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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39323

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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 4, 2023, the registrant had 93,706,790 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

Unless the context otherwise requires, all references in this Quarterly Report on Form 10-Q to "we," "us," "our," "our company" and "Vaxcyte" refer to Vaxcyte, Inc.

"Vaxcyte," "eCRM," and other trademarks of ours appearing in this report are our property. This report 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q 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 potentially being predictive of clinical study results;
- our belief that our pneumococcal conjugate vaccine candidates could receive regulatory approval based on a demonstration of non-inferiority to the standard of care using well-defined surrogate immune endpoints rather than requiring clinical field efficacy studies;
- the timing of the initiation, progress and 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 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 in light of the COVID-19 pandemic;
- 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q. These risks include, but are not limited to, the following:

- We are in the clinical or preclinical phase of vaccine development and have a very limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant net losses since inception and anticipate that we will continue to incur substantial net losses for the foreseeable future. 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, or 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 candidates – VAX-24, which is in clinical development, and VAX-31, which is in preclinical development. If we are unable to successfully develop, obtain approval for and effectively commercialize VAX-24 or VAX-31, our business would be significantly harmed.
- Our primary competitors have significantly greater resources and experience than we do, which may make it difficult for us to successfully develop our vaccine candidates, or may result in others discovering, developing or commercializing products before or more successfully than us.
- We may not be successful in our efforts to use our cell-free protein synthesis platform to expand our pipeline of vaccine candidates and develop marketable products.
- We currently rely on third-party manufacturing and supply partners, including Lonza Ltd. and Sutro Biopharma, Inc. to supply raw materials and components for, and 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.
- Health epidemics, including the effects of the ongoing COVID-19 pandemic, have impacted and could continue to impact our business, including in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations.
- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our vaccine candidates.
- If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

VAXCYTE, INC.
Condensed Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 380,451	$ 834,657
Short-term investments	441,587	96,719
Prepaid expenses and other current assets	18,636	11,179
Total current assets	840,674	942,555
Property and equipment, net	15,205	10,360
Operating lease right-of-use assets	19,658	21,288
Long-term investments	127,815	26,549
Restricted cash	871	871
Other assets	3,940	4,555
Total noncurrent assets	167,489	63,623
Total assets	$ 1,008,163	$ 1,006,178
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 11,615	$ 9,795
Accrued compensation	1,879	1,180
Accrued manufacturing expenses	14,955	8,265
Accrued expenses	18,351	15,375
Operating lease liabilities — current	5,947	5,910
Total current liabilities	52,747	40,525
Operating lease liabilities — long-term	10,638	12,031
Other liabilities	7	9
Total liabilities	63,392	52,565
Commitments and contingencies (Note 6)		
Stockholders' Equity		
Preferred stock, $0.001 par value — 10,000,000 shares authorized at March 31, 2023 and December 31, 2022; no shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value — 500,000,000 shares authorized at March 31, 2023 and December 31, 2022; 80,640,851 and 79,470,670 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	84	82
Additional paid-in capital	1,527,228	1,476,018
Accumulated other comprehensive gain (loss)	47	(361)
Accumulated deficit	(582,588)	(522,126)
Total stockholders' equity	944,771	953,613
Total liabilities and stockholders' equity	$ 1,008,163	$ 1,006,178

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

VAXCYTE, INC.
Condensed Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 58,080	$ 31,678
General and administrative	13,112	7,543
Total operating expenses	71,192	39,221
Loss from operations	(71,192)	(39,221)
Other income (expense), net:		
Interest income	10,393	134
Grant income	654	160
Realized losses on marketable securities	—	(65)
Foreign currency transaction (losses) gains	(317)	6
Total other income (expense), net	10,730	235
Net loss	$ (60,462)	$ (38,986)
Net loss per share, basic and diluted	$ (0.70)	$ (0.68)
Weighted-average shares outstanding, basic and diluted	86,206,817	57,547,808

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

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

	Three Months Ended March 31,	
	2023	**2022**
Net Loss	$ (60,462)	$ (38,986)
Other comprehensive loss:		
Unrealized gains (losses) on investments	408	(592)
Comprehensive loss	$ (60,054)	$ (39,578)

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

VAXCYTE, INC.
Condensed Statements of Stockholders' Equity
(in thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance — December 31, 2022	79,470,670	$ 82	$ 1,476,018	$ (522,126)	$ (361)	$ 953,613
Exercise of stock options	100,964	1	501	—	—	502
Issuance of common stock in connection with at-the-market offering, net of commissions and offering expenses of $1,237	1,041,536	1	41,786	—	—	41,787
Release of restricted stock units	27,681		(727)	—	—	(727)
Vesting of early exercised stock options	—	—	2	—	—	2
Stock-based compensation expense	—	—	9,648	—	—	9,648
Unrealized gains on investments	—	—	—	—	408	408
Net loss	—	—	—	(60,462)	—	(60,462)
Balance — March 31, 2023	80,640,851	$ 84	$ 1,527,228	$ (582,588)	$ 47	$ 944,771

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

VAXCYTE, INC.
Condensed Statements of Stockholders' Equity
(in thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance — December 31, 2021	53,031,978	$ 56	$ 582,844	$ (298,641)	$ (241)	$ 284,018
Exercise of stock options	91,044	—	282	—	—	282
Vesting of early exercised stock options	—	—	2	—	—	2
Issuance of common stock and pre-funded warrants in connection with follow-on public offering, net of issuance costs of $7,376	3,250,000	3	107,619	—	—	107,622
Issuance of common stock in connection with at-the-market offering, net of commissions and offering expenses of $114	126,522	—	3,098	—	—	3,098
Stock-based compensation expense	—	—	4,099	—	—	4,099
Unrealized losses on investments	—	—	—	—	(592)	(592)
Net loss	—	—	—	(38,986)	—	(38,986)
Balance — March 31, 2022	56,499,544	$ 59	$ 697,944	$ (337,627)	$ (833)	$ 359,543

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

VAXCYTE, INC.
Condensed Statements of Cash Flows
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (60,462)	$ (38,986)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	712	582
Stock-based compensation expense	9,648	4,099
Amortization of operating right-of-use assets	1,630	1,787
Net amortization of premiums on investments	(5,990)	321
Loss on disposal of fixed assets	—	44
Asset impairment charges	—	57
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4,702)	2,791
Other assets	615	(1,577)
Operating lease liabilities	(1,356)	5,619
Accounts payable	1,789	(1,933)
Accrued compensation	699	(2,185)
Accrued manufacturing expenses	6,689	2,416
Accrued expenses	3,038	(737)
Net cash used in operating activities	(47,690)	(27,702)
Cash flows from investing activities:		
Purchases of property and equipment	(5,609)	(2,920)
Purchases of investments	(483,779)	(6,972)
Maturities of investments	40,160	59,551
Sale of investments	1,127	—
Proceeds from sale of property and equipment	—	7
Net cash (used in) provided by investing activities	(448,101)	49,666
Cash flows from financing activities:		
Proceeds from exercise of common stock options	502	282
Proceeds from issuance of common stock related to at-the-market offering, net of issuance costs	41,787	3,115
Proceeds from issuance of common stock from follow-on offering, net of issuance costs	—	107,622
Release of restricted stock units	(727)	—
Net cash provided by financing activities	41,562	111,019
Effect of exchange rate changes on cash and cash equivalents	23	(227)
Net (decrease) increase in cash, cash equivalents and restricted cash	(454,206)	132,756
Cash, cash equivalents and restricted cash, beginning of period	835,528	69,856
Cash, cash equivalents and restricted cash, end of period	$ 381,322	$ 202,612
Supplemental disclosures of non-cash investing and financing activities:		
Purchases of property and equipment recorded in accounts payable and accrued expenses	$ 57	$ 664
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 23

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

1. Company Organization and Nature of Business

Vaxcyte, Inc. ("we," "us," "the Company," or "Vaxcyte"), headquartered in San Carlos, California, was incorporated in the state of Delaware on November 27, 2013 as SutroVax, Inc. and we 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 developing broad-spectrum conjugate and novel protein vaccines to prevent or treat bacterial infectious diseases. We are re-engineering the way highly complex vaccines are made through modern synthetic techniques, including advanced chemistry and the XpressCF cell-free protein synthesis platform, exclusively licensed from Sutro Biopharma, Inc. ("Sutro Biopharma"). Unlike conventional cell-based approaches, our system for producing difficult-to-make proteins and antigens is intended to accelerate our ability to efficiently create and deliver high-fidelity vaccines with enhanced immunological benefits.

