESG and anti-ESG practices and regulations, which could be significant and adversely impact our results of operations. Furthermore, if our competitors' corporate responsibility performance is perceived to be greater than ours, potential or current investors may elect to invest with our competitors instead. In addition, if we communicate certain initiatives and goals regarding ESG matters, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors and other key stakeholders or our initiatives are not executed as planned or do not meet evolving legal and regulatory standards, our reputation and financial results could be materially and adversely affected.

Future sales of a substantial number of shares of our common stock, or the perception that such sales could occur, could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the public's perception that such sales could occur, could have an adverse effect on the market price of our common stock.

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 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 ("Board") 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. Among other things, these provisions:

- establish a classified Board 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;
- 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;
- 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 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; and

- require the approval of the holders of at least 66 ⅔% 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 ("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.

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 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 provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors 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 provides that the Court of Chancery of the State of Delaware will, to the fullest extent permitted by applicable law, 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 provides 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), to the fullest extent permitted by applicable law, 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;
- 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 or proceeding 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. Furthermore, Section 22 of the Securities Act of 1933 (as amended, the "Securities Act") creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation 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. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these types of lawsuits. 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.

General Risk Factors

Raising additional capital may cause dilution to our stockholders, 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, including through the use of our "at-the-market" facility. 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.

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, including as a result worsening global economic conditions, including higher inflation rates and changes in interest rates, and civil and political unrest in certain countries and regions. Such volatility and disruptions have caused and may continue to cause 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, including higher inflation rates and changes in interest rates, 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.

The cash and cash equivalents that we use to meet our working capital and operating expense needs and investments we hold are held and managed with financial institutions. If any of the financial institutions in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations. For example, on March 10, 2023, the California Department of Financial Protection and Innovation took control of Silicon Valley Bank ("SVB") and appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. While SVB was our primary bank at the time, we have not experienced any losses on our deposits or investments with SVB as a result of this market event. We continue to maintain a banking relationship with SVB, which is almost entirely comprised of our funds held in custodial accounts of a third-party institution for which SVB Asset Management was the advisor ("SVB Custodial Accounts"). While we were able to recover all deposited amounts from SVB, and continue to have access to all investments held in the SVB Custodial Accounts, there can be no assurance that our current or future banks will not face similar risks as SVB or that we will be able to recover in full our deposits in the event of similar closures. If one or any of the financial institutions in which we hold our funds for working capital and operating expense needs were to fail, we cannot provide any

assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner.

Significant changes and volatility in trade policies could materially affect our business, financial condition, liquidity and results of operations, and stock price.

International trade policies are subject to periodic revision and may change in response to economic, geopolitical or national security considerations. The U.S. government and certain foreign governments have recently announced new or increased tariffs on imported goods, and additional tariffs or increases in tariffs could be assessed in the future. Pharmaceuticals have historically been exempt from tariffs and have, thus far, been exempt from recently imposed tariffs. However, the government has recently launched an investigation under Section 232 of the Trade Expansion Act of 1962 to determine the effects on national security of imports of pharmaceuticals and pharmaceutical ingredients, and their derivative products. This investigation is intended to cover both finished generic and branded drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients and key starting materials, and derivative products of those items. It is possible that this investigation will result in the imposition of tariffs on a range of pharmaceutical products and ingredients, in ways that negatively impact certain aspects of our manufacturing process for our clinical trial product materials and supplies, the level of expenses related to our vaccine candidates or preclinical and clinical development programs, and our business.

We rely on third-party manufacturers with global operations, so our business may be impacted by tariffs. We do not sell
any commercial products nor do we expect to do so in the immediate future, so we cannot pass on the increased costs from
the tariffs to customers. Therefore, we will need to absorb any increased costs, which will put further financial strain on our
business.

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.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely consolidated 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 are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm with our annual reports on Form 10-K. 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 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.

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

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

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

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 depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have control over these analysts. If securities or industry analysts do not publish research or reports about our business, the trading price for our stock would likely be negatively impacted. If one or more of the analysts who cover 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.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

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

Our information security function, overseen by our Senior Vice President of IT and Facilities ("SVP of IT and Facilities") and supported by members of our IT, Legal and Finance departments, and our third-party IT service providers, helps identify, assess and manage our cybersecurity threats and risks. This group identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods, including, for example: using manual and automated monitoring tools; subscribing to reports and services that identify cybersecurity threats; conducting scans of our threat environment; evaluating threats reported to us; conducting internal and external audits for certain data and systems; conducting threat assessments for internal and external threats; conducting vulnerability assessments to identify vulnerabilities; penetration testing; and having third parties conduct threat assessments.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: maintaining an incident response process; conducting risk assessments; encrypting certain of our data; segregating certain of our data; implementing network security controls; maintaining access and physical security controls; asset management processes for managing, tracking, and disposing of assets; monitoring our corporate systems; and providing security awareness training to employees.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, our senior management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our cybersecurity risks.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including, for example, cybersecurity consultants, cybersecurity software and hardware providers, outside legal counsel, penetration testing firms, dark web monitoring services, and forensic investigators.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations, and contract manufacturing organizations. We use certain vendor management processes to help manage cybersecurity risks associated with

our use of certain of these providers. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider, including, for example, requiring our vendors to complete security questionnaires and conducting vulnerability scans related to our vendors' services.

To date, cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected and we believe are not reasonably likely to materially affect us, including our business strategy, results of operations or financial condition. For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including *"If our information technology systems or those of the third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, significant fines or other liability; regulatory investigations or actions; disruptions of our development programs or business operations; harms to our reputation, and other adverse consequences."*

Cybersecurity Governance

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

Our cybersecurity risk assessment and management processes are implemented and maintained by certain individuals in our management, including our SVP of IT and Facilities, who has over 30 years of IT experience, including 10 years of information security experience, in various IT leadership roles in life sciences companies.

Our SVP of IT and Facilities is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel.

Our SVP of IT and Facilities is responsible for preparing budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents and vulnerabilities to members of management depending on the circumstances, including our President and CFO. Our President and CFO works with our incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response processes include reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives quarterly or as needed reports from our SVP of IT and Facilities concerning our significant cybersecurity threats and risk and the processes we have implemented to address them. The audit committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

Our corporate headquarters is located in San Carlos, California, where we currently lease and occupy 195,633 square feet of laboratory and office space pursuant to an Amended and Restated Lease Agreement (the "Amended and Restated Lease"). Our Amended and Restated Lease premises consist of an aggregate of approximately 258,581 square feet of laboratory and office space, of which (i) 16,731 square feet we currently sublet, and (ii) 46,217 square feet of which the lease commencements will begin starting in 2026. Our Amended and Restated Lease expires on February 28, 2035. We use our corporate headquarters primarily for corporate research, development, regulatory, manufacturing and quality functions. We believe that our existing facilities are adequate to meet our current needs.

Item 3. Legal Proceedings.

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that in the opinion of our management, if determined unfavorably to us, would have a material adverse effect on our business, financial condition, operating results or cash flows. Regardless of the outcome, litigation can, among other things, be time consuming and expensive to resolve and divert management resources.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information for Our Common Stock

Our common stock commenced trading on the Nasdaq Global Select Market under the symbol "PCVX" on June 12, 2020.

Holders

As of February 20, 2026, there were approximately 7 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

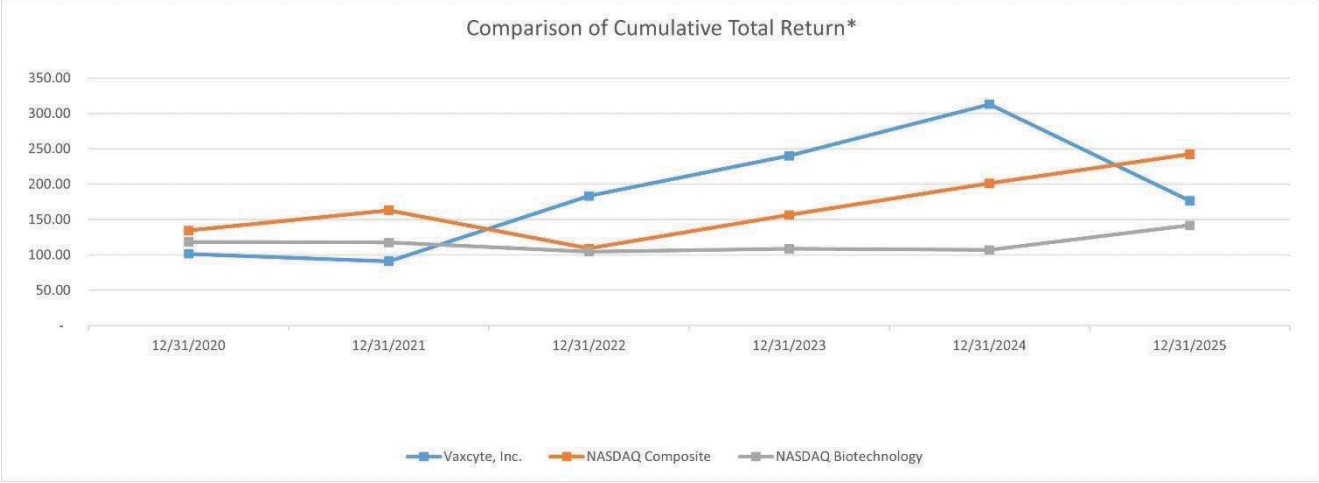
We have not declared or paid any cash dividend on our common stock. We intend to retain any future earnings and do not expect to pay cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors (our "Board") and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board may deem relevant.

Stock Performance Graph

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, except to the extent that we specifically incorporate this information by reference therein, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following stock performance graph compares our cumulative total stock return relative to the cumulative total returns of the Nasdaq Composite Index and the Nasdaq Biotechnology Index for the period from June 12, 2020 (the date our common stock commenced trading on the Nasdaq Global Select Market) through December 31, 2025. The figures below assume an investment of $100 in our common stock at the closing price of $26.15 on June 12, 2020, the date of our IPO, and in each index on the same date and the reinvestment of the full amount of all dividends into shares of common stock; however, no dividends have been declared on our common stock to date. The stockholder returns shown on the graph below are based on historical results and are

not indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



Unregistered Sales of Equity Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes and other financial information included elsewhere in this Annual Report on Form 10-K. For discussion and analysis related to our financial condition and results of operations comparing the year ended December 31, 2023 ("2023") to the year ended December 31, 2022, refer to Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for 2023, which was filed with the Securities and Exchange Commission on February 27, 2024. This discussion and analysis contain forward-looking statements based upon our current beliefs, 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 titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. You should carefully read the "Risk Factors" section of this Annual Report on Form 10-K 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 titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage vaccine innovation company engineering high-fidelity vaccines to protect humankind from the consequences of bacterial diseases. We are re-engineering the way highly complex vaccines are made through the XpressCF™ cell-free protein synthesis platform. Unlike conventional cell-based approaches, our system for producing difficult-to-make proteins and antigens is intended to develop and deliver high-fidelity vaccines with enhanced immunological benefits that are beyond the capabilities of conventional approaches.

Our pipeline includes:

- PCV candidates that we believe are among the broadest-spectrum PCV candidates currently in development, targeting the approximately $8 billion global pneumococcal vaccine market. Pneumococcal disease ("PD") is an infection caused by *Streptococcus pneumoniae* bacteria. It can result in invasive pneumococcal disease ("IPD"), including meningitis and bacteremia, and non-invasive PD, including pneumonia, otitis media and sinusitis. Our broad-spectrum, carrier-sparing PCV candidates, VAX-31, VAX-24 and VAX-XL, are designed to improve upon standard-of-care PCVs for both adults and children by covering the serotypes that are responsible for increasing portions of IPD in circulation and are associated with high case-fatality rates, antibiotic resistance and meningitis, while maintaining coverage of previously circulating strains that are currently contained through continued vaccination.
    - PCV Franchise Adult Indication:
        - VAX-31 is a 31-valent, broad-spectrum, carrier-sparing investigational PCV being developed for the prevention of IPD and pneumonia. VAX-31 is the broadest-spectrum PCV in the clinic, and has the potential to provide protection against both currently circulating and historically prevalent serotypes. VAX-31 was designed to increase coverage, in a single vaccine, to approximately 95% of IPD and approximately 88% of pneumococcal pneumonia circulating in adults in the United

States aged 50 and older, with the potential to provide an incremental 14-34% of coverage for IPD and an incremental 19-31% of coverage for pneumococcal pneumonia over current standard-of-care adult PCVs.

- In September 2024, we announced positive topline results from a Phase 1/2 study of VAX-31 in adults. The VAX-31 Phase 1/2 clinical study was a randomized, observer-blind, active-controlled, dose-finding clinical study designed to evaluate the safety, tolerability and immunogenicity of a single injection of VAX-31 at three dose levels (Low, Middle and High) and compared to Prevnar 20® ("PCV20") in 1,015 healthy adults aged 50 and older. In the Low, Middle and High Doses, all serotypes were dosed at 1.1mcg, 2.2mcg and 3.3mcg, respectively, except serotypes 1, 5 and 22F, which were dosed at 1.65mcg, 3.3mcg, and 4.4mcg, respectively. The Phase 1 portion of the study included 64 healthy adults 50 to 64 years of age and the Phase 2 portion included 951 healthy adults 50 years of age and older. The immunogenicity objectives of the study included an assessment of the induction of antibody responses at Month 1, based on opsonophagocytic activity ("OPA") and immunoglobulin G ("IgG"), at each of the three VAX-31 doses and compared to PCV20 for the 20 serotypes in common, as well as for the additional 11 serotypes contained in VAX-31, but not in PCV20.

  In the Phase 1/2 study, VAX-31 was observed to be well tolerated and demonstrated a safety profile at all doses studied through the full six-month evaluation period similar to PCV20. VAX-31 showed robust OPA immune responses for all 31 serotypes at all doses studied. At the Middle and High Doses, VAX-31 met or exceeded the regulatory immunogenicity criteria for all 31 serotypes and, at the Low Dose, for 29 of 31 serotypes. At the VAX-31 High Dose, average OPA immune responses were greater for 18 of 20 serotypes compared to PCV20 (geometric mean ratio ("GMR") greater than 1.0), with seven of these serotypes achieving statistically higher immune responses compared to PCV20. At the Middle Dose, 13 of 20 serotypes had a GMR greater than 1.0 and five serotypes achieved statistically higher immune responses compared to PCV20. At the Low Dose, 18 of 20 serotypes met the OPA response non-inferiority criteria, 8 of 20 serotypes had a GMR greater than 1.0 and three serotypes achieved statistically higher immune responses. For all 11 incremental serotypes unique to VAX-31, and not in PCV20, all three doses met the superiority criteria.

  Based on these positive results, we selected the High Dose of VAX-31 to advance to an adult Phase 3 program.

- In November 2024, we announced that the FDA granted breakthrough therapy designation ("BTD") for VAX-31 for the prevention of IPD in adults and, in August 2025, we announced that the FDA expanded the BTD for VAX-31 to include the prevention of pneumonia caused by *Streptococcus pneumoniae*.

- In December 2025, following an FDA End-of-Phase 2 meeting, we announced that the first participants were dosed in a Phase 3 pivotal, non-

inferiority trial evaluating VAX-31 for the prevention of IPD and pneumonia in adults compared to standard-of-care PCVs ("OPUS-1"). We expect to announce topline safety, tolerability and immunogenicity data from this study in the fourth quarter of 2026.

- In January 2026, we announced the initiation of an additional Phase 3 trial evaluating VAX-31 when administered concomitantly with a licensed, high-dose seasonal influenza vaccine in pneumococcal-naïve adults aged 50 years and older ("OPUS-2"). In February 2026, we announced the initiation of a separate Phase 3 study evaluating VAX-31 in adults previously vaccinated with a lower-valency pneumococcal vaccine ("OPUS-3"). We expect to report safety, tolerability and immunogenicity data from the OPUS-2 and OPUS-3 studies in the first half of 2027. We are also planning for a manufacturing consistency study (e.g., a lot-to-lot study).

◦ PCV Franchise Pediatric Indication:

- VAX-31 is a 31-valent, broad-spectrum, carrier-sparing investigational PCV also being developed for the prevention of IPD in children. VAX-31 is the broadest-spectrum PCV in the clinic designed to cover approximately 92% of IPD in U.S. children under five years of age and approximately 96% of otitis media due to *Streptococcus pneumoniae* in U.S. children five years of age or under.

  - In December 2024, we announced that the first participants were dosed in the first stage of a Phase 2, randomized, dose-finding study of VAX-31 in infants. Stage 1 of the study evaluated the safety and tolerability of VAX-31 at three dose levels (Low, Middle and High) and compared to PCV20 in 48 infants in a dose-escalation approach. In the Low, Middle and High Doses, all serotypes were dosed at 1.1mcg, 2.2mcg and 3.3mcg, respectively, except serotypes 1, 5 and 22F, which were dosed at 1.65mcg, 3.3mcg, and 4.4mcg, respectively. Participants who received VAX-31 in Stage 1 continued the standard dosing regimen as part of Stage 2.

  - In February 2025, we announced that the Phase 2, randomized, dose-finding study of VAX-31 in healthy infants had advanced to the second stage of the study. Stage 2 of the study is evaluating the safety, tolerability and immunogenicity of VAX-31 at the same three dose levels evaluated in Stage 1 and compared to PCV20. In line with recommendations from the ACIP, the study design includes a primary immunization series consisting of three doses given at two months, four months and six months of age, followed by a subsequent booster dose at 12-15 months of age.

  - In September 2025, we announced advancement of the VAX-31 infant Phase 2 randomized, dose-finding study to the third and final stage following modifications to the protocol to add a new dose arm to evaluate a VAX-31 Optimized Dose (majority of serotypes dosed at 4.4mcg and the

balance dosed at 3.3mcg) and discontinue enrollment in the Low Dose arm. The Middle and High Dose arms continued as planned.

- The modified study is evaluating the safety, tolerability and immunogenicity of VAX-31 and compared to PCV20 in 900 participants, including the 100 participants previously enrolled in the Low Dose arm.

- In January 2026, we announced that we completed enrollment of this study. We expect to announce topline safety, tolerability and immunogenicity data from the primary three-dose immunization series and booster dose either sequentially or together by the end of the first half of 2027.

- Pending the VAX-31 Phase 2 infant study readout, we plan to initiate a Phase 3 program in infants with an Optimized Dose formulation of VAX-24 or VAX-31.

- VAX-24 is a 24-valent, broad-spectrum, carrier-sparing investigational PCV being developed for the prevention of IPD in infants, and it covers more serotypes than any pneumococcal infant vaccine on the market today.

  - In March 2025, we announced positive topline, interim data from the VAX-24 infant Phase 2 study, a randomized, observer-blind, dose-finding two-stage clinical study evaluating the safety, tolerability and immunogenicity of VAX-24 in healthy infants that enrolled 803 participants.

  - In November 2025, we announced final safety, tolerability, and immunogenicity results from the VAX-24 infant Phase 2 study that were consistent with the positive interim data reported in March 2025 and showed that VAX-24 elicited robust, dose-dependent immune responses, with little to no evidence of carrier suppression observed. The final data analysis included full 6-month safety results and complete post-dose 3 (primary immunization series) and post-dose 4 (booster dose) IgG and OPA results. The key immunogenicity endpoints included an assessment of immune responses for each of the VAX-24 dose levels (Low, Mid, Mixed) in comparison with PCV20 for the 20 common and 4 unique serotypes in VAX-24. At 1-month post-dose 3 and post-dose 4, immune responses were assessed based on serotype-specific IgG seroconversion rates (IgG threshold value of ≥0.35mcg/mL). IgG GMRs were also assessed at 1-month post-dose 3 and post-dose 4, along with other key immunogenicity endpoints, including OPA.

    In this study, VAX-24 was well-tolerated and demonstrated a safety profile similar to PCV20 across all doses studied. Post-dose 3 and post-dose 4, all VAX-24 doses evaluated demonstrated robust IgG and OPA immunogenicity responses.

    - Post-dose 3, all VAX-24 doses met target precedent Phase 2 non-inferiority criteria on relative seroconversion rates (lower limit of the 95% confidence interval for the difference between the

proportion of participants achieving the pre-defined seroconversion rate (IgG concentration ≥0.35 mcg/mL) is > -15% for each serotype) for the highest circulating serotypes, as defined by the percentage of IPD caused in individuals <5 yrs of age in the U.S. in 2023 based on the U.S. Center for Disease Control ("CDC") active bacterial core ("ABC") surveillance data, contained in VAX-24. The Low and Mid doses met the seroconversion rate criteria for 20 of 24 serotypes overall and the Mixed Dose met such criteria for 19 of 24 serotypes. The Mid and Mixed Doses met the target Phase 2 IgG GMR point estimate of >0.6 for 21 of 24 serotypes.

- Post-dose 4, all VAX-24 doses met our target Phase 2 IgG GMR point estimate of >0.6 for the three highest circulating serotypes contained in VAX-24. The Mixed Dose met this target for 19 of 24 serotypes overall and the Mid dose met this target for 18 of 24 serotypes. Post-dose 4, VAX-24 elicited robust memory responses across all doses for all serotypes.

- Additionally, the four incremental serotypes unique to VAX-24 that provide expanded serotype coverage relative to PCV20 elicited robust immune responses and met all target criteria across all endpoints at all doses evaluated.

- The final positive data from the VAX-24 infant Phase 2 dose-finding study further validated our rationale for exploring higher doses in the ongoing VAX-31 infant Phase 2 study.

  - VAX-XL is a third-generation PCV candidate designed to provide the broadest coverage of any PCV currently in development.

- VAX-A1, a novel conjugate vaccine candidate designed to prevent disease caused by Group A Streptococcus (“Group A Strep”). Group A Strep is pervasive globally and causes an estimated 800 million cases of illness annually, including pharyngitis, or strep throat, and certain severe invasive infections and sequelae. There is currently no vaccine against Group A Strep, which is one of the leading infectious disease-related causes of death and disability worldwide and a significant contributor to the prescription of antibiotics in children. We believe we have demonstrated preclinical proof of concept for VAX-A1, the data for which were published in December 2020. We plan to initiate a Phase 1 adult study for VAX-A1 in 2026, with the primary objective of assessing safety and tolerability.

- VAX-GI, a novel preclinical vaccine candidate being developed as a preventative treatment for dysentery and shigellosis, which is caused by Shigella bacteria. Shigella is a bacterial illness estimated to cause 80 million to 165 million cases of disease and 600,000 deaths annually, mostly among children. The central antigen in VAX-GI is IpaB, a well-appreciated antigen that other developers have been unable to produce in an amount sufficient to enable a commercial product. With our cell-free technology, we believe we can produce this antigen at substantially improved yields, allowing for commercial-scale production. VAX-GI is being developed in collaboration with the University of

Maryland, Baltimore as well as with partial funding from two research grants awarded by the National Institutes of Health ("NIH"). As part of our continued focus on strategic capital deployment and in order to prioritize our resources towards our PCV franchise, we announced in August 2025 that we had paused the advancement, beyond preclinical development, of VAX-GI while remaining confident in its potential and preserving the option to advance the program in the future.

- Other discovery-stage programs that leverage our cell-free protein synthesis platform, which, if proven successful in preclinical studies, could also be advanced into IND-enabling activities and clinical studies.

Since January 1, 2025, key developments affecting our business include the following:

PCV Franchise Adult Indication:

- ***FDA Expanded VAX-31 Adult BTD to Include Prevention of Pneumonia Caused by Streptococcus Pneumoniae in Addition to IPD:*** In May 2025, the FDA expanded the adult BTD for VAX-31 to include the prevention of pneumonia caused by *Streptococcus pneumoniae* in addition to the prevention of IPD based on the positive topline results from the VAX-31 adult Phase 1/2 study, indicating that VAX-31 may demonstrate substantial improvement over existing therapies.

- ***Advanced Comprehensive Phase 3 Clinical Program to Support Planned BLA Submission and Validate VAX-31 as Potential New Standard-of-Care Adult PCV to Prevent IPD and Pneumonia:*** In August 2025, we announced that through a series of interactions with the FDA, including an End-of-Phase 2 meeting, regarding the VAX-31 adult Phase 3 clinical program, the FDA provided input on the adult commercial licensure requirements, including the approximate number of study participants in the Phase 3 program; key immunogenicity and safety endpoints for the pivotal, non-inferiority study; and a continued indication that the scale of the planned immunogenicity and safety assessments are in line with precedent requirements and will be sufficient to support potential licensure. Additionally, as part of ongoing discussions granted under the VAX-31 adult BTD, the FDA provided input on the chemistry, manufacturing and controls ("CMC") licensure requirements in support of our path to delivering a BLA submission. The VAX-31 High Dose (all serotypes dosed at 3.3mcg or 4.4mcg) has been selected to advance into Phase 3.

- ***Initiated Phase 3 OPUS-1 Trial:*** In December 2025 we announced we dosed the first participants in the OPUS-1 trial, with topline data expected in the fourth quarter of 2026. This trial is evaluating the safety, tolerability and immune responses of VAX-31 in approximately 3,560 adults aged 50 and older through direct, head-to-head comparisons with both Capvaxive® ("PCV21") and PCV20, the current standard-of-care PCVs, with the objective of establishing a best-in-class profile for VAX-31. The trial is also evaluating the safety, tolerability and immune responses of VAX-31 in approximately 440 adults aged 18-49. OPUS-1 is being conducted at approximately 50 sites in the United States.

- ***Initiated Phase 3 OPUS-2 and OPUS-3 Trials:*** In January 2026, we dosed the first participants in OPUS-2, a Phase 3 descriptive study designed to evaluate the safety, tolerability and immunogenicity of VAX-31 when administered concomitantly with, or one month following, a licensed, high-dose seasonal influenza vaccine in approximately 1,300 pneumococcal-naïve adults aged 50 years and older (defined as having no known prior history of IPD, pneumococcal pneumonia, or receipt of any licensed or investigational pneumococcal vaccine). OPUS-2 is being conducted at approximately 25 sites in the United States. In February 2026, we dosed the first participants in OPUS-3, a Phase 3 descriptive study evaluating the safety, tolerability and immunogenicity of a single dose of VAX-31 in

approximately 720 adults aged 50 years and older who have previously received lower-valency pneumococcal vaccines. OPUS-3 is being conducted at approximately 30 sites in the United States. We expect to report safety, tolerability and immunogenicity data from the OPUS-2 and OPUS-3 studies in the first half of 2027. We are also planning for a manufacturing consistency study (e.g. a lot-to-lot study).

- ***Advancing Toward BLA Submission:*** Subject to the results of the Phase 3 studies, which are expected to read out in 2026 and 2027, we plan to submit a BLA shortly following the completion of the last Phase 3 study.

PCV Franchise Infant Indication:

- ***Completed Enrollment of Ongoing VAX-31 Infant Phase 2 Dose-Finding Study:*** In August 2025, we announced that we had modified the ongoing VAX-31 infant Phase 2 randomized, dose-finding study to add a new dose arm to evaluate a VAX-31 Optimized Dose with the majority of serotypes dosed at 4.4mcg and the balance dosed at 3.3mcg. Both the Middle Dose and High Dose VAX-31 arms in the study are proceeding as planned while we elected to discontinue enrollment in the Low Dose arm. In September 2025, we announced that the first participants had received the Optimized Dose and subsequently announced in January 2026 that we had completed enrollment of the study. The modified study will evaluate VAX-31 in 900 dosed participants, including the 100 participants previously enrolled in the Low Dose arm. We expect to announce topline safety, tolerability and immunogenicity data from the primary three-dose immunization series and booster dose either sequentially or together by the end of the first half of 2027.
- ***Reported Positive Interim and Final VAX-24 Infant Phase 2 Dose-Finding Study Data:*** In March 2025, we announced positive topline, interim data from the VAX-24 infant Phase 2 study that enrolled 803 participants. In November 2025, we announced the final safety, tolerability, and immunogenicity results from the study, which were consistent with the positive interim data reported in March 2025 and showed that VAX-24 elicited robust, dose-dependent immune responses, with little to no evidence of carrier suppression observed. The final data analysis included full 6-month safety results and complete post-dose 3 (primary immunization series) and post-dose 4 (booster dose) IgG and OPA results. The totality of data from this study affirms the Company's strategy to include the higher doses that are being evaluated in the ongoing VAX-31 infant Phase 2 dose-finding study.

Other Pipeline Programs:

- ***Advancing VAX-A1, a Vaccine Candidate Designed to Prevent Disease Caused by Group A Strep, Into the Clinic:*** In February 2026, we announced we are planning to initiate a Phase 1 adult study for VAX-A1, a prophylactic vaccine candidate designed to prevent disease caused by Group A Strep, in 2026 with the primary objective of assessing safety and tolerability. Group A Strep remains a major global cause of morbidity and mortality in adults and children and is a leading driver of antibiotic use, underscoring the significant public health burden.

- ***Introduced Development of VAX-XL, Third-Generation PCV Candidate Designed to Further Expand Disease and Serotype Coverage:*** In March 2025, we announced VAX-XL, our third-generation PCV candidate designed to provide the broadest coverage of any PCV currently in development for infants or adults.

Equity Financing:

- ***Completed Public Offering Generating Gross Proceeds of $632.5 million:*** In February 2026, we completed an underwritten public offering of 12,650,000 shares of common stock, which included the full exercise of the underwriters' option to purchase an additional 1,650,000 shares, at a public offering price of $50.00 per share. The aggregate gross proceeds to us from this offering were $632.5 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.

Other Business:

- ***Appointed Dr. Olivier Brandicourt to our Board of Directors:*** In May 2025, we appointed Dr. Olivier Brandicourt to our Board of Directors. Dr. Brandicourt is a veteran biopharmaceutical industry executive and the former Chief Executive Officer of Sanofi S.A. and Bayer HealthCare AG. He brings a wealth of expertise, with significant experience in commercial strategy and execution within the global vaccine market. Dr. Brandicourt is currently a Senior Advisor at Blackstone Life Sciences and serves on the boards of Alnylam Pharmaceuticals, Inc., AvenCell Therapeutics, Inc., BeOne Medicines Ltd. and Dewpoint Therapeutics, Inc.

- ***Appointed Chris Griffith as Chief Business and Strategy Officer:*** In July 2025, Chris Griffith joined Vaxcyte as Chief Business and Strategy Officer. With more than 20 years of experience spanning corporate and business development, portfolio strategy and business operations, Mr. Griffith brings deep expertise to this newly expanded role. His leadership will help ensure strong cross-functional alignment and execution as we advance our late-stage programs and prepare for the next phase of growth.

- ***Announced Plan to Establish Fill-Finish Manufacturing in North Carolina as Key Element of Long-Term U.S. Commercial Supply Strategy Representing Up to $1 Billion in Manufacturing and Services:*** In September 2025, we announced a new agreement with Patheon Manufacturing Services, LLC, part of Thermo Fisher Scientific (collectively, "Thermo Fisher") to provide custom commercial fill-finish capacity for our broad-spectrum PCVs at Thermo Fisher's Greenville, North Carolina facility. The initiative, which includes both manufacturing and related services, represents a long-term U.S. commercial manufacturing commitment of up to $1 billion.

- ***Appointed Mike Mullette as Chief Commercial Officer to Lead Commercialization Strategy and Execution:*** In October 2025, Michael Mullette joined Vaxcyte as Chief Commercial Officer, bringing more than 20 years of global experience in vaccines and biopharmaceuticals, including senior leadership roles at Moderna, Sanofi Pasteur and Lykos Therapeutics. As part of our strategy to prepare for future commercialization of our PCV programs, Mr. Mullette will lead the continued development and execution of global commercialization, including pre-launch planning and cross-functional readiness. He brings extensive launch leadership, having led Moderna’s first ever commercial organization in North America during the COVID-19 pandemic and launched multiple vaccines at Sanofi Pasteur across the U.S., France, Japan, Australia and Canada.

Since our inception in November 2013, we have devoted substantially all of our resources to performing research and development, undertaking preclinical studies, advancing our vaccine candidates through clinical trials, enabling manufacturing activities in support of our product development efforts, 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 common stock,

pre-funded warrants to purchase our common stock and, prior to our initial public offering ("IPO") in June 2020, redeemable convertible preferred stock. We will continue to require additional capital to develop and commercialize 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 clinical trials and manufacturing activities, and our expenditures on other research and development activities. Our net losses were $766.6 million, $463.9 million, and $402.3 million for the years ended December 31, 2025, 2024 and 2023, respectively. As of December 31, 2025, we had an accumulated deficit of $2,154.9 million and cash, cash equivalents and investments of $2,442.6 million. We believe our cash, cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months from the filing date of this Annual Report on Form 10-K.

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 our vaccine candidates through preclinical studies and clinical trials;
- progress in the scale-up of our manufacturing capabilities, in particular to prepare for the potential commercial launches of VAX-31 in the adult population and VAX-31 or VAX-24 in the pediatric population;
- incur additional costs that may be required for secondary supply sources;
- require the manufacture of supplies for our clinical trials;
- conduct clinical trials, in particular VAX-31 and VAX-24;
- pursue regulatory approval of our vaccine candidates;
- establish additional manufacturing capacity to meet potential incremental supply requirements following the potential commercial launches of VAX-31 in the adult population and VAX-31 or VAX-24 in the pediatric population;
- hire additional personnel;
- scale medical affairs and commercial infrastructure to support anticipated product launches;
- expand our facilities to support our growing workforce and lab activities;
- 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 to conduct 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 and have a limited commercial infrastructure. Accordingly, if we obtain regulatory approval for any of our vaccine candidates, we also would expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

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 revenue 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

Lonza Ltd. ("Lonza")

Development and Manufacturing Services Agreements

In April 2022, we entered into a non-exclusive development and manufacturing services agreement with Lonza effective as of March 22, 2022, which was subsequently amended on May 12, 2022, November 21, 2022 and October 31, 2023 (as amended, the "2022 Lonza DMSA"). Pursuant to the 2022 Lonza DMSA, Lonza is obligated to perform services, including manufacturing process development and clinical manufacture and supply of our proprietary PCV candidates. Subject to the terms and conditions set forth in the 2022 Lonza DMSA, Lonza has granted to us a non-exclusive, worldwide, fully paid-up, irrevocable, transferable license, including the right to grant sublicenses, under the New General Application Intellectual Property, to research, develop, make, have made, use, sell and import the Product. Unless earlier terminated, the 2022 Lonza DMSA shall remain in place for a period of five years. Either party may terminate the 2022 Lonza DMSA for any reason on prior written notice to the other party, provided that Lonza may not exercise such right until a specified future date. In addition, either party may terminate the 2022 Lonza DMSA (i) within a given time period upon any material breach that is left uncured by the other party, or (ii) immediately if the other party becomes insolvent. We may also terminate the 2022 Lonza DMSA upon an extended force majeure event. Upon expiration and/or termination of the 2022 Lonza DMSA and/or any purchase order, we will pay Lonza for all service rendered, all costs incurred, all unreimbursed capital equipment and any cancellation fees (each term as defined in the 2022 Lonza DMSA).

In February 2023, we entered into another non-exclusive development and manufacturing services agreement with Lonza effective as of March 1, 2023 (the "2023 Lonza DMSA"). Pursuant to the 2023 Lonza DMSA, Lonza will perform manufacturing process development and the manufacture of components for our PCV candidates, including the polysaccharide antigens, our proprietary eCRM protein carrier and conjugated drug substances. Subject to the terms and conditions set forth in the 2023 Lonza DMSA, Lonza has granted to us a non-exclusive, worldwide, fully paid-up, transferable license, including the right to grant sublicenses (subject to the prior written consent of Lonza), under the New General Application Intellectual Property, to use, sell and import the Product manufactured under the 2023 Lonza DMSA (but no other products). Unless earlier terminated, the 2023 Lonza DMSA shall remain in place for a period of five years and shall automatically renew for one additional two-year period unless either party provides written notice of non-renewal at least two years prior to the fifth anniversary of the effective date. We may terminate the 2023 Lonza DMSA for any reason on prior written notice to the other party on a Project Plan-by-Project Plan basis. Either party may terminate the 2023 Lonza DMSA (i) within a given time period upon any material breach that is left uncured by the other party, (ii) immediately if the other party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, or files or has filed against it, a petition in bankruptcy or has a

receiver appointed for a substantial part of its assets, (iii) upon an extended force majeure event, or (iv) if it becomes apparent to either party at any stage in the provision of the Services that it will be impossible to complete the Services for scientific or technical reasons despite exercise of best commercial efforts by both parties. Pursuant to the reason for termination and the party initiating the termination, we will pay Lonza for some combination of services rendered, costs incurred, unreimbursed capital equipment and/or any cancellation fees. Upon an extended force majeure event, neither party shall have any further liability to the other party (each term as defined in the 2023 Lonza DMSA).

Under each of the 2022 Lonza DMSA and 2023 Lonza DMSA (collectively, the "Lonza Agreements"), we pay Lonza agreed-upon fees for their performance of development and manufacturing services and pass-through expenses incurred by Lonza for raw materials, as well as customary procurement and handling fees. Under each Lonza Agreement, we own all rights, title and interest in and to any and all New Customer Intellectual Property (as defined in each Lonza Agreement), and Lonza owns all rights, title and interest in New General Application Intellectual Property (as defined in each Lonza Agreement).

Commercial Manufacturing and Supply Agreement

On October 13, 2023, we entered into a pre-commercial services and commercial manufacturing supply agreement with Lonza (the "Lonza Commercial Manufacturing and Supply Agreement"). Pursuant to the Lonza Commercial Manufacturing and Supply Agreement, Lonza will (i) construct and build out a dedicated suite (the "Suite") at Lonza's facilities in Visp, Switzerland to manufacture certain key components (including drug substance) for our proprietary PCV franchise and any other products or intermediates we may choose (collectively, the "Products") and (ii) maintain and operate the Suite (utilizing Lonza's employees) to manufacture the Products as a service provided to us, including conducting related quality control and quality assurance operations. Lonza will be a preferred, non-exclusive, supplier of the Products to us, and we retain the right to procure the Products from one or more alternate and/or backup manufacturers of the Products (including at our own facilities).

Under the Lonza Commercial Manufacturing and Supply Agreement, prior to completion of construction and certification of the Suite for commercial operation, we will contribute to the capital expenditure costs to construct the Suite (and will own certain equipment in the Suite to be purchased or otherwise acquired by us), and will pay Lonza a fixed-rate monthly service fee for Lonza's pre-commercial services prior to commencement of commercial operations (which monthly service fee amount is subject to increases in subsequent years). Following commencement of commercial operations of the Suite to manufacture the Products, we will pay Lonza (i) Suite fees based on allocations of certain of Lonza's costs to maintain the facility in which the Suite is located and to provide shared services to us and Lonza's other customers in such facility, (ii) service fees based upon Lonza's actual full-time equivalent employee ("FTE") costs to operate the Suite to manufacture the Products, and (iii) certain other pass-through costs, including for raw materials. In addition, we may be obligated to pay or reimburse Lonza for certain other fees and expenses under the Lonza Commercial Manufacturing and Supply Agreement. Lonza will be eligible for certain financial bonuses, and subject to certain financial penalties, as incentives for the timely completion of certain scale-up activities, receipt of certain regulatory approvals for the Suite and manufacture of the Products in accordance with our commercial requirements.

Unless earlier terminated, the Lonza Commercial Manufacturing and Supply Agreement will remain in effect until December 31, 2038, subject to automatic renewal for up to three additional renewal periods of five years each, unless we elect not to renew (with 24 months advanced notice to Lonza). We are permitted to terminate the Lonza Commercial Manufacturing and Supply Agreement prior to expiration, subject to applicable

termination fees. Within 30 days of the Effective Date, we paid Lonza a repurposing fee (the "Repurposing Fee") of CHF 27.0 million that will be credited back to us over a 10-year period starting upon commencement of commercial production.

2026 Development and Manufacturing Services Agreement

On February 18, 2026, we entered into a development and manufacturing services agreement with Lonza, effective as of January 1, 2026, pursuant to which Lonza will perform manufacturing process development and commercial manufacture and supply of certain key components for our proprietary PCV franchise. Under the agreement, we will pay Lonza for development and manufacturing services, in addition to paying for certain raw material and other costs. We will be required to purchase, and Lonza will be required to supply, the components pursuant to the relevant purchase orders under the agreement. In consideration of the commercial supply services and Lonza's other obligations under the agreement, we will pay Lonza a daily fee for Lonza's operation of the facility solely to actively manufacture the components. With respect to such commercial supply, and subject to termination rights, we and Lonza have agreed to a mutually binding percentage of annual facility capacity that shall be utilized by Lonza fully and exclusively for Lonza's performance of services thereunder, which percentages may be adjusted under certain circumstances.