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 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

These condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, and applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding interim financial reporting. Certain information and footnote disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted in accordance with such rules and regulations.

Unaudited Interim Condensed Financial Statements

The condensed balance sheet as of March 31, 2023, the condensed statements of operations, comprehensive loss and stockholders' equity for the three months ended March 31, 2023 and 2022 and the condensed statements of cash flows for the three months ended March 31, 2023 and 2022 are unaudited. The unaudited interim condensed financial statements have been prepared on the same basis as the audited annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair statement of our financial information. The financial data disclosed in the footnotes to the condensed financial statements related to the three months ended March 31, 2023 and 2022 are also unaudited. The results of operations for the three months ended March 31, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or for any other future annual or interim period. These interim condensed financial statements should be read in conjunction with our audited financial statements and related notes thereto for the year ended December 31, 2022 included in our Annual Report on Form 10-K filed with the SEC on February 27, 2023.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities at the date of the 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.

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 a standby letter of credit, which was issued in the first quarter of 2021, that serves as collateral for the lease agreement for our current corporate headquarters. Cash, cash equivalents and restricted cash as reported within the condensed balance sheets that total to the same amounts shown in the condensed statement of cash flows are as follows:

	March 31, 2023	December 31, 2022
	(in thousands)	
Cash and cash equivalents	$ 380,451	$ 834,657
Restricted cash	871	871
Cash, cash equivalents and restricted cash	$ 381,322	$ 835,528

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 condensed 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 condensed 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 condensed statements of operations only if we sell or intend to sell the security before recovery of its cost basis.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average of shares of common stock outstanding, including pre-funded warrants issued, during the period, without consideration for common stock equivalents. 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. Diluted net loss per share is the same as basic net loss per share since the effects of potentially dilutive securities are antidilutive given the net loss for each period presented.

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 March 31, 2023, our lease population consisted of office operating leases. As of March 31, 2023, we did not have 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 condensed balance sheet. 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 and lease 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 condensed balance sheets.

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 condensed balance sheets. 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 maintained banking relationships with other major banks. The substantial majority of funds we held at SVB, which included cash, cash equivalents and investments were held in custodial accounts of a third-party institution for which SVB Asset Management was the advisor ("SVB Custodial Accounts"). On March 12, 2023, the FDIC confirmed that depositors of SVB would have access to all of their money and, as a result, we regained access to all of our funds deposited with SVB. The FDIC subsequently transferred SVB's deposits and loans to a newly created bridge bank, named Silicon Valley Bridge Bank, N.A. ("Silicon Valley Bridge Bank"). On March 26, 2023, the FDIC announced that First Citizens Bank & Trust Company ("First Citizens Bank") had agreed to purchase and assume all deposits and loans of Silicon Valley Bridge Bank. Management believes that we are not exposed to significant credit risk as our deposits are held at First Citizens Bank, and our investments are held under separate financial institution custodial accounts, each of which management continues to believe to be of high credit quality. We have not experienced any losses on these deposits or investments as a result of this market event. 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. 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 our suppliers. Although we are working to establish secondary sources of supply, we currently source several of our critical raw materials from single-source suppliers. We also use one contract manufacturing organization ("CMO"), Lonza Ltd. ("Lonza"), to handle most of our manufacturing activities for our VAX-24 and VAX-31 programs. If we were to experience disruptions in raw materials supplied by our suppliers, or in manufacturing activities at Lonza, we may experience significant delays in our product development timelines and may incur substantial costs to secure alternative sources of raw materials or manufacturing.

Our future results of operations involve a number of other risks and uncertainties. Factors that could affect our future operating results and cause actual results to vary materially from expectations include, but are not limited to: our early stages of clinical vaccine development; our ability to advance vaccine candidates into, and successfully complete, clinical trials on the timelines we project; our ability to adequately demonstrate sufficient safety 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; 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; general and market conditions; and other risks and uncertainties, including those more fully described in the "Risk Factors" section of this Quarterly Report on Form 10-Q.

3. Fair Value Measurements and Fair Value of Financial Instruments

Assets and liabilities recorded at fair value on a recurring basis in the condensed 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 based on our own data or other assumptions 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. We had no Level 3 securities as of March 31, 2023 or December 31, 2022.

There were no transfers within the hierarchies during the three months ended March 31, 2023 or the year ended December 31, 2022.

The following tables set forth our financial instruments measured at fair value on a recurring basis by level within the fair value hierarchy at March 31, 2023 and December 31, 2022:

		March 31, 2023			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Assets			(in thousands)		
Cash and cash equivalents:					
Cash	Level 1	$ 38,655	$ —	$ —	$ 38,655
Money market funds	Level 1	82,124	—	—	82,124
U.S. Treasury securities	Level 1	4,979	—	—	4,979
Commercial paper	Level 2	254,731	—	(38)	254,693
Total cash and cash equivalents		380,489	—	(38)	380,451
Investments:					
U.S. Treasury securities	Level 1	223,984	218	(26)	224,176
Commercial paper	Level 2	125,074	—	(10)	125,064
Corporate debt	Level 2	120,604	11	(284)	120,331
Asset-backed securities	Level 2	21,383	22	-	21,405
U.S. government agency securities	Level 2	78,272	193	(39)	78,426
Total investments		569,317	444	(359)	569,402
Total assets measured at fair value		$ 949,806	$ 444	$ (397)	$ 949,853

		December 31, 2022			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Assets			(in thousands)		
Cash and cash equivalents:					
Cash	Level 1	$ 56,198	$ —	$ —	$ 56,198
Money market funds	Level 1	680,934	—	—	680,934
Commercial paper	Level 2	92,581	—	(34)	92,547
U.S. government agency securities	Level 2	4,978	—	—	4,978
Total cash and cash equivalents		834,691	—	(34)	834,657
Investments:					
U.S. Treasury securities	Level 1	37,651	—	(70)	37,581
Commercial paper	Level 2	28,161	—	(17)	28,144
Corporate debt	Level 2	25,402	—	(131)	25,271
Asset-backed securities	Level 2	6,954	20	—	6,974
U.S. government agency securities	Level 2	25,427	19	(148)	25,298
Total investments		123,595	39	(366)	123,268
Total assets measured at fair value		$ 958,286	$ 39	$ (400)	$ 957,925

The following table presents the contractual maturities of our investments as of March 31, 2023 (in thousands):

	March 31, 2023
	Fair Value
Due in less than one year	$ 441,587
Due in one to five years	127,815
Total	$ 569,402

4. Balance Sheet Details

Property and Equipment, Net

Property and equipment, net as of March 31, 2023 and December 31, 2022 consisted of the following:

	March 31, 2023	December 31, 2022
	(in thousands)	
Furniture and equipment	$ 1,608	$ 1,608
Computers and computer software	416	416
Lab equipment	18,656	13,100
Leasehold improvements	1,353	1,353
Total property and equipment	22,033	16,477
Less: accumulated depreciation and amortization	(6,828)	(6,117)
Property and equipment, net	$ 15,205	$ 10,360

Depreciation and amortization expense for the three months ended March 31, 2023 and 2022 was $0.7 million and $0.6 million, respectively.