Unless earlier terminated, the agreement will remain in effect until December 31, 2038, subject to automatic renewal for up to three additional renewal periods of five years each, unless we elect not to renew. We may terminate the agreement for convenience, and the agreement contains customary for-cause termination rights for each party. If the Agreement is terminated (i) by us for convenience, or (ii) by Lonza for our uncured failure to pay material, undisputed amounts of money due to Lonza, then we shall pay Lonza certain cancellation fees as specified in the agreement.

Sutro Biopharma

Amended and Restated License Agreement

We are party to an amended and restated license agreement with Sutro Biopharma, dated October 12, 2015, which was subsequently amended on May 9, 2018, May 29, 2018, September 28, 2023 and November 21, 2023 (as amended, the "Sutro Biopharma License Agreement"). Under the Sutro Biopharma License Agreement, we received an exclusive, worldwide, royalty-bearing, sublicensable 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 sublicensable, for the treatment or prophylaxis of infectious diseases, excluding cancer vaccines, and (ii) 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 Biopharma License Agreement, we are obligated to pay Sutro Biopharma a 4% royalty on worldwide aggregate annual net sales of our vaccine products for human health and a 2% royalty on such net sales of vaccine products for animal health. 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 10 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.

On September 28, 2023, we and Sutro Biopharma amended certain terms of the Sutro Biopharma License Agreement, including with respect to (i) royalty reduction provisions applicable in the event of expiration of relevant patent claims, which would result in lower royalties payable by us to Sutro Biopharma under certain circumstances, (ii) the ownership, prosecution, maintenance and enforcement of certain intellectual property rights licensed or arising under the Sutro Biopharma License Agreement (including as agreed to be amended in the Option Agreement (as defined below)), and (iii) the timing and form for financial reporting of royalty payment calculations.

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.

Supply Agreement

In May 2018, we entered into a supply agreement with Sutro Biopharma, which was subsequently amended on February 22, 2021 and November 21, 2023 (as amended, the "Sutro Biopharma Supply Agreement") 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 Biopharma 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. The term of the Sutro Biopharma Supply Agreement is from execution until the later of (i) July 31, 2022, or (ii) the date that we and Sutro Biopharma enter into the Phase 3/Commercial Supply Agreement and Sutro Biopharma is supplying to us each Product under the Phase 3/Commercial Supply Agreement (each term as defined in the Sutro Biopharma Supply Agreement). 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.

Option Agreement

In December 2022, we entered into an option grant agreement with Sutro Biopharma (the "Option Agreement"). Pursuant to the Option Agreement, we acquired from Sutro Biopharma (i) authorization to enter into an agreement with an independent alternate contract manufacturing organization ("CMO") to directly source Sutro Biopharma's cell-free extract, allowing us to have direct oversight over financial and operational aspects of the relationship with the CMO; and (ii) a right, but not an obligation, to obtain certain exclusive rights to internally manufacture and/or source extract from certain CMOs and the right to independently develop and make

improvements to extract (including the right to make improvements to the extract manufacturing process as well as cell lines) for use in connection with the exploitation of certain vaccine compositions (the "Option"). We and Sutro Biopharma agreed to negotiate the terms and conditions of a form definitive agreement to be entered into in the event we exercise the Option, which would include the terms and conditions set forth in an executed term sheet between us (the "Term Sheet") and such terms that were necessary to give effect to each of the terms and conditions set forth in the Term Sheet (the "Form Definitive Agreement").

As consideration for the Option and other rights and authorizations granted to us under the Option Agreement, we paid Sutro Biopharma upfront consideration of $22.5 million, consisting of (i) $10.0 million in cash and $7.5 million worth of shares of our common stock (the number of shares calculated based on the arithmetic average of the daily volume weighted average price of our common stock as traded on Nasdaq in the three consecutive trading days immediately prior to the issuance thereof) in December 2022, and (ii) $5.0 million in October 2023 within five business days after we and Sutro Biopharma mutually agree in writing upon the Form Definitive Agreement on September 28, 2023. The 167,780 shares of common stock issued was recorded at fair value of $8.0 million on the date of settlement, December 22, 2022.

On November 21, 2023 (the "Option Exercise Date"), we exercised the Option by submitting written notice thereof to Sutro Biopharma and concurrently paid Sutro Biopharma $50.0 million in cash as the first of two installment payments for the Option exercise price, followed by the second and final installment of $25.0 million in cash in May 2024. We determined there was no current alternative future use of the acquired manufacturing rights from the Option Agreement and, as a result, the amounts paid were expensed as incurred. Upon the occurrence of certain regulatory milestones, certain additional milestone payments may total up to $60.0 million in cash. In the event that we undergo a change of control, certain rights and payments may be accelerated.

Manufacturing Rights Agreement

Concurrent with the payment of the first installment of the Option exercise price pursuant to the Option Agreement, on November 21, 2023, the manufacturing rights agreement (in the form of the Form Definitive Agreement) between us and Sutro Biopharma (the "Manufacturing Rights Agreement") became effective. Under the Manufacturing Rights Agreement, we received an exclusive (except as to Sutro Biopharma), perpetual (subject to termination), worldwide license, for no additional royalty (i.e., royalty-free, other than any royalties due under the Sutro Biopharma License Agreement), under Sutro Biopharma's relevant patents and know-how, to manufacture or have manufactured extract and improvements to extract (in any form) solely for use in the research, development, use, production, sale, offering for sale, export, import, commercialization or other exploitation of Vaccine Compositions (as defined in the Sutro Biopharma License Agreement) as well as certain rights with respect to certain regulatory matters related to extract and its use in connection with such Vaccine Compositions. We have the right to extend our rights and obligations under the Manufacturing Rights Agreement to our affiliates and to sublicense our rights to manufacture extract and improvements to extract to certain third-party CMOs and other contractors (for our benefit and not for such third party's independent commercial use). For clarity, we are not permitted to manufacture extract for sale to third parties for the independent use of such third parties. Under the Manufacturing Rights Agreement, we have the obligation to protect the confidentiality of the extract manufacturing technology, and Sutro Biopharma has certain audit rights in connection therewith.

Under the Manufacturing Rights Agreement, upon our request and at our cost, Sutro Biopharma will support up to two technology transfers to us (or to an affiliate of ours or certain third-party CMOs designated by us) of certain Sutro Biopharma know-how, materials and information to enable us to manufacture or have

manufactured extract. Under certain circumstances, Sutro Biopharma may source extract from us or certain third-party CMOs, subject to reimbursement for technology transfer costs.

The Manufacturing Rights Agreement contains certain terms with respect to the ownership, prosecution, maintenance and enforcement of certain intellectual property rights licensed or arising under the Manufacturing Rights Agreement, which are generally consistent with the Sutro Biopharma License Agreement.

Unless earlier terminated, the Manufacturing Rights Agreement will remain in effect in perpetuity. Sutro Biopharma may only terminate the Manufacturing Rights Agreement in the event of our (i) uncured, intentional, material breach of certain confidentiality provisions resulting in actual, material harm to Sutro Biopharma's business, (ii) uncured, intentional material breach of certain provisions relating to the use of certain of Sutro Biopharma's know-how outside of the Vaccine Field, (iii) unintentional, material breach of certain provisions relating to the use of certain of Sutro Biopharma's know-how outside of the Vaccine Field that we do not use reasonable best efforts to cease and (to the extent reasonably curable) cure in a timely fashion, or (iv) uncured failure to pay the Option exercise price or any undisputed milestone payment under the Option Agreement when due. We may terminate the Manufacturing Rights Agreement at our discretion upon 60 days' written notice, and both parties may terminate the Manufacturing Rights Agreement upon mutual written consent.

Thermo Fisher Scientific

Commercial Manufacturing and Supply Agreement

On September 24, 2025, we entered into a master services agreement with Patheon Manufacturing Services LLC, part of Thermo Fisher Scientific (collectively, "Thermo Fisher"), pursuant to which Thermo Fisher will formulate, fill, inspect, package, label, test, manufacture and supply drug product for us at Thermo Fisher's facility in Greenville, North Carolina (the "Thermo Fisher Commercial Manufacturing and Supply Agreement"). Pursuant to the Thermo Fisher Commercial Manufacturing and Supply Agreement, we have agreed to order drug product from Thermo Fisher based on certain binding forecast periods and established prices. In addition, we will also pay Thermo Fisher for technology transfer activities and reimburse Thermo Fisher for certain out-of-pocket capital expenditures under the terms of the agreement.

The Thermo Fisher Commercial Manufacturing and Supply Agreement has an initial term of 15 years and will automatically renew for additional three-year periods unless either party provides notice of non-renewal before the end of the then existing term, subject to completion of ongoing services. We are permitted to terminate the Thermo Fisher Commercial Manufacturing and Supply Agreement prior to expiration, subject to the payment of applicable termination fees, plus certain capital expenditure commitments.

Impact of Certain Trends and Macroeconomic Environment

We operate in an industry that is subject to significant government regulation. Our operations are subject to significant risk and uncertainties, including financial, operational, technological, regulatory and political risks. Such factors include, but are not necessarily limited to, the results of clinical testing and trial activities; our ability to adequately demonstrate sufficient safety, tolerability and immunogenicity or efficacy of our vaccine candidates; our ability to enroll subjects in our ongoing and future clinical trials; our ability to successfully manufacture and supply our vaccine candidates for clinical trials or for future potential commercialization; our ability to obtain additional capital to finance our operations; our ability to obtain, maintain and protect our intellectual property rights; developments relating to our competitors and our industry, including competing vaccine candidates; the ability to obtain regulatory approval; the necessary requirements for regulatory

approval; the ability to obtain favorable licensing, manufacturing or other agreements; the political and regulatory environment; general and market conditions; and other risks and uncertainties, including those more fully described in the "Risk Factors" section of this Annual Report on Form 10-K.

The trends towards rising inflation may materially adversely affect our business and corresponding financial position and cash flows. Inflationary factors, such as increases in the cost of our clinical trial materials and supplies, fluctuating interest rates and increases in overhead costs may adversely affect our operating results. Fluctuating interest rates and rising inflation rates also present a challenge impacting the U.S. economy and could make it more difficult for us to obtain traditional financing on acceptable terms, if at all, in the future.

We may experience increases in our operating costs in the near future, including our labor costs and research and development costs, due to rising inflation, tariffs, supply chain constraints, and civil and political unrest in certain countries and regions.

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. Our research and development expenses include internal personnel-related costs (including salaries, employee benefits and stock-based compensation) for our personnel in research and development functions, and external costs including (i) product manufacturing costs, primarily related to acquiring, developing and manufacturing supplies for clinical trials and to prepare for potential future commercial launches, including fees paid to contract manufacturing organizations; (ii) clinical costs related to agreements with contract research organizations , investigative sites and consultants to conduct non-clinical and preclinical studies and clinical trials; (iii) research and development consumables, laboratory supplies and equipment costs; (iv) facility and other allocated shared services; and (v) other expenses primarily including professional and consulting services costs.

Our PCV programs include VAX-31, VAX-24 and VAX-XL, and our non-PCV programs include VAX-A1, VAX-GI, and other discovery-stage programs. In August 2025, we announced that we paused the advancement, beyond preclinical development, of VAX-A1 and VAX-GI while remaining confident in their potential and preserving the option to advance the programs in the future. The majority of our external costs relate to our PCV programs compared to the costs related to non-PCV programs. Most of the external costs associated with our vaccine candidates, particularly our PCV programs, are common in nature, and can be deployed across multiple candidates or redeployed as our vaccine development strategy evolves; as a result, we do not track external costs by candidate, program or project. We do not allocate internal personnel-related costs by program or project because several of our departments support multiple vaccine candidate programs and the hours are not tracked separately by program.

VAX-31 and VAX-24 are in the clinical stages, and VAX-XL and our non-PCV programs are in preclinical stages. The majority of our external costs relate to our clinical-stage programs compared to the costs related to our preclinical-stage programs. Costs associated with preclinical programs are relatively small and insignificant to the overall financial statements. Further, several expenses are shared among various vaccine programs and, as such, we do not separately track external costs by clinical and preclinical stages.

Research and development expenses, including costs related to acquired manufacturing rights, are expensed as incurred if it is determined there is no alternative future use. 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 expect our research and development expenses to increase in absolute dollars for the foreseeable future as we advance our vaccine candidates into and through preclinical studies and clinical trials, manufacture drug product for our clinical trials and to support the potential initial commercial launch of VAX-31 in the adult population, scale up our manufacturing activities, establish additional manufacturing capacity to meet potential incremental supply requirements following the potential commercial launches of VAX-31 in the adult population and VAX-31 or VAX-24 in the pediatric population, pursue regulatory approval of our vaccine candidates and expand our pipeline of vaccine candidates. The process of conducting the necessary preclinical and clinical research and completing the manufacturing requirements 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 or immunogenicity of our vaccine candidates, clinical data, investment in our clinical programs, competition, manufacturing capabilities 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 if, when and to what extent we will generate revenue from the commercialization and sale of our vaccine candidates.

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 and CROs, that conduct research, development and manufacturing activities 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 exceed the level of services provided and result in a prepayment of the research and development expense. Advance payments for goods and services to 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.

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

- the costs and timing of our CMC activities, including fulfilling good manufacturing practice (“GMP”) related standards and compliance, and identifying and qualifying second suppliers;
- the costs related to raw materials we purchase directly or through our third-party manufacturing and supply partners;
- the cost of clinical trials of our vaccine candidates;

- 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 volunteers to participate in our clinical trials;
- the number of subjects that participate in the trials;
- the number of doses that subjects receive;
- subjects dropping out of a study or lost in follow-up;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the cost and timing of manufacturing our vaccine candidates;
- the phase of development of our vaccine candidates;
- the costs of establishing additional manufacturing capacity to meet potential incremental supply requirements following the potential commercial launches of VAX-31 in the adult population and VAX-31 or VAX-24 in the pediatric population;
- the costs that may be required for secondary supply sources; and
- the immunogenicity or efficacy and safety and tolerability profile of our vaccine candidates.

General and Administrative

General and administrative expenses consist primarily of costs and expenses related to personnel (including salaries, employee benefits and stock-based compensation) in our executive, legal, finance and accounting, human resources and other administrative functions; legal services relating to intellectual property and corporate matters; accounting, auditing, consulting and tax services; insurance; and facility and other allocated shared costs not otherwise included in research and development expenses. We expect our general and administrative expenses to continue to increase in absolute dollars for the foreseeable future as we increase our headcount and expand our services to support our continued research and development activities and grow our business.

Other Income (Expense), Net

Other income (expense), net includes interest income earned from our cash, cash equivalents and investments, grant income and foreign currency transaction gains (losses) related to our Swiss Franc and Euro cash and liability balances, loss on disposals of fixed assets and interest expense.

Interest Income

Interest income is earned from our cash and cash equivalents balances and short- and long-term investments. The cost of investment securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in other income, net. Realized gains and losses are also included in other income, net. When the fair value of a debt security declines below its amortized cost basis, any portion of that decline attributable to credit losses, to the extent expected to be nonrecoverable before the sale of the security, is recognized in our consolidated statements of operations. When the fair value of a debt security declines below its amortized cost basis due to changes in interest rates, such amounts are recorded in other comprehensive loss, and are recognized in our consolidated statements of operations only if we sell or intend to sell the security before recovery of its cost basis.

Grant Income

Our vaccine development program for VAX-A1, a novel conjugate vaccine candidate designed to prevent disease caused by Group A Streptococcus, has been funded in part by a grant obtained from Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator ("CARB-X"), a global non-profit partnership dedicated to accelerating antibacterial innovation to tackle the rising global threat of drug-resistant bacteria. The CARB-X grant provided funding of $11.7 million upon the achievement of VAX-A1 development milestones through June 2024. As of the second quarter of 2024, all of these milestones had been successfully achieved, and no further amounts will be funded under this CARB-X grant.

Our vaccine development program for VAX-GI, a novel preclinical vaccine candidate being developed as a preventative treatment for dysentery and shigellosis, which is caused by Shigella bacteria, is currently funded in part by two grants obtained from the NIH administered by the University of Maryland, Baltimore. Our first grant from the NIH was awarded in April 2021 and provides for potential funding up to five years totaling approximately $0.5 million. In June 2023, we received another grant from the NIH that provides for potential funding up to five years totaling approximately $4.6 million. As of December 31, 2025, we have received and expect to continue to receive funding under each of these grants.

We are currently working on a discovery program with the University of North Carolina at Chapel Hill and the University of Chicago to develop a vaccine candidate for the prevention of Chlamydia, which is funded in part by a grant from the NIAID that provides potential funding up to five years totaling approximately $9.5 million. As of December 31, 2025, we have received and expect to continue to receive funding under this grant.

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. We recognized $0.5 million, $1.0 million and $4.8 million in grant income for funding research and development under these awards during the years ended December 31, 2025, 2024 and 2023, respectively. Grant income is included as a component of Other income, net in the consolidated statements of operations.

Results of Operations

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

	Year Ended December 31,			2025 vs. 2024 Change		2024 vs. 2023 Change	
	2025	2024	2023	$	%	$	%
		(in thousands)					
Operating expenses:							
Research and development	$ 794,306	$ 476,644	$ 332,341	$ 317,662	66.6%	$ 144,303	43.4%
Acquired manufacturing rights	—	—	75,000	—	—	(75,000)	(100.0%)
General and administrative	129,369	92,902	60,700	36,467	39.3%	32,202	53.1%
Total operating expenses	923,675	569,546	468,041	354,129	62.2%	101,505	21.7%
Loss from operations	(923,675)	(569,546)	(468,041)	(354,129)	62.2%	(101,505)	21.7%
Other income, net:							
Interest income	119,718	109,994	62,907	9,724	8.8%	47,087	74.9%
Other income (expense)	37,329	(4,375)	2,868	41,704	(953.2%)	(7,243)	(252.5%)
Total other income, net	157,047	105,619	65,775	51,428	48.7%	39,844	60.6%
Net loss	$ (766,628)	$ (463,927)	$ (402,266)	$ (302,701)	65.2%	$ (61,661)	15.3%

Operating Expenses

Research and Development Expenses

	Year Ended December 31,			2025 vs. 2024 Change		2024 vs. 2023 Change	
	2025	2024	2023	$	%	$	%
		(in thousands)					
External costs:							
Product Manufacturing Cost	$ 403,215	$ 173,329	$ 177,398	$ 229,886	132.6 %	$ (4,069)	(2.3)%
Clinical trials related expenses	83,817	66,475	15,459	17,342	26.1 %	51,016	330.0 %
Research Expense	66,423	74,450	46,039	(8,027)	(10.8)%	28,411	61.7 %
Facility and other allocated expenses	31,219	24,393	14,100	6,826	28.0 %	10,293	73.0 %
Other External Costs	16,016	10,863	8,988	5,153	47.4 %	1,875	20.9 %
Total external costs	600,690	349,510	261,984	251,180	71.9 %	87,526	33.4 %
Internal costs:							
Personnel-related expenses	193,616	127,134	70,357	66,482	52.3 %	56,777	80.7 %
Total research and development expenses	$ 794,306	$ 476,644	$ 332,341	$ 317,662	66.6 %	$ 144,303	43.4 %

Research and development expenses increased by $317.7 million, or 66.6%, in 2025 compared to 2024. The increase was driven by external costs, which grew by $251.2 million largely due to increased development and manufacturing activities in connection with the adult and infant PCV programs, including to support the

potential future commercial launches. Product manufacturing costs increased by $229.9 million, clinical trials related expenses increased by $17.3 million, facility and other allocated expenses increased by $6.8 million, and other external costs increased by $5.2 million compared to the prior period which, were partially offset by a $8.0 million decrease in research expenses. The increase in research and development expenses was further driven by internal personnel-related costs, which grew by $66.5 million largely due to headcount growth.

Acquired Manufacturing Rights

In November 2023, we exercised the Option by submitting written notice thereof to Sutro Biopharma and concurrently paid Sutro Biopharma $50.0 million in cash as the first of two installment payments for the Option exercise price, followed by the second and final installment of $25.0 million in cash in May 2024. We determined there was no current alternative future use of the acquired manufacturing rights from the Option Agreement and, as a result, the amounts paid were expensed as incurred in the year ended December 31, 2023. No additional costs were incurred in the years ended December 31, 2025 or 2024.

Upon the occurrence of certain regulatory milestones, we would be obligated to pay Sutro Biopharma certain additional milestone payments totaling up to $60.0 million in cash. In the event that we undergo a change of control, certain rights and payments may be accelerated.

General and Administrative Expenses

General and administrative expenses increased by $36.5 million, or 39.3%, in 2025 compared to 2024. The increase was due to primarily (i) personnel-related costs, which grew by $25.8 million largely due to headcount growth, (ii) professional and consulting services, which grew by $6.2 million, and (iii) a $3.0 million increase in facility and other allocated expenses.

Other Income, Net

Other income, net increased by $51.4 million , or 48.7%, in 2025 compared to 2024. The increase was primarily attributable to a $42.7 million increase in unrealized and realized foreign currency gains due to the weakening of the U.S. Dollar relative to the Swiss Franc. Additionally, interest income increased by $9.7 million which was driven by (i) higher average cash and investment balances in the year ended December 31, 2025 as a result of proceeds from our follow-on equity and ATM financings during the year ended December 31, 2024 and (ii) an increased average duration of our investment portfolio in the year ended December 31, 2025.

Liquidity and Capital Resources

From inception through December 31, 2025, we have incurred losses and negative cash flows from operations and have funded our operations primarily through the issuance of common stock, pre-funded warrants to purchase our common stock and, prior to our IPO, redeemable convertible preferred stock, totaling approximately $4.7 billion in aggregate gross proceeds or $4.5 billion net of underwriting discounts, commissions and offering expenses. As of December 31, 2025, we had $174.0 million of cash and cash equivalents, $2,268.7 million in investments and an accumulated deficit of $2,154.9 million.

On July 2, 2021, we filed a shelf registration statement on Form S-3ASR (the “2021 Shelf Registration Statement”) under which we could, from time to time, sell securities in one or more offerings of our common stock, preferred stock, debt securities or warrants. The 2021 Shelf Registration Statement became automatically effective upon the filing of the Form S-3ASR on July 2, 2021, and was scheduled to expire on July 2, 2024. In

anticipation of such expiration, we filed a new shelf registration statement on Form S-3ASR on May 24, 2024 solely to replace the 2021 Shelf Registration Statement (such replacement registration statement, the "2024 Shelf Registration Statement"). Pursuant to the 2024 Shelf Registration Statement, we may, from time to time, sell securities in one or more offerings of our common stock, preferred stock, debt securities or warrants. The 2024 Shelf Registration Statement became automatically effective upon the filing of the Form S-3ASR on May 24, 2024.

ATM Program

In July 2021, we entered into an Open Market Sales Agreement℠ (the "Original ATM Sales Agreement") with Jefferies LLC ("Jefferies"), which provided that, upon the terms and subject to the conditions and limitations set forth in the Original ATM Sales Agreement, we had the right to issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $150.0 million through Jefferies acting as our sales agent or principal. As of February 27, 2023, we had sold 4,995,709 shares of our common stock under the Original ATM Sales Agreement at a weighted average price of $27.57 per share for aggregate gross proceeds of $137.8 million. On February 27, 2023, we and Jefferies entered into an amendment to the Original ATM Sales Agreement (as amended, the "Amended ATM Sales Agreement") pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $400.0 million. The material terms and conditions of the Original ATM Sales Agreement otherwise remain unchanged. We will pay Jefferies a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Jefferies under the Amended ATM Sales Agreement; however, we are not obligated to make any sales of common stock. As of December 31, 2025, we have sold 4,211,367 shares of our common stock under the Amended ATM Sales Agreement at a weighted average price of $64.19 per share for aggregate gross proceeds of $270.3 million ($264.2 million net of commissions and offering expenses) with $129.7 million remaining for future sales under the Amended ATM Sales Agreement. We have made no sales under the Amended ATM Sales Agreement since August 2024.

Underwritten Follow-on Public Offerings

In January 2022, we completed an underwritten public offering in which we issued 2,500,000 shares of common stock at a price of $20.00 per share and pre-funded warrants to purchase 2,500,000 shares of our common stock at a price of $19.999 per underlying share. In February 2022, the underwriters exercised their option to purchase an additional 750,000 shares of common stock. In aggregate, we received $107.6 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by us, and excluding the exercise of any pre-funded warrants.

In October 2022, we completed an underwritten public offering of 17,812,500 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 2,812,500 shares, at a price of $32.00 per share and pre-funded warrants to purchase 3,750,000 shares of our common stock at a price of $31.999 per underlying share. In aggregate, we received $651.6 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by us, and excluding the exercise of any pre-funded warrants.

In April 2023, we completed an underwritten public offering of 13,030,000 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 1,830,000 shares, at a price of $41.00 per share and pre-funded warrants to purchase 1,000,000 shares of our common stock at a price of $40.999 per underlying share. In aggregate, we received $545.3 million in net proceeds after deducting

underwriting discounts and commissions and other estimated offering expenses payable by us, and excluding the exercise of any pre-funded warrants.

In February 2024, we completed an underwritten public offering of 12,695,312 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 1,757,812 shares, at a price of $64.00 per share and pre-funded warrants to purchase 781,250 shares of our common stock at a price of $63.999 per underlying share. In aggregate, we received $816.5 million in net proceeds after deducting underwriting discounts and commissions and other estimated offering expenses payable by us, and excluding the exercise of any pre-funded warrants.

In September 2024, we completed an underwritten public offering of 12,087,378 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 1,893,203 shares, at a price of $103.00 per share and pre-funded warrants to purchase 2,427,184 shares of our common stock at a price of $102.999 per underlying share. In aggregate, we received $1.4 billion in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by us, and excluding the exercise of any pre-funded warrants.

The pre-funded warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and payment of the exercise price. No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant. The holders of the pre-funded warrants may also satisfy their obligation to pay the exercise price through a "cashless exercise," in which the holder receives the net value of the pre-funded warrant in shares of common stock determined according to the formula set forth in the pre-funded warrant.

The pre-funded warrants will not expire until they are fully exercised. However, we may not effect the exercise of any pre-funded warrants, and a holder will not be entitled to exercise any portion of any pre-funded warrants that, upon giving effect to such exercise, would cause: (i) the aggregate number of shares of our common stock beneficially owned by such holder (together with affiliates) to exceed 4.99% or 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as applicable; or (ii) the combined voting power of our securities beneficially owned by such holder (together with its affiliates) to exceed 4.99% or 9.99% of the combined voting power of all of our securities outstanding immediately after giving effect to the exercise, as applicable, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. However, any holder of a pre-funded warrant may increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days' prior notice for the holder to us.

In January 2025, 1,000,000 shares and 2,500,000 shares underlying the pre-funded warrants from the January 2022 and October 2022 offerings, respectively, were exercised to receive 999,988 shares and 2,499,971 shares of common stock, net of exercise costs, respectively. In June 2025, 640,705 shares underlying pre-funded warrants from the February 2024 offering were exercised to receive 640,685 shares of common stock, net of exercise costs. In October 2025, 853,936 shares underlying pre-funded warrants from the February 2024 and September 2024 offering were exercised to receive 853,914 shares of common stock, net of exercise costs. As of December 31, 2025, no other shares underlying the pre-funded warrants have been exercised.

In February 2026, we completed an underwritten public offering of 12,650,000 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 1,650,000 shares, at a price of $50.00 per share. In aggregate, we received approximately $600.2 million in net proceeds after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

Future Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research, development and manufacturing expenditures related to our programs and, to a lesser extent, capital expenditures for our commercial manufacturing facility build-out and general and administrative expenditures. We anticipate that we will continue to incur significant expenses and capital expenditures for the foreseeable future as we continue to advance our vaccine candidates, expand our corporate infrastructure, further our research and development initiatives for our vaccine candidates, build out and operate our commercial manufacturing facilities, and scale our laboratory and manufacturing operations. 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, cash equivalents and investments as of the date of this Annual Report on Form 10-K will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months from the filing date of this Annual Report on Form 10-K. We have raised substantial capital; however, we will need to raise substantial additional capital to complete development, manufacturing and commercialization of our drug candidates. Until we can generate sufficient 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, pre-funded warrants 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. Our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions, including higher inflation rates and changes in interest rates, and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide. 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 costs of establishing additional manufacturing capacity to meet potential incremental supply requirements following the potential commercial launches of VAX-31 in the adult population and VAX-31 or VAX-24 in the pediatric population;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, which may 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;

- exchange rate fluctuations due to exposure of foreign operations and foreign currency fluctuations and translations;

- any product liability or other lawsuits related to our products;

- 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 impact of macroeconomic factors, including potential effects of changes in federal government regulation, rising inflation which may impact labor costs, research and development costs, tariffs, and supply chain constraints, as well as civil and political unrest in certain countries and regions, which may exacerbate the magnitude of the factors discussed above.

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.

Cash Flows

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

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Net cash used in operating activities	$ (655,577)	$ (452,627)	$ (296,790)
Net cash provided by (used in) investing activities	437,354	(2,005,666)	(773,311)
Net cash provided by financing activities	2,014	2,448,508	639,813
Effect of exchange rate changes on cash and cash equivalents	2,439	426	(6,686)
Net decrease in cash and cash equivalents	$ (213,770)	$ (9,359)	$ (436,974)

Net Cash Flows from Operating Activities

Cash used in operating activities for the year ended December 31, 2025 was $655.6 million, an increase of $203.0 million compared to 2024. The increase was primarily due to higher cash expenditures to support our business growth and increased development and manufacturing activities in connection with the adult and infant PCV programs, including support for the potential future commercial launches. The increase in cash used was partially offset by the timing of payments for manufacturing and accrued expenses in 2025.

Net Cash Flows from Investing Activities

Cash provided by investing activities for the year ended December 31, 2025 was $437.4 million, an increase of $2,443.0 million compared to 2024. The increase was primarily due to decreases of $1,875.2 million in investment purchases and $53.5 million in payments related to manufacturing facility build-out and equipment construction-in-progress compared to 2024, partially offset by a $397.9 million increase in proceeds from maturities of investments and a $107.7 million increase in sales of investments in 2025.

Net Cash Flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2025 was $2.0 million, a decrease of $2,446.5 million compared to 2024. The decrease was primarily due to a decrease in (i) net proceeds from our follow-on public offerings of $2,239.7 million, (ii) net proceeds from the Amended ATM Sales Agreement of $195.9 million, and (iii) proceeds from the issuance of shares through employee equity incentive plans of $14.1 million, partially offset by a decrease in taxes paid related to the net share settlement of equity awards of $3.3 million.

Contractual Obligations and Commitments

Our material cash requirements include the following contractual and other obligations.

Leases

We have operating lease agreements for our office spaces. As of December 31, 2025, we had lease payment obligations totaling $164.2 million, of which $12.1 million is payable within one year.

Option Agreement

On November 21, 2023 (the “Option Exercise Date”), we exercised the Option pursuant to the Option Agreement by submitting written notice thereof to Sutro Biopharma and concurrently paid Sutro Biopharma $50.0 million in cash as the first of two installment payments for the Option exercise price, followed by the second and final installment of $25.0 million in cash on May 13, 2024. Upon the occurrence of certain regulatory milestones, we would be obligated to pay Sutro Biopharma certain additional milestone payments totaling up to $60.0 million in cash. In the event that we undergo a change of control, certain rights and payments may be accelerated.

Purchase Commitments

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 sheets as of December 31, 2025.

We enter into agreements in the normal course of business with CMOs and other vendors for manufacturing services and raw materials purchases. We rely on several third-party manufacturers for our manufacturing requirements. As of December 31, 2025, we had the following amounts of non-cancelable purchase commitments related to manufacturing services and raw materials purchased due to our key manufacturing partners. These amounts represent our minimum contractual obligations, including termination fees. If we terminate certain firm orders with our key manufacturing partners, we will be required to pay for the manufacturing services scheduled or raw materials purchased under our arrangements. The actual amounts we pay in the future to the vendors under such agreements may differ from the purchase order amounts.

Years ending December 31,	**(in thousands)**
2026	$ 447,763
2027	116,422
2028	10,500
2029	10,500
Thereafter	—
Total non-cancelable purchase commitments due to key manufacturing partners	$ 585,185

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 consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated 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 consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued research and development expenses, stock-based compensation and leases. 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 the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results:

Accrued Research and Development Expenses

We have entered into various agreements with CMOs and CROs. As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses, including accrued contract manufacturing 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 and CROs, that conduct research, development and manufacturing 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.

Stock-Based Compensation Expense

Our use of the Monte Carlo simulation model and Black-Scholes option-pricing model requires the input of subjective assumptions, such as expected volatility. In addition to expected volatility, the assumptions, including expected term and risk-free interest rate, used in our option pricing model and simulation model represent management's best estimates. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future.

Refer to Note 2, "Basis of Presentation and Summary of Significant Accounting Policies," and Note 10, "Equity Incentive Plans," to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for more information on assumptions used in estimating stock-based compensation expense.

Recently Adopted Accounting Pronouncements

See Note 2, "Basis of Presentation and Summary of Significant Accounting Policies," to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

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

Interest Rate Risk

Our cash and cash equivalents as of December 31, 2025 and 2024 consisted of readily available checking and money market funds. As of December 31, 2025, we also invested in U.S. Treasury securities, U.S. government agency securities, corporate debt, commercial paper and asset-backed securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. We

do not believe that our cash and cash equivalents have significant risk of default or illiquidity. As of December 31, 2025 and 2024, we had approximately $2,442.6 million and $3,134.7 million in cash, cash equivalents and investments, respectively. For the years ended December 31, 2025 and 2024, we had interest income of $119.7 million and $110.0 million, respectively. The following table shows the impact of a hypothetical 10% increase or decrease in interest rates on our net assets as of December 31, 2025 and our net loss for the year then ended:

	Impact on Net Assets as of December 31, 2025	Impact on Net Loss for the year ended December 31, 2025
Hypothetical Change in Interest Rates	**(in thousands)**	
10% increase	$ 8,476	$ 10,531
10% decrease	(8,476)	(10,531)

Concentrations of Credit Risk

Financial instruments that potentially subject us to a concentration of credit risk consist primarily of cash, cash equivalents and investments. We invest in money market funds, U.S. Treasury securities, U.S. government agency securities, corporate debt, commercial paper and asset-backed securities. We maintain bank deposits in federally insured financial institutions and these deposits may exceed federally insured limits. We are exposed to credit risk in the event of a default by the financial institutions holding our cash and issuers of investments to the extent recorded on the consolidated balance sheets. Our investment policy limits investments to money market funds, certain types of debt securities issued by the U.S. Government and its agencies, corporate debt, commercial paper and asset-backed securities, and places restrictions on the credit ratings, maturities and concentration by type and issuer. We believe that our exposure to credit risks is not significant and that a hypothetical 10% change in credit rates would not have a significant impact on our portfolio.

Foreign Currency Risk

We are exposed to market risk related to changes in foreign currency exchange rates, mainly relating to our contracts 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 (“CHF”), which is the majority of our foreign currency exposure, at market and hold CHF in our bank accounts. As of December 31, 2025, we had approximately $38.9 million of CHF cash and cash equivalents held at three financial institutions. As of December 31, 2024, we had approximately $25.8 million of CHF cash and cash equivalents held at two financial institutions. As of December 31, 2025 and December 31, 2024, we had foreign currency denominated accounts payable and accrued expenses of $129.0 million and $72.4 million, respectively. As of December 31, 2025 and December 31, 2024, we had foreign currency denominated property, plant and equipment of $223.7 million and $157.6 million, respectively. As of December 31, 2025 and December 31, 2024, we had foreign currency denominated other assets of $148.1 million and $62.5 million, respectively. To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements. The following table shows the impact of a hypothetical 10% increase or decrease in

current exchange rates on our net assets as of December 31, 2025 and our net loss for the 12 months ended December 31, 2025:

	Impact on Net Assets as of December 31, 2025	Impact on Net Loss for the year ended December 31, 2025
	(in thousands)	
Hypothetical Change in Currency Exchange Rates		
10% increase	$ 28,129	$ 24,230
10% decrease	(28,129)	(24,230)

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

The rate of inflation in the United States has risen to levels not experienced in decades. Inflation generally affects us by increasing our cost of labor and research and development contract costs. The extent of any future impacts from inflation on our business and our results of operations will be dependent upon how long the elevated inflation levels persist and if the rate of inflation were to accelerate, neither of which we are able to predict. If elevated levels of inflation were to persist or if the rate of inflation were to further increase, the purchasing power of our cash and cash equivalents may be eroded, our expenses could increase faster than anticipated and we may utilize our capital resources sooner than expected. We do not believe inflation had a material effect on our consolidated results of operations during the periods presented.

Item 8. Consolidated Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the stockholders and the Board of Directors of Vaxcyte, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Vaxcyte, Inc. and subsidiary (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 24, 2026, expressed an unqualified opinion on the Company's internal control over financial reporting.

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 PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued Contract Manufacturing Expenses — Refer to Notes 2 and 7 to the financial statements

Critical Audit Matter Description

The Company incurs research and development expenses, including those performed by Lonza, a contract manufacturing organization, under development and manufacturing services agreements, to provide research and development services related to preclinical and clinical-stage vaccine development. At the end of each period, the Company accrues for costs related to manufacturing expenses based on their estimates of the services received for each phase and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on their behalf. This estimation process involves reviewing open contracts and purchase orders, communicating with Company personnel and third parties to identify services that have been performed on their behalf, and estimating the level of service performed and the associated costs incurred for the services for each phase when the Company has not yet been invoiced or otherwise notified of the actual costs.

We identified the Company's accrued contract manufacturing expenses as a critical audit matter primarily due to judgments necessary for management to estimate the cost of services provided but not yet invoiced and the significant volume of transactions. The amount of the accrual at period end is based on the terms and conditions per the agreements and is dependent on management's gathering of information from various sources, including Lonza, regarding the progress of the uninvoiced services at the reporting date. Accordingly, this estimate is subjective as it involves management's judgment to analyze the various sources of information. This required extensive audit effort due to the volume and nature of available information from various sources, including Lonza, and required a high degree of auditor judgment when performing audit procedures to audit management's estimates of accrued contract manufacturing expenses and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the accrued contract manufacturing expenses included the following, among others:

- We tested the effectiveness of controls over the Company's accrued contract manufacturing expense process, including controls over the estimation of contract manufacturing activities completed to date.
- We met with internal research and development personnel and inspected Board of Directors materials to understand the status of contract manufacturing activities. We then compared this information to the judgment applied in management's estimate of the recorded expenses and corresponding accrual.
- We evaluated the completeness of accrued contract manufacturing expenses through subsequent disbursement testing, and by tracing selected contract stages from the tracker obtained from Lonza, the Company's most significant contract manufacturer, to the contract stages used by the Company.
- For a sample of contract stages, we evaluated the accrued contract manufacturing expenses by:
    - Sending written confirmations directly to the contract manufacturing organization to confirm the total budgeted amount and percentage of completion incurred as of year-end.

- Inspecting the development and manufacturing services agreement and related amendments, change orders, statements of work, and agreeing key provisions of the agreements including timeline, budget, and relevant rates, to the Company's analysis of estimated expenses incurred to date.

- Obtaining invoices, if available, to substantiate when the transaction should have been recorded.

- Obtaining cash disbursements to test the accuracy of the accrual.

- Performing a lookback analysis by comparing the estimated accrual balance as of December 31, 2024, to the invoices received after year-end to evaluate the Company's ability to estimate the accrual.

/s/ Deloitte & Touche LLP

San Francisco, California

February 24, 2026

We have served as the Company's auditor since 2017.

VAXCYTE, INC.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 173,959	$ 387,878
Short-term investments	1,387,000	1,359,330
Prepaid expenses and other current assets	66,402	40,777
Total current assets	1,627,361	1,787,985
Property and equipment, net	257,370	198,045
Operating lease right-of-use assets	116,009	72,102
Long-term investments	881,664	1,387,510
Restricted cash	1,466	1,317
Other assets	118,847	64,359
Total noncurrent assets	1,375,356	1,723,333
Total assets	$ 3,002,717	$ 3,511,318
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 70,904	$ 48,452
Accrued compensation	23,000	20,555
Accrued contract manufacturing expenses	74,654	36,159
Accrued expenses	31,068	29,123
Operating lease liabilities — current	6,124	5,891
Total current liabilities	205,750	140,180
Operating lease liabilities — long-term	111,357	65,219
Other liabilities	100	100
Total liabilities	317,207	205,499
Commitments and contingencies (Note 7)		
Stockholders' Equity		
Preferred stock, $0.001 par value — 10,000,000 authorized at December 31, 2025 and December 31, 2024; no shares issued and outstanding at December 31, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value — 500,000,000 shares authorized at December 31, 2025 and December 31, 2024; 131,058,858 and 124,893,034 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	134	128
Additional paid-in capital	4,838,736	4,697,883
Accumulated other comprehensive income (loss)	1,587	(3,873)
Accumulated deficit	(2,154,947)	(1,388,319)
Total stockholders' equity	2,685,510	3,305,819
Total liabilities and stockholders' equity	$ 3,002,717	$ 3,511,318

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

VAXCYTE, INC.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Year Ended December 31,		
	2025	**2024**	**2023**
Operating expenses:			
Research and development	$ 794,306	$ 476,644	$ 332,341
Acquired manufacturing rights (Note 7)	—	—	75,000
General and administrative	129,369	92,902	60,700
Total operating expenses	923,675	569,546	468,041
Loss from operations	(923,675)	(569,546)	(468,041)
Other income, net:			
Interest income	119,718	109,994	62,907
Other income (expense)	37,329	(4,375)	2,868
Total other income, net	157,047	105,619	65,775
Net loss	$ (766,628)	$ (463,927)	$ (402,266)
Net loss per share, basic and diluted	$ (5.63)	$ (3.80)	$ (4.14)
Weighted-average shares outstanding, basic and diluted	136,089,506	121,997,348	97,157,690

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

VAXCYTE, INC.
Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,		
	2025	**2024**	**2023**
Net Loss	$ (766,628)	$ (463,927)	$ (402,266)
Other comprehensive loss:			
Unrealized gains (losses) on investments	9,463	(4,398)	538
Foreign currency translation adjustments, net	(4,003)	346	2
Comprehensive Loss	$ (761,168)	$ (467,979)	$ (401,726)

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

VAXCYTE, INC.