Accrued Expenses

Accrued expenses as of March 31, 2023 and December 31, 2022 consisted of the following:

	March 31, 2023	December 31, 2022
	(in thousands)	
Clinical studies	$ 1,713	$ 1,518
Other research and development [(1)]	13,939	12,446
Other accrued expenses	2,699	1,411
Total	$ 18,351	$ 15,375

(1) The balances as of March 31, 2023 and December 31, 2022 include $5.0 million of accrued manufacturing rights. See Note 6, “Commitments and Contingencies, Sutro Option Agreement,” for further details.

5. Leases

Operating Lease Obligations

In January 2021, we entered into a lease agreement for our current corporate headquarters facility located in San Carlos, California and a license agreement for temporary lab and office space in Palo Alto, California. The lease term for our current corporate headquarters facility began on December 3, 2021 and expires on December 31, 2025. We have two 60-month renewal options. We extended the license agreement for our temporary headquarters in the Palo Alto office by 60 days to March 3, 2022 to accommodate our relocation plan. The original term of the license agreement for the temporary space in Palo Alto terminated when the San Carlos office leasehold improvements were completed and we moved into our current corporate headquarters. These two agreements are accounted for as a combined lease because the contracts were negotiated as a package with the same commercial objective. Upon commencement of the San Carlos lease in December 2021, we recorded a ROU asset and lease liability of $28.4 million and $12.9 million, respectively.

In July 2016, we entered into a five-year lease agreement for our previous headquarters facility located in Foster City, California. The original term of the lease was from September 1, 2016 to August 31, 2021, with two 30-month renewal options. In July 2019, we leased another facility in Foster City, California as a result of growth in personnel and lab space requirements. The original term of this lease was from July 1, 2019 to October 31, 2021, with no renewal options. In November 2020, we extended the terms of both of these leases for six months to March 1, 2022 and April 30, 2022, respectively. In February 2022, we entered into an early termination agreement for one of the facilities in Foster City and terminated our lease on February 12, 2022 instead of April 30, 2022.

Information related to our lease are as follows (dollar amounts in thousands):

	Three Months Ended	
	March 31, 2023	March 31, 2022
Cash paid for operating lease liabilities	$ 1,671	$ 621
Weighted-average remaining lease term (in years)	2.54	3.54
Weighted-average discount rate	7.6%	7.6%

Maturities of lease liabilities as of March 31, 2023 were as follows:

Years ending December 31,	(in thousands)
Remainder of 2023	$ 4,456
2024	6,850
2025	7,022
Thereafter	—
Total future undiscounted lease payments	18,328
Less: Imputed interest	(1,743)
Total lease liabilities	$ 16,585

Rent expense recognized under the leases was $1.9 million and $2.2 million for the three months ended March 31, 2023 and 2022, respectively.

6. 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 March 31, 2023, we did not have any material indemnification claims that were probable or reasonably possible and consequently have not recorded related liabilities.

Indemnification

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 director and officer 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 Agreement

In October 2016, we entered into a non-exclusive development and manufacturing services agreement, as amended, with Lonza (the “2016 Lonza DMSA”) pursuant to which Lonza was obligated to perform manufacturing process development and the manufacture of components for VAX-24, including the polysaccharide antigens, our proprietary eCRM protein carrier and conjugated drug substances. Subject to the terms and conditions set forth in the 2016 Lonza DMSA, Lonza 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 manufactured under the

2016 Lonza DMSA (each term as defined in the 2016 Lonza DMSA). The term of the 2016 Lonza DMSA expired on March 31, 2023. In September 2017, we and Lonza agreed to defer the completion payments for any stage that commenced after December 31, 2019 or had not been completed by December 31, 2019 until the earlier of the completion of all Investigational New Drug ("IND")-enabling activities or December 31, 2020. In March 2020, Lonza agreed to defer the completion payments until the earlier of the completion of all IND-enabling activities or April 30, 2021. In April 2021, Lonza further agreed to defer 50% of the completion payments until the earlier of the completion of all IND-enabling activities or December 31, 2021. Pursuant to this agreement, all deferred completion payments were paid in December 2021.

In June 2018, we entered into a letter agreement with Lonza (the "Lonza Letter Agreement") pursuant to which we agreed to certain terms for potential future payments in shares of our common stock as partial satisfaction of future obligations to Lonza. The Lonza Letter Agreement stated that the initial pre-IND cash payments under the 2016 Lonza DMSA were subject to a specified dollar cap (the "Initial Cash Cap"). After the Initial Cash Cap was reached, we had the option to make any further pre-IND payments owed to Lonza in cash, in shares of our common stock at then market prevailing prices, or a combination of both, at our election. In April 2021, we reached the Initial Cash Cap and notified Lonza that we would be exercising our option to issue approximately $10.0 million in shares of our common stock as payment for a portion of pre-IND payments due April 30, 2021. In June 2021, we issued 399,680 shares of our common stock to Lonza at a price of $25.02 per share to pay for $10.0 million of the pre-IND payments due April 30, 2021.

In October 2018, we entered into a second non-exclusive development and manufacturing services agreement with Lonza (the "2018 Lonza DMSA"), pursuant to which Lonza is obligated to perform services including manufacturing process development and the manufacture and supply of VAX-24 finished drug product. Subject to the terms and conditions set forth in the 2018 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 (each term as defined in the 2018 Lonza DMSA). Unless earlier terminated, the 2018 Lonza DMSA will remain in place for a period of five years. Either party has the right to terminate the 2018 Lonza DMSA upon a six-month notice period, provided that Lonza may not exercise such right until a specified future date. Either party has the right to terminate the 2018 Lonza DMSA if the other party commits a material breach under the applicable agreement and does not cure such breach within a given time period, for specified bankruptcy events or if a party receives a notice from the other party or otherwise becomes aware that a debarment, suspension, exclusion, sanction or declaration of ineligibility action has been brought against the other party, and we may terminate the 2018 Lonza DMSA for an extended force majeure event.

In April 2022, we entered into a third non-exclusive development and manufacturing services agreement, as amended, with Lonza (the "2022 Lonza DMSA") effective as of March 22, 2022. Pursuant to the 2022 Lonza DMSA, Lonza is obligated to perform services including manufacturing process development and clinical manufacture and supply of our proprietary pneumococcal conjugate vaccine ("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 a fourth non-exclusive development and manufacturing services agreement with Lonza (the "2023 Lonza DMSA") effective as of March 1, 2023. Pursuant to the 2023 Lonza DMSA, Lonza will perform manufacturing process development and the manufacture of components for VAX-24 and VAX-31, 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 2016 Lonza DMSA, 2018 Lonza DMSA, 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 right, title and interest in and to any and all New Customer Intellectual Property (as defined in each Lonza Agreement), and Lonza owns all right, title and interest in New General Application Intellectual Property (as defined in each Lonza Agreement).

Sutro Option Agreement

In December 2022, we entered into an Option Agreement with Sutro Biopharma, pursuant to which 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 have agreed to negotiate the terms and conditions of a form definitive agreement to be entered into in the event we exercise the Option, which shall include the terms and conditions set forth in an executed term sheet between us (the "Term Sheet"), and such terms that are necessary to give effect to each of the terms and conditions set forth in the Term Sheet (the "Form Definitive Agreement"). The Option period is five years from the date of the Option Agreement, subject to potential acceleration in the event we undergo a change of control.

As consideration for the Option and other rights and authorizations granted to us under the Option Agreement, we agreed to pay 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 to be 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), and (ii) $5.0 million payable within five business days after we and Sutro Biopharma mutually agree in writing upon the Form Definitive Agreement. 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. In the event that we elect to exercise the Option, we would pay Sutro Biopharma an aggregate Option exercise price of $75.0 million in cash in two installments and, upon the occurrence of certain regulatory milestones, 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.

We determined there is no current alternative future use of the acquired manufacturing rights from the Sutro Option Agreement. As a result, the amounts paid and accrued for were expensed as incurred. As of March 31, 2023 and December 31, 2022, the $5.0 million accrued commitment remains outstanding and is included in accrued expenses in the accompanying condensed balance sheet.

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 March 31, 2023, we had the following amounts due 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)**
Remainder of 2023	$ 97,648
2024	47,478
Total non-cancelable purchase commitments due to our key manufacturing partners	$ 145,126

7. 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 80,640,851 and 79,470,670 shares were issued and outstanding as of March 31, 2023 and December 31, 2022, 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 of directors. As of March 31, 2023 and December 31, 2022, no dividends had been declared. Each share of common stock is entitled to one vote.

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 may elect 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 an 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, which is in addition to the $150.0 million aggregate offering price under the Original ATM Sales Agreement. 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 March 31, 2023, we have sold 534,400 shares of our common stock under the Amended ATM Sales Agreement at an average price of $37.42 per share for aggregate gross proceeds of $20.0 million ($19.6 million net of commissions and offering expenses).

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. In February 2022, the underwriters exercised their option to purchase an additional 750,000 shares of common stock. In aggregate, we received approximately $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.

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. 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.

Common stock reserved for future issuance under the 2020 Equity Incentive Plan (the "2020 Plan") and the 2014 Equity Incentive Plan (the "2014 Plan") was as follows, and excludes 36,710 shares issued outside of the 2014 Plan and 2020 Plan:

	March 31, 2023	December 31, 2022
Options issued and outstanding	9,147,034	7,715,494
Restricted stock units outstanding	773,660	456,766
Shares available for future stock option grants	6,776,052	4,679,598
Total	16,696,746	12,851,858

Refer to Note 14, "Subsequent Events" for details of our underwritten public offering that was closed subsequent to March 31, 2023.

8. Pre-Funded Warrants

In connection with our underwritten public offering in January 2022, we issued 3,250,000 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 connection with our underwritten public offering in October 2022, we issued 17,812,500 shares of our common stock 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.

The public offering price for the pre-funded warrants were equal to the public offering price of our common stock, less the $0.001 exercise price of each pre-funded warrant and were recorded as a component of stockholders' equity within additional paid-in-capital.

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. As of March 31, 2023, no shares underlying the pre-funded warrants had been exercised.

Refer to Note 14, “Subsequent Events” for details of our underwritten public offering that was closed subsequent to March 31, 2023.

9. Equity Incentive Plans

2020 and 2014 Equity Incentive Plans

In June 2020, our board of directors adopted, and our stockholders approved, the 2020 Plan, which became effective on June 11, 2020. Under the 2020 Plan, we may grant stock options, appreciation rights, restricted stock and restricted stock units (“RSUs”) 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. The exercise price of stock options granted under the 2020 Plan must be at least equal to the fair market value of the common stock on the date of grant, except that an incentive stock option granted to an employee who owns more than 10% of the shares of our common stock shall have an exercise price of no less than 110% of the fair value per share on the grant date and expire five years from the date of grant. The maximum term of stock options granted under the 2020 Plan is 10 years, unless subject to the provisions regarding 10% stockholders. Our stock options granted to new employees generally vest over four years at a rate of 25% upon the first anniversary of the vesting commencement date and monthly thereafter. Our other stock options granted to employees generally vest on terms consistent with stock options granted to new employees or monthly over four years from the vesting commencement date. Our RSUs granted to new employees generally vest over four years at a rate of 25% upon one year from the grant date, then 12.5% every six months thereafter. Our other RSUs granted to employees generally vest over three and a half years at a rate of 25% upon six months from the grant date, then 12.5% every six months thereafter. 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 will be automatically increased on the first day of each calendar year during the ten-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 of directors. Effective January 1, 2023, the number of shares of common stock available under the 2020 Plan increased by 3,973,533 shares pursuant to the evergreen provision. As of March 31, 2023, an aggregate of 6,776,052 shares of common stock were available for issuance under the 2020 Plan.

Our 2014 Plan permitted the granting of incentive stock options, non-statutory stock options, restricted stock and other stock-based awards. Subsequent to the adoption of the 2020 Plan, no additional equity awards can be made under the 2014 Plan. As of March 31, 2023, 2,488,567 shares and 7,432,127 shares of common stock were subject to outstanding options and RSUs under the 2014 Plan and 2020 Plan, respectively.

The terms of the 2014 Plan permit the exercise of options granted prior to vesting, subject to required approvals. The unvested shares are subject to our lapsing repurchase right upon termination of employment at the original purchase price. Shares purchased by employees pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be issued until those shares vest according to their respective vesting schedules. Cash received for early exercised stock options is recorded as other liabilities on the condensed balance sheet and is reclassified to common stock and additional paid-in capital as such shares vest.

At March 31, 2023 and December 31, 2022, 2,779 and 3,705 shares, respectively, remained subject to our right of repurchase as a result of the early exercised stock options. The remaining liabilities related to early exercised shares as of March 31, 2023 and December 31, 2022 were both less than $0.1 million and were recorded in other liabilities.

Stock Options and Restricted Stock Units Activity

Stock options and RSUs activity under our 2020 Plan and 2014 Plan, which excludes options to purchase 36,710 shares granted outside of the 2020 Plan and 2014 Plan, was as follows:

		Options Outstanding			
Stock Options and Restricted Stock Units Activity	Options and Restricted Stock Units Available for Grant	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balances — December 31, 2022	4,679,598	7,715,494	$ 18.70		
Additional shares authorized	3,973,533				
Options granted	(1,574,642)	1,574,642	$ 41.84		
Options exercised	1,080 (1)	(102,044)	$ 5.40		
Options forfeited	41,058	(41,058)	$ 31.95		
Restricted stock units granted	(374,458)				
Restricted stock units withheld	17,525				
Restricted stock units forfeited	12,358				
Balances — March 31, 2023	6,776,052	9,147,034	$ 22.77	8.32	$ 146,986
Vested and expected to vest — March 31, 2023		9,147,034	$ 22.77	8.32	$ 146,986
Exercisable at March 31, 2023		3,242,028	$ 10.88	6.85	$ 86,670

(1) Net exercise – shares returned to the Plan.

During the three months ended March 31, 2023 and 2022, 100,964 and 91,044 shares of stock options, respectively, were exercised for cash at a weighted-average price per share of $5.40 and $3.18, respectively. The weighted-average grant date fair value of options granted for the three months ended March 31, 2023 and 2022 was $27.18 and $16.34, respectively. The intrinsic value of the stock options exercised was $3.8 million and $1.8 million for the three months ended March 31, 2023 and 2022, respectively.