Consolidated Statements of Stockholders' Equity

(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance — December 31, 2022	79,470,670	$ 82	$ 1,476,018	$ (522,126)	$ (361)	$ 953,613
Issuance of common stock in connection with employee incentive plans	768,218	1	7,653	—	—	7,654
Issuance of common stock and pre-funded warrants in connection with public follow-on offering, net of issuance costs of $29,952	13,030,000	13	545,289	—	—	545,302
Issuance of common stock in connection with at-the market offering, net of issuance costs of $2,237	2,095,943	2	90,739	—	—	90,741
Taxes paid related to the net share settlement of equity awards	—	—	(3,876)	—	—	(3,876)
Stock-based compensation expense	—	—	48,760	—	—	48,760
Other comprehensive income	—	—	—	—	540	540
Net loss	—	—	—	(402,266)	—	(402,266)
Balance — December 31, 2023	95,364,831	98	2,164,583	(924,392)	179	1,240,468
Issuance of common stock in connection with employee incentive plans	2,122,953	2	27,142	—	—	27,144
Issuance of common stock and pre-funded warrants in connection with follow-on public offerings, net of commissions and offering expenses of $117,785	24,782,690	25	2,239,688	—	—	2,239,713
Issuance of common stock in connection with at-the-market offering, net of commissions and offering expenses of $4,393	2,622,560	3	195,940	—	—	195,943
Taxes paid related to the net share settlement of equity awards	—	—	(14,292)	—	—	(14,292)
Stock-based compensation expense	—	—	84,822	—	—	84,822
Other comprehensive loss	—	—	—	—	(4,052)	(4,052)
Net loss	—	—	—	(463,927)	—	(463,927)
Balance — December 31, 2024	124,893,034	128	4,697,883	(1,388,319)	(3,873)	3,305,819
Issuance of common stock in connection with employee incentive plans	1,171,266	1	13,004	—	—	13,005
Issuance of common stock from underlying pre-funded warrants in connection with follow-on public offerings	4,994,558	5	(5)	—	—	—
Taxes paid related to the net share settlement of equity awards	—	—	(10,991)	—	—	(10,991)
Stock-based compensation expense	—	—	138,845	—	—	138,845
Other comprehensive income	—	—	—	—	5,460	5,460
Net loss	—	—	—	(766,628)	—	(766,628)
Balance — December 31, 2025	131,058,858	$ 134	$ 4,838,736	$ (2,154,947)	$ 1,587	$ 2,685,510

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

VAXCYTE, INC.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,		
	2025	**2024**	**2023**
Cash flows from operating activities:			
Net loss	$ (766,628)	$ (463,927)	$ (402,266)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	16,396	7,003	3,156
Stock-based compensation expense	138,845	84,822	48,760
Amortization of operating lease right-of-use assets	8,464	8,842	7,015
Net accretion of discounts on investments	(14,434)	(38,704)	(34,775)
Unrealized foreign exchange loss (gain)	(34,768)	4,232	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(16,800)	(5,827)	17,870
Operating lease right-of-use assets	(52,371)	(49,948)	(16,724)
Other assets	(39,886)	(26,511)	(33,007)
Operating lease liabilities	46,371	41,886	11,284
Accounts payable	19,906	34,584	11,225
Accrued compensation	2,302	9,517	9,876
Accrued contract manufacturing expenses	31,059	(22,943)	44,501
Accrued expenses	5,967	(35,653)	36,295
Net cash used in operating activities	(655,577)	(452,627)	(296,790)
Cash flows from investing activities:			
Purchases of property and equipment	(13,713)	(22,427)	(16,062)
Purchases of manufacturing facility build-out and equipment construction-in-progress	(43,260)	(96,732)	(51,815)
Purchases of investments	(1,211,499)	(3,086,701)	(1,329,896)
Maturities of investments	1,531,136	1,133,235	611,876
Sales of investments	174,690	66,959	12,586
Net cash provided by (used in) investing activities	437,354	(2,005,666)	(773,311)
Cash flows from financing activities:			
Proceeds from issuance of common stock and pre-funded warrants from follow-on offerings, net of issuance costs	—	2,239,713	545,302
Proceeds from issuance of common stock under at-the-market offering, net of issuance costs	—	195,943	90,741
Proceeds from issuance of shares through employee equity incentive plans	13,005	27,144	7,646
Taxes paid related to the net share settlement of equity awards	(10,991)	(14,292)	(3,876)
Net cash provided by financing activities	2,014	2,448,508	639,813
Effect of exchange rate changes on cash and cash equivalents	2,439	426	(6,686)
Net decrease in cash, cash equivalents and restricted cash	(213,770)	(9,359)	(436,974)
Cash, cash equivalents and restricted cash, beginning of period	389,195	398,554	835,528
Cash, cash equivalents and restricted cash, end of period	$ 175,425	$ 389,195	$ 398,554
Reconciliation of cash, cash equivalents and restricted cash:			
Cash and cash equivalents	$ 173,959	$ 387,878	$ 397,451
Restricted cash	1,466	1,317	1,103
Cash, cash equivalents and restricted cash	$ 175,425	$ 389,195	$ 398,554
Supplemental disclosures of non-cash investing and financing activities:			
Purchases of property and equipment recorded in accounts payable and accrued expenses	$ 7,538	$ 13,179	$ 8,510

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

VAXCYTE, INC.
Notes to Consolidated Financial Statements

1. Company Organization and Nature of Business

Vaxcyte, Inc. ("we," "our," "us," "Vaxcyte" and the "Company") refers to Vaxcyte, Inc., a Delaware corporation, and our wholly-owned consolidated subsidiary, or as the context may require, Vaxcyte, Inc. only. We are headquartered in San Carlos, California, and were incorporated in the state of Delaware on November 27, 2013 as SutroVax, Inc., and changed our name to Vaxcyte, Inc. on May 15, 2020. We are a clinical-stage vaccine innovation company engineering high-fidelity vaccines to protect humankind from the consequences of bacterial diseases. We are re-engineering the way highly complex vaccines are made through the XpressCF™ cell-free protein synthesis platform. Unlike conventional cell-based approaches, our system for producing difficult-to-make proteins and antigens is intended to develop and deliver high-fidelity vaccines with enhanced immunological benefits that are beyond the capabilities of conventional approaches.

Our primary activities since incorporation have been to perform research and development, undertake preclinical and clinical studies and conduct manufacturing activities in support of our product development and commercial readiness efforts; organize and staff our Company; establish our 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 and Principles of Consolidation

These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the Securities and Exchange Commission (the "SEC") regarding annual reporting.

The consolidated financial statements include the Company and its wholly owned subsidiary. All intercompany transactions and balances have been eliminated upon consolidation.

Certain prior period amounts in the consolidated financial statements have been reclassified to conform to current period presentation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements. On an ongoing basis, we evaluate our estimates and assumptions, including those related to stock-based compensation expense, accruals for certain research and development costs, the valuation of deferred tax assets and income taxes. Management bases our 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 and Other Risks and Uncertainties

Financial instruments that potentially subject us to a concentration of credit risk consist primarily of cash, cash equivalents and investments. We invest in money market funds, U.S. Treasury securities, U.S. government agency securities, corporate debt, commercial paper and asset-backed securities. We maintain bank deposits in federally insured financial institutions and these deposits may exceed federally insured limits. We are exposed to credit risk in the event of a default by the financial institutions holding our cash and issuers of investments to the extent recorded on the consolidated balance sheets. Our investment policy limits investments to money market funds, certain types of debt securities issued by the U.S. Government and its agencies, corporate debt, commercial paper and asset-backed securities, and places restrictions on the credit ratings, maturities and concentration by type and issuer. We have not experienced any significant losses on our deposits of cash, cash equivalents or investments.

We are subject to supplier concentration risk from certain vendors. Although we are working to establish secondary sources of supply, we currently source several of our critical raw materials from single-source suppliers. We currently use a contract manufacturing organization ("CMO"), Lonza Ltd. ("Lonza"), to handle most of our manufacturing activities for our VAX-31 and VAX-24 programs. As another CMO, Patheon Manufacturing Services LLC, part of Thermo Fisher Scientific (collectively, "Thermo Fisher") will formulate, fill, inspect, package, label, test, manufacture and supply drug product for our PCV programs. If we were to experience disruptions in raw materials supplied by our suppliers, or in manufacturing activities at Lonza and/or at Thermo Fisher, we may experience significant delays in our product development timelines and may incur substantial costs to secure alternative sources of raw materials or manufacturing.

The "Risk Factors" section of this Annual Report on Form 10-K describes more details on these risks and other risks and uncertainties that could affect our business and our future.

Cash, Cash Equivalents and Restricted Cash

We consider all highly liquid investments purchased with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market funds and commercial paper and are stated at their fair values. Restricted cash consists of three standby letters of credit that serve as collateral for the lease agreements for our current corporate headquarters.

Investments

Our investments have been classified and accounted for as available-for-sale securities. Fixed income securities consist of U.S. Treasury securities, U.S. government agency securities, corporate debt, commercial paper and asset-backed securities. These securities are recorded on the consolidated balance sheets at fair value. Unrealized gains and losses on these securities are included as a separate component of accumulated other comprehensive gain (loss). The cost of investment securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in other income (expense), net. Realized gains and losses are also included in other income (expense), net. When the fair value of a debt security declines below its amortized cost basis, any portion of that decline attributable to credit losses, to the extent expected to be nonrecoverable before the sale of the security, is recognized in our consolidated statements of operations. When the fair value of a debt security declines below its amortized cost basis due to

changes in interest rates, such amounts are recorded in other comprehensive loss, and are recognized in our consolidated statements of operations only if we sell or intend to sell the security before recovery of its cost basis.

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 our 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.

Assets and liabilities recorded at fair value on a recurring basis in the consolidated 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. Our 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. We recognize 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. U.S. Treasury securities are valued using Level 1 inputs based on unadjusted, quoted prices in active markets that are observable at the measurement date for identical assets or liabilities. Level 2 securities, consisting of corporate debt, commercial paper, U.S. government agency

securities and asset-backed securities, are measured based on other observable inputs, including broker or dealer quotations or alternative pricing sources. When quoted prices in active markets for identical assets or liabilities are not available, we rely on non-binding quotes from our investment managers, which are based on proprietary valuation models of independent pricing services. These models generally use inputs such as observable market data, quoted market prices for similar instruments or historical pricing trends of securities relative to our peers. To validate the fair value determinations provided by our investment managers, we review the pricing movement in the context of overall market trends and trading information from our investment managers. In addition, we assess the inputs and methods used in determining the fair value in order to determine the classification of securities in the fair value hierarchy.

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 consolidated balance sheets and the resulting gain or loss is reflected in the consolidated statements of operations in the period realized.

Leases

We determine if an arrangement is a lease at inception. In addition, we determine whether a lease meets the classification criteria of a finance or operating lease at the lease commencement date considering whether: (i) the lease transfers ownership of the underlying asset to the lessee at the end of the lease term; (ii) the lease grants the lessee an option to purchase the underlying asset that the lessee is reasonably certain to exercise; (iii) the lease term is for a major part of the remaining economic life of the underlying asset; (iv) the present value of the sum of the lease payments and residual value guaranteed by the lessee equals or exceeds substantially all of the fair value of the underlying asset; and (v) the underlying asset is such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. As of December 31, 2025 and 2024, our lease population consisted of real estate operating leases and we did not have any finance leases.

Operating leases are included in Operating lease right-of-use ("ROU") assets, Operating lease liabilities — current and Operating lease liabilities — long term in our consolidated balance sheets. ROU assets represent our right to use the underlying assets for the lease term and lease liabilities represent our obligation to make lease payments arising from the leases. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, if the rate implicit in the lease is not readily determinable, we use our incremental borrowing rate based on the information available at the lease commencement date. We determine the incremental borrowing rate based on an analysis of corporate bond yields with a credit rating similar to ours. The determination of our incremental borrowing rate requires management judgment, including development of a synthetic credit rating and cost of debt, as we currently do not carry any debt. We believe that the estimates used in determining the incremental borrowing rate are reasonable based upon current facts and circumstances. Applying different judgment to the same facts and circumstances could yield a different incremental borrowing rate. The operating lease ROU assets also include adjustments for prepayments and accrued lease payments and exclude lease incentives. ROU assets and lease liabilities may include options to extend or terminate leases if it is reasonably certain that we will exercise such options. Lease payments which are fixed and determinable are amortized as rent expense on a straight-line basis over the expected lease term. Variable lease costs, which are

dependent on usage, a rate or index, including common area maintenance charges, are expensed as incurred. Lease agreements that include lease and non-lease components are accounted for as a single lease component. Lease agreements with non-cancelable terms of less than 12 months are not recorded on our consolidated balance sheets.

Impairment of Long-Lived Assets

We review 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 were no impairments of long-lived assets during the years ended December 31, 2025, 2024 or 2023.

Research and Development

Research and development costs are expensed as incurred. Research and development costs include salaries, stock-based compensation and benefits for employees performing research and development activities, an allocation of facility and overhead expenses, expenses incurred under agreements with consultants, CMOs, contract research organizations ("CROs") and investigative sites that conduct preclinical studies, clinical trials other supplies and costs associated with product development efforts, preclinical activities, clinical trials and regulatory operations.

Acquired Manufacturing Rights

Acquired manufacturing rights are expensed as incurred on our consolidated statements of operations when it is determined there is no alternative future use.

Total research and development costs including acquired manufacturing rights were $794.3 million, $476.6 million and $407.3 million for the years ended December 31, 2025, 2024 and 2023, respectively.

Accrued Research and Development

We have entered into various agreements with CROs and CMOs. Our research and development accruals, which include accrued manufacturing expenses, 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 services provided, but not yet invoiced, are included in accrued expenses on the consolidated balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, we 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

We account for income taxes using the asset and liability method. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference

between the consolidated 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 our deferred income tax assets, we consider all available positive and negative evidence, including our operating results, ongoing tax planning and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. In the event we determine that we would be able to realize our deferred income tax assets in the future in excess of their net recorded amount, we 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, 2025 and 2024, we have recorded a full valuation allowance on our 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

For equity awards granted to employees, non-employees and directors, stock-based compensation is measured at grant date based on the fair value of the award. We determine the grant-date fair value of stock options with only service conditions using the Black-Scholes option-pricing model. The fair value of restricted stock and restricted stock unit ("RSU") awards with only service conditions are determined based on the number of units granted and the closing price of our common stock as of the grant-date. The grant-date fair value of awards with only service conditions is recognized as share-based compensation expense on a straight-line basis over the employees' requisite service period or the non-employees' vesting period as the services are rendered.

The estimated fair value of awards that contain market conditions are determined based on the Monte Carlo simulation model. We recognize share-based compensation expense for awards with market conditions on a straight-line basis over the requisite service period for each separately vesting portion of the award. Forfeitures are accounted for as they occur.

Comprehensive Loss

Comprehensive loss includes net loss and other comprehensive loss for the period. Other comprehensive loss consists of unrealized loss on investments and foreign currency translation adjustments, net.

Foreign Currency Transactions

For our international operations, the local currency has been determined to be the functional currency. We translate functional currency assets and liabilities to their U.S. dollar equivalents at exchange rates in effect as of the balance sheet date and income and expense amounts at average exchange rates for the period. Gains and losses from foreign currency translation are included in accumulated other comprehensive loss within stockholders' equity in the consolidated balance sheets.

Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common stock outstanding, including pre-funded warrants, 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, common stock subject to repurchase, and stock options are considered to be potentially dilutive securities. Shares of common stock into which the pre-funded warrants may be exercised are considered outstanding for the purposes of computing net loss per share because the shares may be issued for little consideration, are fully vested and are exercisable after the original issuance date.

Recently Adopted Accounting Standards

In December 2023, the FASB issued Accounting Standards Update ("ASU") 2023-09—Income Taxes: Improvements to Income Tax Disclosures, which includes amendments that further enhance income tax disclosures, primarily through standardization and disaggregation of rate reconciliation categories and income taxes paid by jurisdiction. The new standard is effective for annual periods beginning after December 15, 2024. We adopted this ASU on a retrospective basis effective with our annual reporting period beginning January 1, 2025. See Note 12, Income Taxes for additional information.

Recently Issued Accounting Standards Not Yet Adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by us as of the specified effective date. We believe that the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40) (“ASU 2024-03”). The amendments in ASU 2024-03 intend to improve the disclosures about a public business entity’s expenses and address requests from investors for more detailed information about the types of expenses (including purchases of inventory, employee compensation, depreciation, amortization and depletion). This new guidance is effective for us for annual periods beginning after December 15, 2026. We are currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU No. 2025-06, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software (“ASU 2025-06”). The amendments in ASU 2025-06 intend to modernize the accounting for software costs that are accounted for under Subtopic 350-40, Intangibles—Goodwill and Other—Internal-Use Software (referred to as “internal-use software”). This new guidance is effective for us for annual periods beginning after December 15, 2027. We are currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-10, Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities. The amendments in ASU 2025-10 intend to establish authoritative guidance on the accounting for government grants received by business entities. This guidance is effective for us beginning with our 2029 fiscal year annual reporting period, with early adoption permitted. We

are currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11 to amend the guidance in “Interim Reporting” (Topic 270). The update provides clarifications intended to improve the consistency and usability of interim disclosure requirements, including a comprehensive listing of required interim disclosures and a new disclosure principle for reporting material events occurring after the most recent annual period. The amendments do not change the underlying objectives of interim reporting but are designed to enhance clarity in application. The guidance is effective for fiscal years beginning after December 15, 2027, including interim periods within those fiscal years. We are currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-12 “Codification Improvements” to address suggestions received from stakeholders on the Accounting Standards Codification ("the Codification") and to make other incremental improvements to U.S. GAAP. The update represents changes to the Codification that (i) clarify, (ii) correct errors, or (iii) make minor improvements. The amendments make the Codification easier to understand and apply. The guidance is effective for fiscal years beginning after December 15, 2026, including interim periods within those fiscal years. We are currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

3. Fair Value Measurements and Fair Value of Financial Instruments

The following tables set forth our financial instruments measured at fair value on a recurring basis by level within the fair value hierarchy at December 31, 2025 and 2024:

		December 31, 2025			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Assets		(in thousands)			
Cash and cash equivalents:					
Cash	Level 1	$ 85,417	$ —	$ —	$ 85,417
Money market funds	Level 1	52,302	—	—	52,302
U.S. Treasury securities	Level 1	—	—	—	—
Commercial paper	Level 2	36,245	—	(5)	36,240
Total cash and cash equivalents		173,964	—	(5)	173,959
Investments:					
U.S. Treasury securities	Level 1	945,072	1,969	(40)	947,001
Commercial paper	Level 2	28,763	3	—	28,766
Corporate debt	Level 2	897,564	2,862	(30)	900,396
Asset backed securities	Level 2	152,164	249	(27)	152,386
U.S. government agency securities	Level 2	219,854	289	(28)	220,115
Certificate of Deposit	Level 2	20,000	—	—	20,000
Total investments		2,263,417	5,372	(125)	2,268,664
Total assets measured at fair value		$ 2,437,381	$ 5,372	$ (130)	$ 2,442,623

	Fair Value Hierarchy Level	December 31, 2024			
		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Assets			(in thousands)		
Cash and cash equivalents:					
Cash	Level 1	$ 60,531	$ —	$ —	$ 60,531
Money market funds	Level 1	73,566	—	—	73,566
U.S. Treasury securities	Level 1	8,983	2	—	8,985
Commercial paper	Level 2	244,833	1	(38)	244,796
Total cash and cash equivalents		387,913	3	(38)	387,878
Investments:					
U.S. Treasury securities	Level 1	1,463,329	1,533	(5,305)	1,459,557
Commercial paper	Level 2	182,308	48	(18)	182,338
Corporate debt	Level 2	691,972	888	(1,331)	691,529
Asset backed securities	Level 2	195,801	309	(72)	196,038
U.S. government agency securities	Level 2	217,617	243	(482)	217,378
Total investments		2,751,027	3,021	(7,208)	2,746,840
Total assets measured at fair value		$ 3,138,940	$ 3,024	$ (7,246)	$ 3,134,718

We had no Level 3 securities either as of December 31, 2025 or 2024.

There were no transfers within the hierarchies during the years ended December 31, 2025 or 2024.

As of December 31, 2025 and 2024, we had investments with a total fair market value of $0.3 billion and $1.5 billion in an unrealized loss position, of which $120.2 million and $10.5 million, respectively, were in a continuous unrealized loss position for more than 12 months. The gross unrealized losses of securities that have been in a continuous unrealized loss position were not material at December 31, 2025 or $7.2 million at December 31, 2024.

Unrealized losses related to our investments are primarily due to interest rate fluctuations as opposed to credit quality. We do not intend to sell any of the securities in an unrealized loss position and it is not likely that we would be required to sell these securities before recovery of their amortized cost basis, which may be at maturity. We did not recognize any credit losses related to our investments during the years ended December 31, 2025 or 2024.

The following table presents the contractual maturities of our investments as of December 31, 2025 (in thousands):

	December 31, 2025
	Fair Value
Due in less than one year	$ 1,387,000
Due in one to five years	881,664
Total	$ 2,268,664

4. Commercial Manufacturing and Supply Agreements

Lonza Ltd. ("Lonza")

On October 13, 2023, we entered into a pre-commercial services and commercial manufacturing supply agreement with Lonza (the " Lonza Commercial Manufacturing and Supply Agreement").

Pursuant to the Lonza Commercial Manufacturing and Supply Agreement, Lonza will (i) construct and build out a dedicated suite (the "Suite") at Lonza's facilities in Visp, Switzerland to manufacture certain key components (including drug substance) for our proprietary PCV franchise and any other products or intermediates we may choose (collectively, the "Products") and (ii) maintain and operate the Suite (utilizing Lonza's employees) to manufacture the Products as a service provided to us, including conducting related quality control and quality assurance operations. Lonza will be a preferred, non-exclusive, supplier of the Products to us, and we retain the right to procure the Products from one or more alternate and/or backup manufacturers of the Products (including at our own facilities).

Under the Lonza Commercial Manufacturing and Supply Agreement, prior to completion of construction and certification of the Suite for commercial operation, we will contribute to the capital expenditure costs to construct the Suite (and will own certain equipment in the Suite to be purchased or otherwise acquired by us), and will pay Lonza a fixed-rate monthly service fee for Lonza's pre-commercial services prior to commencement of commercial operations (which monthly service fee amount is subject to increases in subsequent years). Following commencement of commercial operations of the Suite to manufacture the Products, we will pay Lonza (i) Suite fees based on allocations of certain of Lonza's costs to maintain the facility in which the Suite is located and to provide shared services to us and Lonza's other customers in such facility, (ii) service fees based upon Lonza's actual full-time equivalent employee ("FTE") costs to operate the Suite to manufacture the Products, and (iii) certain other pass-through costs, including for raw materials. In addition, we may be obligated to pay or reimburse Lonza for certain other fees and expenses under the Lonza Commercial Manufacturing and Supply Agreement. Lonza will be eligible for certain financial bonuses, and subject to certain financial penalties, as incentives for the timely completion of certain scale-up activities, receipt of certain regulatory approvals for the Suite and manufacture of the Products in accordance with our commercial requirements.

Unless earlier terminated, the Lonza Commercial Manufacturing and Supply Agreement will remain in effect until December 31, 2038, subject to automatic renewal for up to three additional renewal periods of five years each, unless we elect not to renew (with 24 months advanced notice to Lonza). We are permitted to terminate the Commercial Manufacturing and Supply Agreement for convenience or for Lonza's uncured material breach,

in each case subject to certain notice obligations. Lonza is permitted to terminate the Lonza Commercial Manufacturing and Supply Agreement in the event that we commit certain specified material breaches, including uncured failure to pay material and undisputed amounts of money due to Lonza, subject to certain notice obligations. Either party may terminate the Commercial Manufacturing and Supply Agreement in certain circumstances in the event of the other party's bankruptcy. In the event that we terminate the agreement for convenience, or Lonza terminates the agreement in the event that we commit certain specified material breaches, then certain termination consequences may be triggered, including that (i) we would forfeit any outstanding entitlement to credit from Lonza of the Repurposing Fee (as defined below), and (ii) we would be obligated to pay Lonza a termination penalty equal to the greater of (a) CHF 70.0 million, or (b) a prespecified number of months' FTE fees for the actual FTEs assigned to us as of the date of termination. Within 30 days of the Effective Date, we paid Lonza a repurposing fee (the "Repurposing Fee") of CHF 27.0 million that will be credited back to us over a 10-year period starting upon commencement of commercial production. In the event of a termination under certain circumstances, Lonza shall be obligated to provide certain wind-down and transition services to us for up to 12 months and 24 months, respectively.

As of December 31, 2025 and 2024, we have incurred $217.1 million and $151.8 million of capital expenditures related to the Vaxcyte owned facility buildout and equipment, respectively. In addition, as of December 31, 2025 and 2024, we have incurred $118.3 million and $62.5 million of facility buildout expenditures that are owned and controlled by Lonza, including the Repurposing Fee, which have been accounted for as prepaid lease payments and will be recorded as a ROU asset under Accounting Standards Codification ("ASC") 842 when control over the Suite is transferred to us, which we expect to occur when the buildout of the Suite is complete and manufacturing activities commence (see Note 5, "Balance Sheet Details"), respectively.

Thermo Fisher Scientific

On September 24, 2025, we entered into a master services agreement with Patheon Manufacturing Services LLC, part of Thermo Fisher Scientific (collectively, "Thermo Fisher"), pursuant to which Thermo Fisher will formulate, fill, inspect, package, label, test, manufacture and supply drug product for us at its facility in Greenville, North Carolina (the "Thermo Fisher Commercial Manufacturing and Supply Agreement"). Pursuant to the Thermo Fisher Commercial Manufacturing and Supply Agreement, we have agreed to order drug product from Thermo Fisher based on certain binding forecast periods and established prices. In addition, we will also pay Thermo Fisher for technology transfer activities and reimburse Thermo Fisher for certain out-of-pocket capital expenditures under the terms of the agreement.

The Thermo Fisher Commercial Manufacturing and Supply Agreement has an initial term of 15 years and will automatically renew for additional three-year periods unless either party provides notice of non-renewal before the end of the then existing term, subject to completion of ongoing services. We are permitted to terminate the Thermo Fisher Commercial Manufacturing and Supply Agreement prior to expiration, subject to the payment of applicable termination fees, plus certain capital expenditure commitments.

5. Balance Sheet Details

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of December 31, 2025 and 2024 consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
VAT receivable	$ 25,204	$ 2,421
Interest receivable	21,356	20,262
Prepaid expenses	17,040	15,732
Deposits for equipment purchases	1,208	327
Other current assets	1,594	2,035
Total	$ 66,402	$ 40,777

Property and Equipment, Net

Property and equipment, net as of December 31, 2025 and 2024 consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Manufacturing facility build-out and equipment construction-in-progress	$ 217,077	$ 151,785
Lab and manufacturing equipment	62,546	55,541
Furniture and equipment	1,608	1,608
Computers, computer software and office equipment	1,670	1,001
Leasehold improvements	7,239	4,384
Total property and equipment	290,140	214,319
Less: accumulated depreciation and amortization	(32,770)	(16,274)
Property and equipment, net	$ 257,370	$ 198,045

Depreciation and amortization expense for the years ended December 31, 2025, 2024, and 2023 was $16.4 million, $7.0 million, and $3.2 million, respectively.

Other Assets

Other assets as of December 31, 2025 and 2024 consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Manufacturing facility construction buildout	$ 118,339	$ 62,477
Other long-term assets	508	1,882
Total	$ 118,847	$ 64,359

Accrued Expenses

Accrued expenses as of December 31, 2025 and 2024 consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Clinical studies	$ 11,811	$ 2,348
Other research and development	9,239	24,698
VAT payable	4,706	102
Other accrued expenses	5,312	1,975
Total	$ 31,068	$ 29,123

6. Leases

Operating Lease Obligations

Office facility

In January 2021, we entered into a lease agreement (the "Original Lease") for our current corporate headquarters facility located in San Carlos, California (the "Headquarters Facility"). The lease term began on December 3, 2021, as amended on October 17, 2023, and was set to expire on December 31, 2025.

In September 2023, we entered into an assignment and assumption of lease agreement (the "Assignment Agreement") for an expanded lease space in the same building as our Headquarters Facility (the "Assumed Lease Premises"). The assumed lease had an original contractual term of 10 years, set to expire on November 30, 2031. Pursuant to the Assignment Agreement, the base rent was abated for three full calendar months following the October 1, 2023 effective date of the Assignment Agreement. Thereafter, we were obligated to pay an aggregate of approximately $1.9 million in rent payments for the remaining nine months of the first year, with a 3% rent adjustment (not inclusive of rent abatement) every year thereafter.

In November 2024, we amended and restated the Original Lease (the "Amended and Restated Lease") as a single, unified lease for our Headquarters Facility which includes the existing space under the Original Lease and the Assumed Lease Premises (collectively, the "Existing Premises") and expanded space covering additional floors (the "Additional Premises"), which resulted in a lease modification in accordance with ASC 842. The Amended and Restated Lease has an initial contractual term of 10 years, contains rent-free periods, scheduled rent increases, lease incentives and the option of two consecutive rights to extend the term for sixty months each. The effective date of the Amended and Restated Lease was November 15, 2024 which, for the purposes of lease accounting, is the commencement date of the lease of the Existing Premises. The commencement dates of the Additional Premises occur when certain leasehold improvements and specifications are substantially complete, the first, second and third of which occurred on February 10, 2025, November 24, 2025 and December 22, 2025, respectively, and the last of which is estimated to occur in 2026. Our Amended and Restated Lease expires on February 28, 2035.

In November 2024, we entered into a sublease agreement, for which we are sublessor, for a portion of our Existing Premises. This sublease has a contractual term of two years, expiring on December 31, 2026, unless earlier terminated, with two conditional options to extend the term of the sublease for a period of 12 months each. The commencement date of this sublease was December 12, 2024.

In July 2024, we entered into a sublease agreement, for which we are the sublessee for a new operating lease in the same campus as our corporate headquarters. This sublease has rent-free periods, scheduled rent increases, and a contractual term of two years, expiring on June 30, 2026, unless earlier terminated.

Manufacturing facility

In October 2023, we entered into the Commercial Manufacturing and Supply Agreement. We have concluded that this agreement contains an embedded lease and will be accounted for in accordance with ASC 842 upon the commencement date. As of December 31, 2025, the lease had not commenced and, as such, no lease liability or ROU asset was recorded on the consolidated balance sheets and no operating lease expense was recorded on the consolidated statements of operations. See Note 4, "Commercial Manufacturing and Supply Agreement," for further details.

Information related to assumptions for our calculation of our ROU assets and lease liabilities, and cash paid for operating lease liabilities was as follows (dollar amounts in thousands):

	December 31,	
	2025	**2024**
Weighted-average remaining lease term (in years)	9.11	9.60
Weighted-average discount rate	7.2 %	7.2 %

	December 31,	
	2025	**2024**
Cash paid for operating lease liabilities	$ 12,729	$ 11,511

Maturities of lease liabilities as of December 31, 2025 were as follows:

Years ending December 31,	(in thousands)
2026	$ 12,104
2027	15,788
2028	17,339
2029	17,859
2030	18,395
Thereafter	82,805
Total future undiscounted lease payments	164,290
Less: Imputed interest	(46,709)
Present value of lease liabilities	$ 117,581

Rent expense recognized under the leases was $15.4 million, $11.5 million and $8.5 million for the years ended December 31, 2025, 2024 and 2023, respectively.

7. Commitments and Contingencies

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. We do not believe that there is any litigation or asserted or unasserted claim pending that could, individually or in the aggregate, have a material adverse effect on our results of operations or financial condition.

Guarantees and Indemnifications

In the normal course of business, we enter into agreements that contain a variety of representations and provide for general indemnification. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. As of December 31, 2025 and 2024, we did not have any material indemnification claims that were probable or reasonably possible and consequently have not recorded related liabilities.

To the extent permitted under Delaware law, we have agreed to indemnify our directors and officers for certain events or occurrences while the director or officer is, or was, serving at our 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 we could be required to make under these indemnification agreements is not specified in the agreements; however, we have directors and officers insurance coverage that

reduces our exposure and enables us to recover a portion of any future amounts paid. We have not incurred any material costs as a result of such indemnification and are not currently aware of any indemnification claims.

Development and Manufacturing Services Agreements with Lonza

In April 2022, we entered into a non-exclusive development and manufacturing services agreement with Lonza effective as of March 22, 2022, which was subsequently amended on May 12, 2022, November 21, 2022 and October 31, 2023 (as amended, the "2022 Lonza DMSA"). Pursuant to the 2022 Lonza DMSA, Lonza is obligated to perform services including manufacturing process development and clinical manufacture and supply of our proprietary PCV candidates.

In February 2023, we entered into another non-exclusive development and manufacturing services agreement with Lonza effective as of March 1, 2023 (the "2023 Lonza DMSA"). Pursuant to the 2023 Lonza DMSA, Lonza will perform manufacturing process development and the manufacture of components for our PCV candidates, including the polysaccharide antigens, our proprietary eCRM protein carrier and conjugated drug substances.

Under each of the 2022 Lonza DMSA and 2023 Lonza DMSA (collectively, the "Lonza Agreements"), we pay Lonza agreed-upon fees for their performance of development and manufacturing services and pass-through expenses incurred by Lonza for raw materials, as well as customary procurement and handling fees. Under each Lonza Agreement, we own all rights, title and interest in and to any and all New Customer Intellectual Property (as defined in each Lonza Agreement), and Lonza owns all rights, title and interest in New General Application Intellectual Property (as defined in each Lonza Agreement). For additional information about the Lonza Agreements, see "Manufacturing and Supply—*Lonza Agreements—Development and Manufacturing Services Agreements*" included in Part I, Item 1. Business of this Annual Report on Form 10-K.

Commercial Manufacturing and Supply Agreements

For details of the Commercial Manufacturing and Supply Agreements with Lonza and Thermo Fisher, see Note 4.

Sutro Option Agreement

In December 2022, we entered into an option agreement with Sutro Biopharma (the "Option Agreement"). Pursuant to the Option Agreement, we acquired from Sutro Biopharma (i) authorization to enter into an agreement with an independent alternate CMO to directly source Sutro Biopharma's cell-free extract, allowing us to have direct oversight over financial and operational aspects of the relationship with the CMO; and (ii) a right, but not an obligation, to obtain certain exclusive rights to internally manufacture and/or source extract from certain CMOs and the right to independently develop and make improvements to extract (including the right to make improvements to the extract manufacturing process as well as cell lines) for use in connection with the exploitation of certain vaccine compositions (the "Option"). We and Sutro Biopharma agreed to negotiate the terms and conditions of a form definitive agreement to be entered into in the event we exercised the Option, which would include the terms and conditions set forth in an executed term sheet between us (the "Term Sheet") and such terms that were necessary to give effect to each of the terms and conditions set forth in the Term Sheet (the "Form Definitive Agreement").

As consideration for the Option and other rights and authorizations granted to us under the Option Agreement, we paid Sutro Biopharma upfront consideration of $22.5 million, consisting of (i) $10.0 million in cash and

$7.5 million worth of shares of our common stock (the number of shares calculated based on the arithmetic average of the daily volume weighted average price of our common stock as traded on Nasdaq in the three consecutive trading days immediately prior to the issuance thereof) in December 2022, and (ii) $5.0 million in October 2023 within five business days after we and Sutro Biopharma mutually agreed in writing upon the Form Definitive Agreement on September 28, 2023. The 167,780 shares of common stock issued was recorded at fair value of $8.0 million on the date of settlement, December 22, 2022.

On November 21, 2023 (the "Option Exercise Date"), we exercised the Option by submitting written notice thereof to Sutro Biopharma and concurrently paid Sutro Biopharma $50.0 million in cash as the first of two installment payments for the Option exercise price, followed by the second and final installment of $25.0 million in cash in May 2024. We determined there was no current alternative future use of the acquired manufacturing rights from the Option Agreement and, as a result, the amounts paid were expensed as incurred. Upon the occurrence of certain regulatory milestones, we agreed to pay Sutro Biopharma certain additional milestone payments totaling up to $60.0 million in cash. No milestone payments were made in the year ended December 31, 2025. In the event that we undergo a change of control, certain rights and payments may be accelerated.

Manufacturing Rights Agreement with Sutro Biopharma

Concurrent with the payment of the first installment of the Option exercise price pursuant to the Option Agreement, on November 21, 2023, the manufacturing rights agreement (in the form of the Form Definitive Agreement) between us and Sutro Biopharma (the "Manufacturing Rights Agreement") became effective. Pursuant to the Manufacturing Rights Agreement, we obtained exclusive rights to independently, or through certain third parties, develop, improve and manufacture cell-free extract for use in connection with our vaccine candidates.

For additional information about the Manufacturing Rights Agreement, see "Manufacturing and Supply—*Sutro Biopharma Agreements—Manufacturing Rights Agreement*" included in Part I, Item 1. Business of this Annual Report on Form 10-K.

Purchase Commitments

We enter into agreements in the normal course of business with CMOs and other vendors for manufacturing services and raw materials purchases. We rely on several third-party manufacturers for our manufacturing requirements. As of December 31, 2025, we had the following amounts of non-cancelable purchase commitments related to manufacturing services and raw materials purchased due to our key manufacturing partners. These amounts represent our minimum contractual obligations, including termination fees. If we terminate certain firm orders with key manufacturing partners, we will be required to pay for the manufacturing

services scheduled or raw materials purchased under our arrangements. The actual amounts we pay in the future to our vendors under such agreements may differ from the purchase order amounts.

Years ending December 31,	(in thousands)
2026	$ 447,763
2027	116,422
2028	10,500
2029	10,500
Thereafter	—
Total non-cancelable purchase commitments due to key manufacturing partners	$ 585,185

8. Stockholders' Equity

Preferred Stock

Our certificate of incorporation authorizes us to issue up to 10,000,000 shares of preferred stock with $0.001 par value per share. There were no shares of preferred stock issued or outstanding as of December 31, 2025 and 2024. Our board of directors ("Board") are authorized to provide for the issue of all or any of the shares of preferred stock in one or more series, and to fix, determine or alter the voting powers, designation, preferences and rights of the preferred shares, and the qualifications, limitations or restrictions of any wholly unissued shares, to establish from time to time the number of shares constituting any such series, and to increase or decrease the number of shares, if any. Holders of outstanding shares of preferred stock shall be entitled to receive dividends, when, and as declared by the Board in preference and priority to any declaration or payment of any distribution on common stock. The right to receive dividends on preferred shares of preferred stock shall not be cumulative and no right to dividends shall accrue to holders of preferred stock. No dividends have been paid or declared as of December 31, 2025 and 2024.

Common Stock

Our certificate of incorporation authorizes us to issue up to 500,000,000 shares of common stock with $0.001 par value per share, of which 131,058,858 and 124,893,034 shares were issued and outstanding as of December 31, 2025 and 2024, respectively. The holders of our common stock are also entitled to receive dividends whenever funds are legally available, when and if declared by our Board. As of December 31, 2025 and 2024, no dividends have been declared.