In March 2022, our board of directors 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 (the “RSU Agreement”), which is intended to serve as a standard form agreement for RSU grants issued to employees. RSU activity for the three months ended March 31, 2023 was as follows:

	Shares	Weighted-Average Grant-Date Fair Value
Unvested at December 31, 2022	456,766	$ 26.70
Granted	374,458	41.59
Vested and released	(45,206)	24.58
Cancelled	(12,358)	33.67
Unvested at March 31, 2023	773,660	$ 33.92

The weighted-average grant date fair value of RSUs granted during the three months ended March 31, 2023 and 2022 was $41.59 and $24.67, respectively. The aggregate fair value of unvested RSU is calculated using the closing price of our common stock on the grant date. As of March 31, 2023, the unrecognized stock-based compensation cost of unvested RSUs was $24.4 million, which is expected to be recognized over a weighted-average period of 3.1 years.

2020 Employee Stock Purchase Plan

In June 2020, our board of directors 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 will be automatically increased on the first day of each calendar year during the ten-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 of directors. Activity under our 2020 ESPP was as follows:

	Shares
Balance - December 31, 2021	1,070,704
Additional shares authorized	530,319
Shares purchased	(61,709)
Balance - December 31, 2022	1,539,314
Additional shares authorized	794,706
Shares purchased	—
Balance - March 31, 2023	2,334,020

Effective January 1, 2023, the number of shares of common stock available under the 2020 ESPP increased by 794,706 shares pursuant to the evergreen provision of the 2020 ESPP.

Stock-based Compensation

We estimated the fair value of employee stock options using the Black-Scholes option-pricing model for the three months ended March 31, 2023 and 2022 using the following weighted-average assumptions:

	Three Months Ended March 31,	
	2023	2022
Fair Value Assumptions		
Expected volatility	73.6% - 74.0%	78.1% - 78.9%
Expected dividend yield	0%	0%
Expected term (in years)	5.3 - 5.4	5.4
Risk-free interest rate	3.7% - 4.3%	1.6% - 2.4%

We estimated the fair value of shares under the 2020 ESPP using the Black-Scholes option-pricing model for the three months ended March 31, 2023 and 2022 using the following weighted-average assumptions:

	Three Months Ended March 31,	
	2023	2022
Fair Value Assumptions		
Expected volatility	86.4% - 99.7%	86.7% - 97.5%
Expected dividend yield	0%	0%
Expected term (in years)	0.5 - 2.0	0.5 - 2.0
Risk-free interest rate	4.5% - 4.7%	0.1% - 0.5%

We recorded total stock-based compensation expense for the three months ended March 31, 2023 and 2022 related to the 2014 Plan, the 2020 Plan and the 2020 ESPP in the condensed statements of operations and allocated the amounts as follows:

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Research and development	$ 4,527	$ 1,775
General and administrative	5,121	2,324
Total	$ 9,648	$ 4,099

10. Retirement Plan

We sponsor a qualified 401(k) Plan. The 401(k) Plan is a defined contribution plan covering eligible employees. Participants may contribute a portion of their annual compensation limited to a maximum annual amount set by the Internal Revenue Service. For the three months ended March 31, 2023 and 2022, the Company contributed $0.4 million and $0.2 million, respectively, to the retirement plan.

11. Funding Arrangement

In July 2019, we received a cost-reimbursement research award from Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (“CARB-X”), a public-private partnership funded under a Cooperative Agreement from Assistant Secretary for Preparedness and Response/Biomedical Advanced Research and Development Authority (“BARDA”) and by awards from Wellcome Trust, Germany’s Federal Ministry of Education and Research, the United Kingdom Global Antimicrobial Resistance Innovation Fund and the Bill & Melinda Gates Foundation. In connection with this funding, we entered into a cost-reimbursement sub-award agreement with the Trustees of Boston University, the administrator of the program. The initial award provided the potential for funding up to four years to develop a universal vaccine to prevent infections caused by Group A Strep bacteria, which include pharyngitis, impetigo and necrotizing fasciitis. The initial award committed initial funding of up to $1.6 million for our VAX-A1 program and, subject to a CARB-X decision to extend the options, up to $15.1 million in total funding available upon achievement of development milestones over the next four years. Specified research expenditures are reimbursable expenses associated with agreed-upon activities needed to advance the research project supported by the grant. These expenditures can include labor, laboratory supplies, travel, consulting and third-party vendor research and development support costs. CARB-X has awarded us total funding to date of $11.7 million, with potential funding of up to $14.6 million upon the achievement of future VAX-A1 development milestones.

In April 2021, we received a cost-reimbursement research award from the National Institutes of Health (“NIH”). In connection with this funding, we entered into a cost-reimbursement sub-award agreement with the University of Maryland, Baltimore, the administrator of the program. The award provides for potential funding up to five years totaling approximately $0.5 million to develop a vaccine to prevent infections caused by Shigella.

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 $0.7 million and $0.2 million of grant income under the CARB-X and Shigella awards and recorded the amounts in Other income (expense), net in the condensed statement of operations during the three months ended March 31, 2023 and 2022, respectively. A grant receivable of $1.3 million and $1.0 million representing unreimbursed, eligible costs incurred under the CARB-X and Shigella agreements was recorded and included in Prepaid expenses and other current assets in the condensed balance sheets as of March 31, 2023 and December 31, 2022, respectively.

12. 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:

	Three Months Ended March 31,	
	2023	2022
Net loss (in thousands)	$ (60,462)	$ (38,986)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted[(1)]	86,206,817	57,547,808
Net loss per share, basic and diluted	$ (0.70)	$ (0.68)

(1) Includes shares of common stock into which pre-funded warrants may be exercised as of March 31, 2023 and does not include any pre-funded warrants issued subsequent to that date. See Note 8 - Pre-Funded Warrants.

The following potentially dilutive securities outstanding as of the periods presented below were excluded from the computation of diluted net loss per share for the three months ended March 31, 2023 because including them would have been antidilutive:

	As of March 31,	
	2023	2022
Stock options	9,183,744	6,859,801
Restricted stock units	773,660	373,441
Employee stock purchase plan shares	117,203	—
Total	10,074,607	7,233,242

13. Income Taxes

In determining quarterly provisions for income taxes, we use the annual estimated effective tax rate applied to the actual year-to-date profit or loss, adjusted for discrete items arising in that period. Our annual estimated effective tax rate differs from the U.S. federal statutory rate primarily as a result of state taxes and changes in our valuation allowance against our deferred tax assets. For all periods presented, we have incurred net pre-tax losses in the United States. During the three months ended March 31, 2023, there were no material changes to our unrecognized tax benefits, and we do not expect to have any significant changes to unrecognized tax benefits through the end of the fiscal year. For the three months ended March 31, 2023, we reported zero tax provision. We do not have any tax audits or other issues pending.

14. Subsequent Events

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. In aggregate, we received $545.1 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.

Item 2. 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 condensed financial statements and related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto for the year ended December 31, 2022 filed with the Securities and Exchange Commission, or the SEC, on February 27, 2023. This discussion and analysis contains 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 Quarterly Report on Form 10-Q. You should carefully read the "Risk Factors" section of this Quarterly Report on Form 10-Q 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 developing broad-spectrum conjugate and novel protein vaccines to prevent or treat bacterial infectious diseases. We are re-engineering the way highly complex vaccines are made through modern synthetic techniques, including advanced chemistry and the XpressCF cell-free protein synthesis platform, exclusively licensed from Sutro Biopharma, Inc., or Sutro Biopharma. Unlike conventional cell-based approaches, our system for producing difficult-to-make proteins and antigens is intended to accelerate our ability to efficiently create and deliver high-fidelity vaccines with enhanced immunological benefits.