ATM Program

In July 2021, we entered into an Open Market Sales Agreement℠ (the "Original ATM Sales Agreement") with Jefferies LLC ("Jefferies") to issue and sell, from time to time at our discretion, shares of our common stock at an aggregate offering price up to $150.0 million through Jefferies acting as our sales agent or principal, however, we are not obligated to make any sales of common stock. As of February 27, 2023, we had sold 4,995,709 shares of our common stock under the Original ATM Sales Agreement at a weighted average price of $27.57 per share for aggregate gross proceeds of $137.8 million. On February 27, 2023, we and Jefferies entered into an amendment to the Original ATM Sales Agreement (as amended, the "Amended ATM Sales Agreement") to offer and sell additional shares of our common stock with an aggregate offering price up to another $400.0 million, which is in addition to the $150.0 million aggregate offering price under the Original ATM Sales Agreement. As of December 31, 2025, we have sold 4,211,367 shares of our common stock under the Amended ATM Sales Agreement at a weighted average price of $64.19 per share for aggregate gross

proceeds of $270.3 million, or $264.2 million net of commissions and offering expenses, with $129.7 million remaining for future sales under the Amended ATM Sales Agreement. The gross proceeds of the shares sold net of commission and related offering expenses are reflected as an addition to common stock and additional paid-in capital on our consolidated balance sheets.

The following table summarizes the share activity under the Original and Amended ATM Sales Agreements:

	Year Ended December 31,		
	2025	2024	2023
Number of shares sold under the ATM program	—	2,622,560	2,095,943
Weighted average sales price per share	$ —	$ 76.39	$ 44.38
Aggregate gross proceeds, in thousands [1]	$ —	$ 200,333	$ 92,976

[1] Includes $4.4 million and $2.2 million of commissions and offering expenses during the years ended December 31, 2024 and 2023, respectively.

Underwritten Follow-on Public Offerings

On January 13, 2022, we completed an underwritten public offering in which we issued 2,500,000 shares of our common stock at a price of $20.00 per share and pre-funded warrants to purchase 2,500,000 shares of our common stock at a price of $19.999 per underlying share. Each pre-funded warrant has an exercise price of $0.001 per share. In February 2022, the underwriters exercised their option to purchase an additional 750,000 shares of common stock. In aggregate, we received $107.6 million in net proceeds after deducting issuance costs, and excluding the exercise of any pre-funded warrants.

On October 28, 2022, we completed an underwritten public offering of 17,812,500 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 2,812,500 shares, at a price of $32.00 per share and pre-funded warrants to purchase 3,750,000 shares of our common stock at a price of $31.999 per underlying share. Each pre-funded warrant has an exercise price of $0.001 per share. In aggregate, we received $651.6 million in net proceeds after deducting issuance costs, and excluding the exercise of any pre-funded warrants.

On April 21, 2023, we completed an underwritten public offering of 13,030,000 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 1,830,000 shares, at a price of $41.00 per share and pre-funded warrants to purchase 1,000,000 shares of our common stock at a price of $40.999 per underlying share. Each pre-funded warrant has an exercise price of $0.001 per share. In aggregate, we received $545.3 million in net proceeds after deducting issuance costs, and excluding the exercise of any pre-funded warrants.

On February 2, 2024, we completed an underwritten public offering of 12,695,312 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 1,757,812 shares, at a price of $64.00 per share and pre-funded warrants to purchase 781,250 shares of our common stock at a price of $63.999 per underlying share. Each pre-funded warrant has an exercise price of $0.001 per share. In aggregate, we received $816.5 million in net proceeds after deducting issuance costs, and excluding the exercise of any pre-funded warrants.

On September 6, 2024, we completed an underwritten public offering of 12,087,378 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 1,893,203 shares, at a price of $103.00 per share and pre-funded warrants to purchase 2,427,184 shares of our common stock at a price of $102.999 per underlying share. Each pre-funded warrant has an exercise price of $0.001 per share. In aggregate, we received $1.4 billion in net proceeds after deducting issuance costs, and excluding the exercise of any pre-funded warrants.

The pre-funded warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and payment of the exercise price. No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant. The holders of the pre-funded warrants may also satisfy their obligation to pay the exercise price through a "cashless exercise," in which the holder receives the net value of the pre-funded warrant in shares of common stock determined according to the formula set forth in the pre-funded warrant.

The pre-funded warrants will not expire until they are fully exercised. However, we may not effect the exercise of any pre-funded warrants, and a holder will not be entitled to exercise any portion of any pre-funded warrants that, upon giving effect to such exercise, would cause: (i) the aggregate number of shares of our common stock beneficially owned by such holder (together with affiliates) to exceed 4.99% or 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as applicable; or (ii) the combined voting power of our securities beneficially owned by such holder (together with its affiliates) to exceed 4.99% or 9.99% of the combined voting power of all of our securities outstanding immediately after giving effect to the exercise, as applicable, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. However, any holder of a pre-funded warrant may increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days' prior notice for the holder to us.

In January 2025, 1,000,000 shares and 2,500,000 shares underlying the pre-funded warrants from the January 2022 and October 2022 offerings were exercised to receive 999,988 shares and 2,499,971 shares of common stock, net of exercise costs, respectively. In June 2025, 640,705 shares underlying pre-funded warrants from the February 2024 offering were exercised to receive 640,685 shares of common stock, net of exercise costs. In October 2025, 853,936 shares underlying pre-funded warrants from the February 2024 and September 2024 offerings were exercised to receive 853,914 shares of common stock, net of exercise costs. As of December 31, 2025, no other shares underlying the pre-funded warrants have been exercised.

9. Equity Incentive Plans

Equity Incentive Plans

Our 2020 Equity Incentive Plan ("2020 Plan") became effective in June 2020 and replaced our 2014 Equity Incentive Plan ("2014 Plan"). Under the 2020 Plan, we may grant stock options, appreciation rights, restricted stock, RSUs, or any other award to employees, consultants and directors. Stock options granted under the 2020 Plan may be either incentive stock options or nonqualified stock options. Incentive stock options may be granted only to our employees, including officers and directors who are also employees. Nonqualified stock options may be granted to our employees, officers, directors, consultants and advisors.

Awards granted under our 2020 Plan vest over the periods determined by our Board, generally three to four years from the date of grant, and our options expire no more than 10 years after the date of grant.

We net-share settle equity awards held by certain employees by withholding shares upon vesting to satisfy tax withholding obligations. The shares withheld to satisfy employee tax withholding obligations are returned to our 2020 Plan and will be available for future issuance. Payments for employees' tax obligations to the tax authorities are recognized as a reduction to additional paid-in capital and reflected as financing activities in our consolidated statements of cash flows.

A total of 10,150,000 shares of common stock were approved to be initially reserved for issuance under the 2020 Plan. The number of shares that remained available for issuance under the 2014 Plan as of the effective date of the 2020 Plan, and shares subject to outstanding awards under the 2014 Plan as of the effective date of the 2020 Plan that are subsequently canceled, forfeited or repurchased by us, will be added to the shares reserved under the 2020 Plan. In addition, the number of shares of common stock available for issuance under the 2020 Plan is automatically increased on the first day of each calendar year during the 10-year term of the 2020 Plan, beginning with January 1, 2021 and ending with January 1, 2030, by an amount equal to 5% of the outstanding number of shares of our common stock on December 31 of the preceding calendar year or such lesser amount as determined by our Board. As of December 31, 2025, an aggregate of 8,821,691 shares of common stock were available for issuance under the 2020 Plan. Effective January 1, 2026, the number of shares of common stock available under the 2020 Plan increased by 6,552,942 shares pursuant to the evergreen provision of the 2020 Plan.

As of December 31, 2025, 859,884 shares and 13,238,879 shares of common stock were subject to outstanding options and RSUs under the 2014 Plan and 2020 Plan, respectively.

Stock Option Activity

Stock option activity under our 2020 Plan and 2014 Plan, which excludes options to purchase 29,638 shares granted outside of the 2020 Plan and 2014 Plan, for the year ended December 31, 2025 was as follows:

	Options Outstanding				PCSOs Outstanding			
	(in thousands, except share and per share data)							
Stock Option Activity	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balances — December 31, 2024	9,366,936	$ 39.40	7.48	$ 406,730	639,710	$ 102.70	9.85	$ —
Granted	2,451,479	$ 53.39			—			
Exercised	(634,401)	$ 14.39			—			
Forfeited	(223,213)	$ 55.91			(17,850)	102.70		
Balances — December 31, 2025	10,960,801	$ 43.64	7.16	$ 130,351	621,860	$ 102.70	8.85	$ —
Vested and expected to vest — December 31, 2025	10,960,801	$ 43.64	7.16	$ 130,351	621,860	$ 102.70	8.85	$ —
Exercisable at December 31, 2025	6,705,775	$ 35.16	6.25	$ 109,070	—			

During the years ended December 31, 2025, 2024 and 2023, options to purchase 634,401, 1,813,828 and 538,888 shares of common stock, respectively, were exercised for cash at a weighted-average price per share of $14.39, $13.97 and $10.50, respectively. The intrinsic value of the stock options exercised was $35.0 million, $130.7 million and $21.2 million for the years ended December 31, 2025, 2024 and 2023, respectively. The weighted-average grant date fair value of options granted for the years ended December 31, 2025, 2024 and

2023 was $32.09, $49.36 and $28.74, respectively. The total fair value of stock options vested was $73.7 million, $51.3 million and $41.8 million for the years ended December 31, 2025, 2024 and 2023, respectively.

In November 2024, we granted 639,710 performance contingent stock options ("PCSOs") with both service and market conditions to certain employees. The market condition relates to the achievement of a share price threshold that requires the average price of our common stock to be equal to or greater than $154.05 for a period of one calendar year. To the extent that the market conditions are met, one-third of the PCSOs vest on the third, fourth and fifth anniversary date of the grant date, subject to continued service. The maximum contractual term of our outstanding PCSOs is 10 years from the date of grant. As of December 31, 2025, the market condition for the PCSOs had not been met. No PCSOs were granted in the year ended December 31, 2025.

Stock Unit Award Activity

In March 2022, our Board authorized the issuance of RSUs under our 2020 Plan and adopted a form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement, which is intended to serve as a standard form agreement for RSU grants issued to employees.

In November 2024, we granted 175,513 shares of performance-based stock units ("PSUs"), which contain service and market conditions to certain employees. Subject to continuous service requirements, the market condition is measured based on our total shareholder return (“TSR”) relative to the TSR of our peer group comprised in the Nasdaq Biotechnology Index over a period of four years. No PSUs were granted in the year ended December 31, 2025.

Stock unit award activity for the year ended December 31, 2025 was as follows:

	RSUs				PSUs			
	(in thousands, except share and per share data)							
	Number of Shares	Weighted-Average Grant-Date Fair Value	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value	Number of Shares	Weighted-Average Grant-Date Fair Value	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
	(in thousands, except share and per share data)							
Unvested at December 31, 2024	1,241,272	$ 67.32	1.46	$ 101,611	175,513	$ 151.48	3.85	$ 14,367
Granted	1,799,831	49.04			—			
Vested and released	(630,006)	62.29			—			
Cancelled	(70,508)	69.52			—			
Unvested at December 31, 2025	2,340,589	$ 54.55	1.42	$ 107,995	175,513	$ 151.48	2.85	$ 8,098

Shares Available for Grant

Shares available for grant under our 2020 Plan for the year ended December 31, 2025 were as follows:

	Number of Shares
Balance — December 31, 2024	6,275,934
Shares authorized	6,244,651
Options and RSUs granted	(4,251,310)
Shares forfeited [1]	311,571
Shares withheld for taxes	240,845
Balance — December 31, 2025	8,821,691

[1] A total of 1,791 shares were forfeited under the 2020 Plan due to net exercises of stock options.

2020 Employee Stock Purchase Plan

In June 2020, our Board adopted, and our stockholders approved, the 2020 Employee Stock Purchase Plan (the "2020 ESPP"), which became effective on June 11, 2020. The 2020 ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. Employees enrolled in the 2020 ESPP purchase shares of common stock at a price per share equal to 85% of the lower of the fair market value at the start or end of the six-month purchase periods within the two-year offering period. A total of 650,000 shares of common stock were approved to be initially reserved for issuance under the 2020 ESPP. In addition, the number of shares of common stock available for issuance under the 2020 ESPP is automatically increased on the first day of each calendar year during the 10-year term of the 2020 Plan, beginning with January 1, 2021 and ending with January 1, 2030, by an amount of 1% of the outstanding number of shares of our common stock on December 31 of the preceding calendar year or such lesser amount as determined by our Board. Effective January 1, 2026, the number of shares of common stock available under the 2020 ESPP increased by 1,310,588 shares pursuant to the evergreen provision of the 2020 ESPP.

During the years ended December 31, 2025, 2024 and 2023, employees purchased 147,870, 90,517 and 76,275 shares of common stock through our 2020 ESPP at an average price of $27.14, $38.60 and $26.71 per share, respectively. As of December 31, 2025, a total of 2,019,358 shares of our common stock remain available for future issuance under our 2020 ESPP.

Stock-based Compensation

The following assumptions were used in the Black-Scholes options pricing model for stock options and ESPP shares.

	Year Ended December 31,		
	2025	2024	2023
Expected volatility			
Stock Options	63.5% - 67.5%	69.2% - 71.1%	71.3% - 74.0%
ESPP	51.7% - 108.4%	38.1% - 62.7%	38.1% - 99.7%
Expected term (in years)			
Stock Options	5.2 - 5.4	5.3 - 5.4	5.3 - 5.4
ESPP	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0
Risk-free interest rate			
Stock Options	3.6% - 4.5%	3.5% - 4.5%	3.5% - 4.6%
ESPP	3.6% - 4.4%	4.3% - 5.4%	4.2% - 5.4%

No PCSOs or PSUs were granted in the years ended December 31, 2025 or 2023. The following assumptions were used in the Monte Carlo simulation model for PCSOs and PSUs granted in the year ended December 31, 2024 to estimate our stock-based compensation expense.

	PCSOs	PSUs
Expected volatility	61.6%	59.9%
Expected term (in years)	5.9	5.9
Risk-free interest rate	4.2%	4.1%

Our expected dividend yield is zero as we have not declared and do not anticipate declaring any dividends.

We recorded total stock-based compensation expense for the years ended December 31, 2025, 2024 and 2023 related to the 2014 Plan, the 2020 Plan and the 2020 ESPP in the consolidated statements of operations and allocated the amounts as follows:

	Year Ended December 31,		
	2025	2024	2023
		(In thousands)	
Research and development	$ 74,054	$ 42,819	$ 23,275
General and administrative	64,791	42,003	25,485
Total stock-based compensation expense	$ 138,845	$ 84,822	$ 48,760

As of December 31, 2025, there was $301.6 million of unrecognized stock-based compensation expense related to unvested employee and non-employee awards, which is expected to be recognized over a weighted-average period of 2.7 years.

10. Funding Arrangement

Our vaccine development program for VAX-A1, a novel conjugate vaccine candidate designed to prevent disease caused by Group A Streptococcus, has been funded in part by a grant obtained from Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator ("CARB-X"), a global non-profit partnership dedicated to accelerating antibacterial innovation to tackle the rising global threat of drug-resistant bacteria. The CARB-X grant provided funding of $11.7 million upon the achievement of VAX-A1 development milestones

through June 2024. As of the second quarter of 2024, all of these milestones had been successfully achieved, and no further amounts will be funded under this CARB-X grant.

Our vaccine development program for VAX-GI, a novel preclinical vaccine candidate being developed as a preventative treatment for dysentery and shigellosis, which is caused by Shigella bacteria, is currently funded in part by two grants obtained from the National Institutes of Health ("NIH") administered by the University of Maryland, Baltimore. Our first grant from the NIH was awarded in April 2021 and provides for potential funding up to five years totaling approximately $0.5 million. In June 2023, we received another grant from the NIH that provides for potential funding up to five years totaling approximately $4.6 million. We have received and expect to continue to receive funding under each of these grants.

We are currently working on a discovery program with the University of North Carolina at Chapel Hill and the University of Chicago to develop a vaccine candidate for the prevention of Chlamydia, which is funded in part by a grant from the NIAID that provides potential funding up to five years totaling approximately $9.5 million. As of December 31, 2025, we have received and expect to continue to receive funding under this grant.

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. We recognized $0.5 million, $1.0 million and $4.8 million of grant income and recorded the amounts in Other income (expense), net in the consolidated statements of operations during the years ended December 31, 2025, 2024 and 2023, respectively. The grant receivable related to unreimbursed, eligible costs incurred under the agreements, recorded within prepaid expenses and other current assets, was not material as of December 31, 2025, and was $0.4 million as of December 31, 2024.

11. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per share and excludes shares which are legally outstanding, but subject to repurchase by us:

	Year Ended December 31,		
	2025	**2024**	**2023**
Net loss (in thousands)	$ (766,628)	$ (463,927)	$ (402,266)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	136,089,506	121,997,348	97,157,690
Net loss per share, basic and diluted	$ (5.63)	$ (3.80)	$ (4.14)

The following potentially dilutive securities were excluded from the computation of diluted net loss per share for the period presented because including them would have been antidilutive:

	Year Ended December 31,		
	2025	2024	2023
Stock options	11,612,299	10,036,284	9,351,546
Restricted stock units	2,516,102	1,416,785	753,462
Employee stock purchase plan	345,087	112,260	103,628
Total	14,473,488	11,565,329	10,208,636

12. Income Taxes

Our loss before income taxes was primarily derived from our business operations within the United States.

The Company has not recognized a current or deferred tax expense/(benefit) for federal, state or foreign jurisdictions in the years ending December 31, 2025, 2024 or 2023, respectively, due to tax losses in the various jurisdictions.

There were no federal, state, local or foreign income taxes paid, net of refunds, for the years ended December 31, 2025, 2024 or 2023.

The differences between income tax expected at the U.S. federal statutory income tax rate of 21% and the reported income tax rate are summarized as follows:

	Year Ended December 31,					
	2025	%	2024	%	2023	%
	(In Thousands, Except for Percentages)					
Loss from continuing operations						
U.S. Federal Statutory Tax Rate	$ (160,792)	21.0 %	$ (97,425)	21.0 %	$ (84,476)	21.0 %
State and Local Income Taxes, Net of Federal Income Tax Effect [1]	(29)	— %	65	— %	39	— %
Effect of Cross-Border Tax Laws						
Global intangible low-taxed	11,407	(1.5)%	—	— %	—	— %
Tax Credits						
Research and Development tax credits	(8,706)	1.1 %	(11,297)	2.4 %	(6,644)	1.6 %
Change in Valuation Allowance	139,663	(18.2)%	108,613	(23.4)%	87,744	(21.8)%
Nondeductible/Non-taxable Items						
Stock Based Compensation	3,089	(0.4)%	(18,483)	4.0 %	(1,668)	0.4 %
Section 162(m) Limitation	12,103	(1.6)%	16,420	(3.5)%	4,525	(1.1)%
Other [2]	3,265	(0.4)%	2,107	(0.5)%	480	(0.1)%
Effective Tax Rate	$ —	— %	$ —	— %	$ —	— %

[1] State taxes in California represented the majority (greater than 50%) of the tax effect within this category.

[2] Other includes immaterial foreign tax effects and immaterial worldwide changes in unrecognized tax benefits in the years ending December 31, 2025, 2024 and 2023.

There was no impact from the changes in tax laws, tax rates or cross-border tax regulations enacted for the years ended December 31, 2025, 2024 or 2023.

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 our deferred tax assets and liabilities as of December 31, 2025 and 2024:

	As of December 31,	
	2025	2024
	(in thousands)	
Deferred tax assets:		
Net operating losses	$ 336,106	$ 195,869
Unrealized gain/loss	—	3,465
Accrued and others	6,471	14,637
R&D Credits	38,272	26,709
Capitalized R&D expenditures	221,258	155,356
Accrued manufacturing expenses	471	6,909
Lease liability	35,114	21,228
Intangible assets	27,337	29,253
Stock compensation	22,800	14,652
Capitalized Interest	732	—
Total deferred tax assets	688,561	468,078
Less: Valuation allowance	(645,313)	(446,098)
Net deferred tax asset	43,248	21,980
Deferred tax liabilities:		
ROU asset	(34,674)	(21,524)
Fixed Assets	(1,295)	(456)
Unrealized gain/loss	(7,279)	—
Total deferred tax liabilities	(43,248)	(21,980)
Net deferred taxes	$ —	$ —

At December 31, 2025, we have net operating loss ("NOL") carryforwards of approximately $796.1 million and $1,907.7 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. The federal and state NOL 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 carryover period and do not expire. Our state

NOL carryforwards generally have a 20-year carryover period. We had no foreign NOL carryforwards at December 31, 2025.