Our pipeline includes:

- Pneumococcal conjugate vaccine, or PCV, candidates that we believe are among the most broad-spectrum PCV candidates currently in development, targeting the approximately $7 billion global pneumococcal vaccine market. Pneumococcal disease is an infection caused by Streptococcus pneumoniae, or pneumococcus, bacteria. It can result in invasive pneumococcal disease, or IPD, including meningitis and bacteremia, and non-invasive pneumococcal disease, including pneumonia, otitis media and sinusitis.

    - Our lead vaccine candidate, VAX-24, is a 24-valent, broad-spectrum investigational PCV being developed for the prevention of IPD. VAX-24 is intended to improve upon the standard-of-care PCV vaccines for both children and adults by covering the serotypes that are responsible for most of the pneumococcal disease currently in circulation.

        - VAX-24 Adult Program:

            - On October 24, 2022, we announced positive topline results from both the Phase 1 and Phase 2 portions of a clinical proof-of-concept study evaluating the safety, tolerability and immunogenicity of VAX-24 in 800 healthy adults aged 18-64. 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 Pfizer Inc.'s, or Pfizer's, Prevnar 20®, or PCV20, in 64 healthy adults aged 18-49. 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 aged 50-64. VAX-24 met the primary safety and tolerability objectives, demonstrating a safety profile similar to PCV20, for all doses studied. In this study, VAX-24 met or exceeded the established regulatory immunogenicity standards for all 24 serotypes at the conventional 2.2mcg dose, which we intend to move forward into a Phase 3 program. At this dose, VAX-24 met the standard opsonophagocytic activity, or OPA, response non-inferiority criteria for all 20 serotypes common with PCV20, of which 16 achieved higher immune responses. Additionally, at all three doses, VAX-24 met the standard superiority criteria for all four serotypes unique to VAX-24. VAX-24 has the potential to cover an additional 10-28 percent of strains causing IPD in adults over the current standard-of-care PCVs.
            - On April 17, 2023, we announced positive results from a 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. The Phase 2 study in adults aged 65 and older evaluated the

safety, tolerability and immunogenicity of a single injection of VAX-24 at three dose levels, 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. In this Phase 2 study, VAX-24 demonstrated robust OPA immune responses for all 24 serotypes at all doses studied, confirming the prior adult study results. The VAX-24 2.2mcg dose, which we plan to advance to Phase 3, 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. In the prespecified pooled analyses of data from both adult studies, VAX-24 met the OPA response non-inferiority criteria for all 20 serotypes common with PCV20 and met the superiority criteria for the four additional serotypes unique to VAX-24.

  - We expect to hold regulatory interactions with the U.S. Food and Drug Administration, or the FDA, in the second half of 2023 to inform the Phase 3 program. We expect topline safety, tolerability and immunogenicity data from the Phase 3 pivotal, non-inferiority study in adults in 2025. The FDA has granted Fast Track and Breakthrough Therapy designations for VAX-24 in adults.

- VAX-24 Pediatric Program: In March 2023, we announced that the first participants were dosed in a Phase 2 study of VAX-24 in healthy infants, after the FDA cleared our Investigational New Drug, or IND, application in February 2023. The Phase 2 infant study is being conducted in two stages. Stage 1 of the study is evaluating 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 VAXNEUVANCE®, or PCV15 in approximately 48 infants in a dose-escalation approach. The Stage 2 portion will evaluate the safety, tolerability and immunogenicity of VAX-24 at the same three dose levels and compared to PCV15 or PCV20 in approximately 750 infants. The study design includes a primary immunization series consisting of three doses followed by a subsequent booster dose. We expect to share topline safety, tolerability and immunogenicity data following the primary three-dose immunization series by 2025.

o Our second PCV candidate, VAX-31, builds on what has been established with VAX-24 and is designed to expand the breadth of coverage to 31 strains without compromising immunogenicity due to carrier suppression. VAX-31 was designed to provide coverage for approximately 90% of pneumococcal disease currently circulating in the U.S. population. We anticipate the submission of the VAX-31 adult IND application to the FDA and announcement of subsequent FDA clearance in the second half of 2023. We expect topline safety, tolerability and immunogenicity data from a Phase 1/2 study in adults in 2024.

o VAX-A1, a novel conjugate vaccine candidate designed to prevent disease caused by Group A Streptococcus, or Group A Strep. Group A Strep is pervasive globally and causes 700 million cases of illness annually, including pharyngitis, or strep throat, and certain severe invasive infections such as sepsis, necrotizing fasciitis and toxic shock syndrome. 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 the very young. We believe we have demonstrated preclinical proof of concept for VAX-A1, the data for which were published in December 2020. We nominated the final vaccine candidate for VAX-A1 in the first quarter of 2021 and initiated IND-enabling activities in the second half of 2021. We continue to advance the development of VAX-A1 and we intend to provide further information about the anticipated timing of an IND application as the program progresses.

o VAX-PG, a novel protein vaccine candidate targeting the keystone pathogen responsible for periodontitis, a chronic oral inflammatory disease affecting an estimated 65 million adults in the United States. We believe we have generally demonstrated preclinical proof of concept for a periodontitis protein vaccine, the data for which was published in February 2019. We nominated a final vaccine candidate for VAX-PG in the fourth quarter of 2022 and we continue to progress the program. Our initial goal is to develop a therapeutic vaccine to slow or stop disease progression; however, the results from clinical trials may inform the potential adoption of prophylactic immunization.

o VAX-GI, a new vaccine program designed to prevent Shigella, a bacterial illness that affects an estimated 188 million people worldwide each year and results in approximately 164,000 deaths annually, mostly among

children under five years of age in low- and middle-income settings.

- 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, 2023, key developments affecting our business include the following:

- ***Reported VAX-24 Phase 2 Program Results, Including Adult 65+ Data and Full Six-Month Safety Data from Both Studies:*** In April 2023, we announced positive results from the VAX-24 Phase 2 study 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. The Phase 2 study in adults aged 65 and older evaluated the safety, tolerability and immunogenicity of a single injection of VAX-24 at three dose levels, 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. In this Phase 2 study, VAX-24 demonstrated robust OPA immune responses for all 24 serotypes at all doses studied, confirming the prior adult study results. The VAX-24 2.2mcg dose, which we plan to advance to Phase 3, 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. In the prespecified pooled analyses of data from both adult studies, VAX-24 met the OPA response non-inferiority criteria for all 20 serotypes common with PCV20 and met the superiority criteria for the four additional serotypes unique to VAX-24.
- ***Completed Successful $575 Million Follow-On Financing:*** 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. The aggregate gross proceeds to us from the offering were $575.2 million, before deducting underwriting discounts and commissions and other estimated offering expenses payable by us, and excluding the exercise of any pre-funded warrants.
- ***Dosed First Participants in Infant Phase 2 Study Evaluating VAX-24 for the Prevention of IPD:*** In March 2023, we announced that the first participants were dosed in the Phase 2 study of VAX-24 in healthy infants, after the FDA cleared our IND application in February 2023. This study is evaluating the safety, tolerability and immunogenicity of VAX-24, our lead, broad-spectrum 24-valent PCV candidate designed to prevent IPD.
- ***Announced New Vaccine Program VAX-GI:*** In February 2023, we announced that we added a new vaccine program, VAX-GI, designed to prevent Shigella, a bacterial illness that affects an estimated 188 million people worldwide each year and results in approximately 164,000 deaths annually, mostly among children under five years of age in low- and middle-income settings.
- ***VAX-24 Granted Breakthrough Therapy Designation from FDA for the Prevention of IPD in Adults Aged 18 and Older:*** In January 2023, we announced that the FDA granted Breakthrough Therapy designation for VAX-24 for the prevention of IPD in adults. With Breakthrough Therapy designation, we will have access to all of the elements of the FDA's Fast Track program, as well as the ability to receive guidance and support from the FDA on an efficient drug development program and an organizational commitment from senior managers within the FDA. The FDA's decision was based on positive topline results from the Phase 1/2 proof-of-concept study of VAX-24 in adults 18-64 years of age.