At December 31, 2025, we have research credit carryforwards of $40.3 million and $12.3 million available to offset future income tax liabilities, if any, for federal and California income tax purposes, respectively. The federal research and development tax credit carryforwards expire beginning in 2039 unless previously utilized. The California tax credits can be carried forward indefinitely.

Utilization of the NOL 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 NOL before utilization. We have experienced ownership changes in the past. There were no ownership changes identified in 2025, as such we determined that no federal research credits will expire unutilized or are excluded from our research credit carryforwards. Subsequent ownership changes may affect the limitation in future years.

We have evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets. Based on our history of operating losses, we have concluded that it is more likely than not that the benefit of our deferred tax assets will not be realized. Accordingly, we have provided a full valuation allowance for deferred tax assets as of December 31, 2025 and 2024.

We have uncertain tax benefits ("UTBs") totaling $14.0 million and $9.5 million as of December 31, 2025 and 2024, respectively, which were netted against deferred tax assets subject to valuation allowance. The UTBs had no effect on the effective tax rate. We recognize 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, 2025 or 2024. We do not expect our UTBs to change significantly over the next 12 months.

A reconciliation of the beginning and ending unrecognized tax benefit amount is as follows:

	December 31,		
	2025	2024	2023
		(in thousands)	
Balance at the beginning of the year	$ 9,525	$ 4,447	$ 1,754
Additions based on tax positions related to current year	4,316	5,166	2,208
Additions based on tax positions related to prior years	195	—	485
Reductions based on tax positions related to prior years	—	(88)	—
Balance at end of year	$ 14,036	$ 9,525	$ 4,447

We file U.S. federal, state and foreign tax returns in certain jurisdictions in which we operate as required. In general, we are no longer subject to tax examination by the Internal Revenue Service or state taxing authorities for years before 2019. Although the federal and state statutes are closed for purposes of assessing additional income tax in those prior years, the taxing authorities may still make adjustments to the NOL and credit carryforwards used in open years. Therefore, the tax statutes should be considered open as it relates to the NOL and credit carryforwards used in open years. Our Swiss corporate income and capital tax returns are subject to

examination by the Swiss tax authorities for five years after the end of the corresponding tax period. We do not have any tax audits or other issues pending.

It is our intention to reinvest the earnings of our non-U.S. subsidiary in those operations and not to repatriate the earnings to the United States. Accordingly, we do not provide for deferred taxes on differences between financial reporting and tax basis in our investments in foreign subsidiaries as they are considered permanent in duration or are not expected to reverse in the foreseeable future. As of December 31, 2025, there are no unremitted earnings of our foreign subsidiary.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law in the United States, and contains a wide range of tax reform provisions, including extending and modifying certain key Tax Act provisions, such as 100% bonus depreciation and the business interest expense limitation. Additionally, the OBBBA repealed mandatory capitalization and amortization of domestic R&D expenses, reverting to the immediate expensing of R&D expenditures for tax years beginning in 2025. The enactment of this legislation did not have a material impact on our consolidated financial statements, effective income tax rate, or cash tax position for the year ended December 31, 2025.

13. Segment Reporting

We operate and manage our business as one reportable and operating segment. Our 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 based on consolidated net loss, as is reported in our consolidated statements of operations.

Our long-lived assets are based in the United States and Switzerland. Long-lived assets are comprised of property and equipment. As of December 31, 2025 and 2024, property and equipment based in the United States was $39.7 million and $40.8 million, respectively. As of December 31, 2025 and 2024, property and equipment based in Switzerland was $217.7 million and $157.2 million, respectively.

This following table presents segment operation results for the year ended December 31, 2025, 2024 and 2023:

	Year Ended December 31,		
	2025	2024	2023
Operating expenses:			
Research and development - external costs [1]	$ 600,690	$ 349,510	$ 261,984
Research and development - internal costs [2]	193,616	127,134	70,357
Acquired manufacturing rights (Note 7)	—	—	75,000
General and administrative	129,369	92,902	60,700
Total operating expenses	$ 923,675	$ 569,546	$ 468,041
Total other income, net	$ 157,047	$ 105,619	$ 65,775
Net loss	$ 766,628	$ 463,927	$ 402,266

[1] Research and development - external costs consist primarily of product and clinical development, research, facility, depreciation, professional and consulting services expenses attributed to the research and development departments.

(2) Research and development - internal costs consist of internal employee costs including stock-based compensation expenses.

14. Subsequent Events

In February 2026, we completed an underwritten public offering of 12,650,000 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 1,650,000 shares, at a price of $50.00 per share. In aggregate, we received approximately $600.2 million in net proceeds after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

On February 18, 2026, we entered into a Development and Manufacturing Services Agreement with Lonza. Under the agreement, Lonza will perform manufacturing process development and commercial manufacture and supply of certain key components for our proprietary PCV franchise. The agreement has an initial term through December 31, 2038, with options for additional renewal periods. Under the terms of the agreement, if we elect to terminate the agreement for convenience prior to the expiration of the initial term or any committed renewal period, we will be obligated to pay Lonza the greater of a fixed dollar amount or an amount based on certain cancellation fees specified in the agreement.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our Chief Executive Office ("CEO") and our Chief Financial Officer ("CFO"), our principal executive officer and principal financial officer, respectively, have evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (as amended, the "Exchange Act") as of December 31, 2025. Based on this evaluation, our CEO and CFO have concluded that our disclosure controls and procedures as of December 31, 2025 were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements for external purposes in accordance with GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in its 2013 Internal Control - Integrated Framework. Based on this assessment, our management has concluded that our internal control over financial reporting was effective as of December 31, 2025. Pursuant to Section 404(c) of the Sarbanes-Oxley Act, our independent registered public accounting firm has issued an attestation report on the effectiveness of our internal control over financial reporting for the year ended December 31, 2025, which is included below.

Report of Independent Registered Public Accounting Firm

To the stockholders and the Board of Directors of Vaxcyte, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Vaxcyte, Inc. and subsidiary (the "Company") as of December 31, 2025, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control — Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets and related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows as of and for the year ended December 31, 2025, of the Company and our report dated February 24, 2026 , expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized

acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

San Francisco, California

February 24, 2026

Item 9B. Other Information.

Trading Arrangements

The adoption, modification or termination of contracts, instructions or written plans for the purchase or sale of our securities by our Section 16 officers or directors for the three months ended December 31, 2025, each of which was entered into during an open trading window and is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act ("10b5-1 Plan"), were as follows:

Elvia Cowan, our Senior Vice President of Finance and Principal Accounting Officer, adopted a 10b5-1 Plan on December 8, 2025, with an effective date of March 10, 2026. Ms. Cowan's 10b5-1 Plan provides for the potential exercise and sale of up to 41,060 shares of our common stock, and expires on February 28, 2027, or upon the earlier completion of all authorized transactions thereunder.

Jim Wassil, our Executive Vice President, Chief Operating Officer, adopted a 10b5-1 Plan on December 9, 2025, with an effective date of March 10, 2026. Mr. Wassil's 10b5-1 Plan provides for the potential exercise and sale of up to 70,056 shares of our common stock, and expires on March 1, 2027, or upon the earlier completion of all authorized transactions thereunder.

During the three months ended December 31, 2025, none of our other directors or Section 16 officers adopted, modified or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

Item 1.01 Entry into a Material Definitive Agreement

On February 18, 2026, Vaxcyte Switzerland GmbH, a subsidiary of Vaxcyte, Inc. (the "Company"), entered into a Development and Manufacturing Services Agreement (the "Agreement") with Lonza Ltd ("Lonza"), effective as of January 1, 2026 (the "Effective Date"), pursuant to which Lonza will perform manufacturing process development and commercial manufacture and supply of certain key components for the Company's proprietary pneumococcal conjugate vaccine franchise (the "Product").

Under the Agreement, the Company will pay Lonza for development and manufacturing services, in addition to paying for certain raw material and other costs. The Company will be required to purchase, and Lonza will be required to supply, Product pursuant to the relevant purchase orders under the Agreement. In consideration of the Product commercial supply services and Lonza's other obligations under the Agreement, the Company will pay Lonza a daily fee for Lonza's operation of the facility solely to actively manufacture Product. With respect to such commercial supply, and subject to termination rights, the parties have agreed to a mutually binding percentage of annual facility capacity that shall be utilized by Lonza fully and exclusively for Lonza's performance of services thereunder, which percentages may be adjusted under certain circumstances. For such services during the Initial Term (as defined below), and subject to termination rights, the Company shall pay Lonza fees totaling mid-eight-figures to high-eight-figures of Swiss Francs per year, calculated based on a formula.

The Company has the right to conduct a technology transfer for the manufacture of the Product to other manufacturers or its own facilities, and Lonza will, subject to certain conditions, provide certain information and support in furtherance of any such technology transfer. Under the Agreement, the Company receives a perpetual, irrevocable, royalty-free license under Lonza's intellectual property to exploit and commercialize the

Product or products incorporating the Product, as well as a perpetual, irrevocable, royalty-free license under Lonza's intellectual property to the extent incorporated into the manufacturing process for, or otherwise necessary to make or have made, the Product or products incorporating the Product, including the right to make or have made such products.

Unless earlier terminated, the Agreement will remain in effect until December 31, 2038 (the "Initial Term"), subject to automatic renewal for up to three additional renewal periods of five years each, unless the Company elects not to renew (together with the Initial Term, collectively, the "Term"). The Company may terminate the Agreement for convenience, and the Agreement contains customary for-cause termination rights for each party. If the Agreement is terminated (i) by the Company for convenience, or (ii) by Lonza for the Company's uncured failure to pay material, undisputed amounts of money due to Lonza, then the Company shall pay Lonza the greater of a fixed dollar amount in the low-eight-figures and an amount based on certain cancellation fees as Lonza's sole and exclusive remedy.

The Agreement also includes customary provisions relating to, among others, insurance and indemnification, intellectual property, assignment and change of control, non-competition, warranties and confidentiality.

The foregoing description of the terms of the Agreement does not purpose to be complete and is subject to, and qualified in its entirety by reference to, the complete text of the Agreement, which will be filed with the Securities and Exchange Commission as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2026.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K since we intend to file our definitive proxy statement for our 2026 Annual Meeting of Stockholders (the "2026 Proxy Statement") pursuant to Regulation 14A of the Exchange Act, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the 2026 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item of Form 10-K will be included under the captions "Proposal No. 1—Election of Directors," "Executive Officers," "Delinquent Section 16(a) Reports," if applicable and "Corporate Governance and Board Matters" in our 2026 Proxy Statement, and is incorporated herein by reference.

We have adopted a written Code of Business Conduct and Ethics ("Ethics Code") that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The Ethics Code is available on our website at www.vaxcyte.com. If we make any substantive amendments to the Ethics Code or grant any waiver from a provision of the Ethics Code to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website or in a Current Report on Form 8-K.

Item 11. Executive Compensation.

The information required by this item of Form 10-K will be included under the captions "Executive Compensation" (other than information included under the subcaption "Pay Versus Performance Disclosure"), "Director Compensation," "Corporate Governance and Board Matters," and "Certain Relationships and Related Person Transactions" in our 2026 Proxy Statement, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item of Form 10-K will be included under the captions "Security Ownership of Certain Beneficial Owners and Management," "Director Compensation," and "Executive Compensation" in our 2026 Proxy Statement, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item of Form 10-K will be included under the captions "Certain Relationships and Related Person Transactions," and "Corporate Governance and Board Matters" in our 2026 Proxy Statement, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item of Form 10-K will be included under the caption "Proposal No. 2—Ratification of Independent Registered Public Accounting Firm" in our 2026 Proxy Statement, and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) All Consolidated Financial Statements

The consolidated financial statements and Report of Independent Registered Public Accounting Firm filed as part of this Annual Report on Form 10-K are listed in the "Index to Consolidated Financial Statements" under Part II, Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

All financial statement schedules have been omitted because of the absence of conditions under which they are required or because the required information, where material, is shown in the consolidated financial statements, financial notes or supplementary financial information.

(3) Exhibits

The list of exhibits filed with this Annual Report on Form 10-K is set forth in the Exhibit Index preceding the signature page and is incorporated herein by reference or filed with this Annual Report on Form 10-K, in each case as indicated herein (numbered in accordance with Item 601 of Regulation S-K).

Item 16. Form 10-K Summary

None.

Exhibit Index

		Incorporated by Reference			
Exhibit	**Description**	**Form**	**File Number**	**Exhibit**	**Filing Date**
3.1	Second Amended and Restated Certificate of Incorporation of Vaxcyte, Inc.				X
3.2	Amended and Restated Bylaws of Vaxcyte, Inc., as amended.	10-Q	001-39323	3.2	November 6, 2023
4.1	Form of Common Stock Certificate of the Registrant.	S-1/A	333-238630	4.1	June 8, 2020
4.2	Description of Capital Stock.	10-K	001-39323	4.2	March 29, 2021
4.3	Form of Pre-Funded Warrant.	8-K	001-39323	4.1	January 13, 2022
4.4	Form of Pre-Funded Warrant.	8-K	001-39323	4.1	October 27, 2022
4.5	Form of Pre-Funded Warrant.	8-K	001-39323	4.1	April 20, 2023

Exhibit	Description	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
4.6	Form of Pre-Funded Warrant.	8-K	001-39323	4.1	January 31, 2024
4.7	Form of Pre-Funded Warrant.	8-K	001-39323	4.1	September 6, 2024
10.1#	Vaxcyte, Inc. Amended and Restated 2014 Equity Incentive Plan and forms of agreements thereunder.	S-1	333-238630	10.2	May 22, 2020
10.2#	Vaxcyte, Inc. 2020 Equity Incentive Plan.	10-Q	001-39323	10.1	August 8, 2023
10.3#	Form of Stock Option Grant Notice and Stock Option Agreement (2020 Equity Incentive Plan).	10-Q	001-39323	10.2	August 8, 2023
10.4#	Form of Restricted Stock Unit Grant Notice (2020 Equity Incentive Plan).	10-Q	001-39323	10.2	May 9, 2022
10.5#	Vaxcyte, Inc. 2020 Employee Stock Purchase Plan.	S-1/A	333-238630	10.4	June 8, 2020
10.6	Form of Indemnification Agreement entered into by and between the Registrant and each director and executive officer.	S-1	333-238630	10.5	May 22, 2020
10.7#	Executive Employment Agreement entered into by and between the Registrant and Grant Pickering, dated January 21, 2016.	S-1	333-238630	10.6	May 22, 2020
10.8#	Executive Employment Agreement entered into by and between the Registrant and Jim Wassil, dated November 15, 2019.	S-1	333-238630	10.11	May 22, 2020
10.9#	Offer Letter entered into by and between the Registrant and Andrew Guggenhime, dated April 16, 2020.	S-1	333-238630	10.13	May 22, 2020
10.10#	Offer Letter entered into by and between the Registrant and Mikhail Eydelman, dated March 4, 2022.	10-Q	001-39323	10.1	May 9, 2022
10.11#	Offer Letter entered into by and between Registrant and Harp Dhaliwal, dated September 29, 2021.				X
10.12#	Form of Executive Change in Control and Severance Agreement entered into by and between the Registrant and each eligible employee.	S-1	333-238630	10.14	May 22, 2020
10.13#	Form of Amendment to Executive Change in Control and Severance	8-K	001-39323	10.1	December 19, 2025

Exhibit	Description	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
	Agreements entered into by and between the Registrant and each eligible employee.				
10.14+†	Master Services Agreement for Drug Product Development and Manufacturing between Registrant and Lonza Ltd., dated March 22, 2022, as amended.	10-K	001-39323	10.12	February 27, 2024
10.15+†	Development and Manufacturing Services Agreement by and between the Registrant and Lonza Ltd., dated March 1, 2023.	10-Q	001-39323	10.1	May 8, 2023
10.16+†	Commercial Manufacturing and Supply Agreement by and between the Registrant and Lonza Ltd., dated October 13, 2023.	10-K	001-39323	10.14	February 27, 2024
10.17+†	Amended and Restated SutroVax Agreement by and between the Registrant and Sutro Biopharma, Inc., dated October 12, 2015, as amended.	S-1	333-238630	10.18	May 22, 2020
10.18+†	Third Amendment to Amended and Restated SutroVax Agreement by and between Sutro Biopharma, Inc. and the Registrant, dated September 28, 2023.	10-Q	001-39323	10.3	November 6, 2023
10.19+†	Supply Agreement by and between the Registrant and Sutro Biopharma, Inc., dated May 29, 2018, as amended.	10-K	001-39323	10.19	February 27, 2023
10.20+†	Option Grant Agreement by and between Registrant and Sutro Biopharma, Inc., dated December 19, 2022.	10-K	001-39323	10.20	February 27, 2023
10.21+†	Manufacturing Rights Agreement by and between the Registrant and Sutro Biopharma, Inc., dated November 21, 2023.	10-K	001-39323	10.19	February 27, 2024
10.22+†	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.	S-1	333-238630	10.20	May 22, 2020

Exhibit	Description	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
10.23	First Amendment to License Agreement by and between the Registrant and The Regents of the University of California, represented by its San Diego campus, dated August 16, 2019.	10-K	001-39323	10.21	February 27, 2024
10.24+†	Amended and Restated Lease Agreement by and between the Registrant and ARE-San Francisco No. 63, LLC, dated as of November 15, 2024.	10-K	001-39323	10.22	February 25, 2025
10.25#	Form of Non-U.S. Stock Option Grant Notice and Stock Option Agreement (2020 Equity Incentive Plan).	10-K	001-39323	10.26	February 27, 2024
10.26#	Form of Non. U.S. Restricted Stock Unit Grant Notice (2020 Equity Incentive Plan).	10-K	001-39323	10.27	February 27, 2024
10.27#	Form of Performance Restricted Stock Unit Award Grant Notice and Agreement.	10-Q	001-39323	10.1	May 7, 2025
10.28#	Form of Performance Contingent Stock Option Grant Notice and Agreement.	10-Q	001-39323	10.2	May 7, 2025
10.29+†	Commercial Manufacturing and Supply Agreement by and between the Registrant and Patheon Manufacturing Services LLC (part of Thermo Fisher Scientific), dated September 24, 2025.	10-Q	001-39323	10.1	November 4, 2025
19.1	Vaxcyte, Inc. Insider Trading Policy	10-K	001-39323	19.1	February 25, 2025
21.1	Subsidiary of Registrant.	10-K	001-39323	21.1	February 27, 2024
23.1	Consent of Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney. Reference is made to the signature page hereto.				X
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.				X
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.				X

Exhibit	Description	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 13a-14(b) or 15d-14(b) of the Securities Exchange Act, as amended, and 18 U.S.C. Section 1350.				X
97.1#	Incentive Compensation Recoupment Policy.	10-K	001-39323	97.1	February 27, 2024
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.				X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).				X

X Filed herewith.

# Indicates a management contract or compensatory plan or arrangement.

+ Pursuant to Item 601(b)(10)(iv) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by "[***]") because we have determined that the information is not material and is the type that we treat as private or confidential.

† Schedules and exhibits to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule or exhibit will be furnished to the Securities and Exchange Commission (the "SEC") upon request; provided, however, that we may request confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended(the "Exchange Act"), for any schedule or exhibit so furnished.

* The certification attached as Exhibit 32.1 that accompanies this Annual Report on Form 10-K is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Vaxcyte, Inc.

Date: February 24, 2026

By: /s/ Grant E. Pickering

Grant E. Pickering

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 Andrew Guggenhime, and each of them, as his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the SEC, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Grant E. Pickering **Grant E. Pickering**	Chief Executive Officer and Director *(Principal Executive Officer)*	February 24, 2026
/s/ Andrew Guggenhime **Andrew Guggenhime**	President and Chief Financial Officer *(Principal Financial Officer)*	February 24, 2026
/s/ Elvia Cowan **Elvia Cowan**	Senior Vice President, Finance and Chief Accounting Officer *(Principal Accounting Officer)*	February 24, 2026
/s/ Carlos Paya **Carlos Paya, M.D., Ph.D.**	Director	February 24, 2026
/s/ Olivier Brandicourt **Olivier Brandicourt, M.D.**	Director	February 24, 2026
/s/ Annie Drapeau **Annie Drapeau**	Director	February 24, 2026
/s/ John Furey **John Furey**	Director	February 24, 2026
/s/ Halley Gilbert **Halley Gilbert**	Director	February 24, 2026
/s/ Jacks Lee **Jacks Lee**	Director	February 24, 2026
/s/ Teri Loxam **Teri Loxam**	Director	February 24, 2026
/s/ Heath Lukatch **Heath Lukatch, Ph.D.**	Director	February 24, 2026