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 and 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, or 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 preclinical studies, clinical trials and manufacturing activities, and our expenditures on other research and development activities. Our net loss was $60.5 million for the three months ended March 31, 2023. As of March 31, 2023, we had an accumulated deficit of $582.6 million. As of March 31, 2023, we had cash, cash equivalents and investments of $949.9 million, which we believe will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months from the filing date of this Quarterly Report on Form 10-Q.

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 our Phase 3 program for and a potential commercial launch of VAX-24;
- incur additional costs that may be required for secondary supply sources;
- require the manufacture of supplies for our clinical trials, in particular our clinical trials for our PCV candidates, VAX-24 and VAX-31;
- pursue regulatory approval of our vaccine candidates;
- establish additional manufacturing capacity to meet potential incremental supply requirements following the potential initial commercial launch of VAX-24;
- hire additional personnel;
- operate as a public company;
- acquire, discover, validate and develop additional vaccine candidates; and
- obtain, maintain, expand and protect our intellectual property portfolio.

We rely and will continue to rely on third parties 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 or 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

In October 2016, we entered into a non-exclusive development and manufacturing services agreement, as amended, with Lonza, or the 2016 Lonza DMSA, pursuant to which Lonza was obligated to perform manufacturing process development and the manufacture of components for VAX-24, including the polysaccharide antigens, our proprietary eCRM protein carrier and conjugated drug substances. Subject to the terms and conditions set forth in the 2016 Lonza DMSA, Lonza 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 manufactured under the 2016 Lonza DMSA (each term as defined in the 2016 Lonza DMSA). The term of the 2016 Lonza DMSA expired on March 31, 2023.

In June 2018, we entered into a letter agreement with Lonza, or the Lonza Letter Agreement, pursuant to which we agreed to certain terms for potential future payments in shares of our common stock as partial satisfaction of future obligations to Lonza. The Lonza Letter Agreement stated that the initial pre-IND cash payments under the 2016 Lonza DMSA were subject to a specified dollar

cap, or the Initial Cash Cap. After the Initial Cash Cap was reached, we had the option to make any further pre-IND payments owed to Lonza in cash, in shares of our common stock at then market prevailing prices, or a combination of both, at our election. In April 2021, we reached the Initial Cash Cap and notified Lonza that we would be exercising our option to issue approximately $10.0 million in shares of our common stock as payment for a portion of pre-IND payments due April 30, 2021. In June 2021, we issued 399,680 shares of our common stock to Lonza at a price of $25.02 per share to pay for $10.0 million of the pre-IND payments due April 30, 2021.

In October 2018, we entered into a second non-exclusive development and manufacturing services agreement with Lonza, or the 2018 Lonza DMSA, pursuant to which Lonza is obligated to perform services including manufacturing process development and the manufacture and supply of VAX-24 finished drug product. Subject to the terms and conditions set forth in the 2018 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 (each term as defined in the 2018 Lonza DMSA). Unless earlier terminated, the 2018 Lonza DMSA will remain in place for a period of five years. Either party has the right to terminate the 2018 Lonza DMSA upon a six-month notice period, provided that Lonza may not exercise such right until a specified future date. Either party has the right to terminate the 2018 Lonza DMSA if the other party commits a material breach under the applicable agreement and does not cure such breach within a given time period, for specified bankruptcy events or if a party receives a notice from the other party or otherwise becomes aware that a debarment, suspension, exclusion, sanction or declaration of ineligibility action has been brought against the other party, and we may terminate the 2018 Lonza DMSA for an extended force majeure event.

In April 2022, we entered into a third non-exclusive development and manufacturing services agreement with Lonza, as amended, or the 2022 Lonza DMSA, effective as of March 22, 2022. 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 a fourth non-exclusive development and manufacturing services agreement with Lonza, or the 2023 Lonza DMSA, effective as of March 1, 2023. Pursuant to the 2023 Lonza DMSA, Lonza will perform manufacturing process development and the manufacture of components for VAX-24 and VAX-31, 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 2016 Lonza DMSA, 2018 Lonza DMSA, 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 right, title and interest in New General Application Intellectual Property (as defined in each Lonza Agreement).

For additional details regarding our relationship with Lonza, see Note 6, “Commitments and Contingencies,” to our condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Sutro Biopharma

Sutro Biopharma is a clinical stage, publicly traded drug discovery, development and manufacturing company using precise protein engineering and rational design (enabled by Sutro Biopharma's proprietary XpressCF platform technology) to advance next-generation oncology therapeutics. Following our corporate formation, we acquired an exclusive license to Sutro Biopharma's proprietary cell-free protein synthesis platform, XpressCF, for the discovery, development and sale of vaccines for the treatment or prevention of infectious diseases, excluding cancer vaccines. Under a related supply agreement with Sutro Biopharma, we have an exclusive relationship in our field to buy extract and certain custom reagents for use in manufacturing the vaccine compositions covered by the exclusive license, which we use to produce our protein carriers and certain of our antigens. Under a separate agreement with Sutro Biopharma, we enhanced our rights with respect to access to a second supplier of extract and acquired an option to access expanded rights to develop and manufacture extract, among other rights.

Amended and Restated License Agreement with Sutro Biopharma

We are party to a license agreement with Sutro Biopharma, or the Sutro Biopharma License Agreement, on August 1, 2014. The Sutro Biopharma License Agreement was amended on October 12, 2015 and again on May 9, 2018 and May 29, 2018. 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 ten years after the first commercial sale of such vaccine composition. The latest expiration date of a licensed Sutro Biopharma patent application, if issued, would be 2036, subject to any adjustment or extension of patent term that may be available in a particular country. In addition, we are obligated to pay Sutro Biopharma a percentage of net sublicensing revenue received in the low teen percentages. In addition, in the event we sublicense our non-manufacturing rights under the Sutro Biopharma License Agreement before a specified date, we are obligated to pay Sutro Biopharma a percentage, in the low double-digits, of the sublicensing revenue we receive under such agreement.

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 with Sutro Biopharma

In May 2018, we entered into a supply agreement, or the Sutro Biopharma Supply Agreement, with Sutro Biopharma pursuant to which we purchase from Sutro Biopharma extract and custom reagents for use in manufacturing non-clinical and certain clinical supply of vaccine compositions utilizing the technology licensed under the Sutro 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) or the date that we and Sutro Biopharma enter into the Phase 3/Commercial Supply Agreement and Sutro 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 with Sutro Biopharma

In December 2022, we entered into an option grant agreement with Sutro Biopharma, or 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, or the Option. We and Sutro Biopharma have agreed to negotiate the terms and conditions of a form definitive agreement to be entered into in the event we exercise the Option, which shall include the terms and conditions set forth in an executed term sheet between us, or the Term Sheet, and such terms that are necessary to give effect to each of the terms and conditions set forth in the Term Sheet, or the Form Definitive Agreement. The Option period is five years from the date of the Option Agreement, subject to potential acceleration in the event we undergo a change of control.

As consideration for the Option and other rights and authorizations granted to us under the Option Agreement, we agreed to pay 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 to be 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), and (ii) $5.0 million payable within five business days after we and Sutro Biopharma mutually agree in writing upon the Form Definitive Agreement. 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. In the event that we elect to exercise the Option, we would pay Sutro Biopharma an aggregate Option exercise price of $75.0 million in cash in two installments and, upon the occurrence of certain regulatory milestones, 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.

For additional details regarding our outstanding non-cancelable purchase commitments with our manufacturing partners, see Note 6, "Commitments and Contingencies," to our condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Impact of COVID-19 and Other Trends

We are continuing to closely monitor the impact of the global COVID-19 pandemic on our business. In particular, the COVID-19 pandemic slowed raw material supply chains and travel restrictions delayed the qualification of key analytical equipment used in manufacturing and curtailed in-person CMO oversight of manufacturing, affecting our manufacturing processes. As the pandemic continues, we could see an additional impact on our ability to advance our programs, obtain supplies from our contract manufacturers or interact with regulators, ethics committees or other important agencies due to limitations in regulatory authority, employee resources or otherwise. In any event, if the COVID-19 pandemic continues and persists for an extended period of time, we could experience significant disruptions to our development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

Additionally, the recent trends towards rising inflation may also 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, interest rates and overhead costs may adversely affect our operating results. Rising interest and inflation rates also present a recent 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, supply chain constraints, and consequences associated with COVID-19 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 and include personnel-related costs (including salaries, employee benefits and stock-based compensation) for our personnel in research and development functions; costs related to acquiring, developing and manufacturing supplies for preclinical studies, clinical trials and other studies, including fees paid to CMOs; costs and expenses related to agreements with contract research organizations, or CROs, investigative sites and consultants to conduct non-clinical and preclinical studies and clinical trials; professional and consulting services costs; research and development consumables costs; laboratory supplies and equipment costs; and facility and other allocated costs.

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

We expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance our vaccine candidates into and through preclinical studies and clinical trials, scale up our manufacturing activities, establish additional manufacturing capacity to meet potential incremental supply requirements following the potential initial commercial launch of VAX-24, 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 chemistry, manufacturing and controls, or CMC, activities, including fulfilling good manufacturing practice, or GMP, related standards and compliance, and identifying and qualifying second suppliers;
- the costs related to raw materials estimates from our third-party manufacturing and supply partners;
- the cost of clinical trials of our vaccine candidates being greater than we anticipate;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

- the number of sites included in the trials;
- the countries in which the trials are conducted;
- delays in adding a sufficient number of trial sites and recruiting suitable 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 initial commercial launch of VAX-24;
- the costs that may be required for secondary supply sources; and
- the immunogenicity or efficacy and safety 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 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. We expect continued increases in general and administrative expenses related to compliance with the rules and regulations of the SEC and The Nasdaq Stock Market LLC, or Nasdaq, insurance expenses, investor relations and corporate communications activities and other administrative and professional services.

Other Income (Expense), Net

Other income (expense), net includes interest income earned from our cash and cash equivalents, grant income and foreign currency transaction gains (losses) related to our Swiss Franc and Euro cash and liability balances (see Note 2, “Basis of Presentation and Summary of Significant Accounting Policies” and Note 3, “Fair Value Measurements and Fair Value of Financial Instruments” to our condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for more detail).

Grant Income

In July 2019, we received a cost-reimbursement research award from Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator, or CARB-X, a public-private partnership funded under a Cooperative Agreement from Assistant Secretary for Preparedness and Response/Biomedical Advanced Research and Development Authority and by awards from Wellcome Trust, Germany’s Federal Ministry of Education and Research, the United Kingdom Global Antimicrobial Resistance Innovation Fund and the Bill & Melinda Gates Foundation. In connection with this funding, we entered into a cost-reimbursement sub-award agreement with the Trustees of Boston University, the administrator of the program, or the CARB-X agreement. CARB-X has awarded us total funding to date of $11.7 million, with potential funding of up to $14.6 million upon the achievement of future VAX-A1 development milestones. Separately, the National Institute of Health, or NIH, awarded us up to $0.5 million in April 2021 to advance the development of a vaccine against Shigella infection. Grant income pursuant to our award agreements is recognized as we incur and pay qualifying expenses over the periods of the awards. We recognized $0.7 and $0.2 million in grant income for funding research and development during the three months ended March 31, 2023 and 2022, respectively. Grant income is included as a component of Other income (expense), net in the condensed statements of operations.

Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

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

	Three Months Ended March 31,		Change	
	2023	2022	$	%
	(in thousands)			
Operating expenses:				
Research and development	$ 58,080	$ 31,678	$ 26,402	83.3 %
General and administrative	13,112	7,543	5,569	73.8 %
Total operating expenses	71,192	39,221	31,971	81.5 %
Loss from operations	(71,192)	(39,221)	(31,971)	81.5 %
Other income (expense), net:				
Interest income	10,393	134	10,259	*
Grant income	654	160	494	308.8 %
Realized loss on marketable securities	—	(65)	65	(100.0)%
Foreign currency transaction gains (losses)	(317)	6	(323)	*
Total other income (expense), net	10,730	235	10,495	*
Net loss	$ (60,462)	$ (38,986)	$ (21,476)	55.1 %

** not meaningful*

Operating Expenses

Research and Development Expenses

The following table summarizes our research and development expenses for the periods presented:

	Three Months Ended March 31,		Change	
	2023	2022	$	%
	(in thousands)			
Product and clinical development [1]	$ 33,095	$ 13,802	$ 19,293	139.8 %
Personnel-related	12,981	6,230	6,751	108.4 %
Professional and consulting services	1,592	1,270	322	25.4 %
Research and development consumables	3,259	4,199	(940)	(22.4)%
Facility related and other allocated	4,599	4,492	107	2.4 %
Laboratory supplies and equipment	1,914	1,250	664	53.1 %
Other [2]	640	435	205	47.1 %
Total research and development expenses	$ 58,080	$ 31,678	$ 26,402	83.3 %

(1) Includes expenses for third-party manufacturing and outsourced contract services, including preclinical studies, clinical trials and outsourced assays.
(2) Includes travel-related expenses and other miscellaneous office expenses.

Research and development expenses increased by $26.4 million, or 83.3%, during the three months ended March 31, 2023 compared to the corresponding period in 2022. The increase of $19.3 million in product and clinical development expenses was primarily due to VAX-24 adult Phase 3 readiness activities and the initiation of our VAX-24 Phase 2 study in healthy infants. The increase of $6.8 million in personnel-related expenses was primarily due to higher salaries, benefits and stock-based compensation expense resulting from the growth in the number of employees in our research and development functions and associated increase in the number of options and restricted stock units, or RSUs, granted.

General and Administrative Expenses

General and administrative expenses increased by $5.6 million, or 73.8%, during the three months ended March 31, 2023 compared to the corresponding period in 2022. The increase was primarily due to increases of $4.4 million in personnel-related expenses, which was related to higher salaries, benefits and stock-based compensation expense resulting from an increase in the number of options and RSUs granted and the growth in the number of employees in our general and administrative functions, and $1.4 million in higher professional and consulting services.

Other Income (Expense), Net

Other income (expense), net increased by $10.5 million, during the three months ended March 31, 2023 compared to the corresponding period in 2022. The increase was primarily attributable to $10.4 million in interest income as a result of higher cash and investment balances resulting from our follow-on offerings in 2022 combined with an increase in the interest rates earned by such cash and investments.

Liquidity and Capital Resources

From inception through March 31, 2023, 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 $1.53 billion in aggregate gross proceeds and $1.46 billion net of underwriting discounts, commissions and offering expenses. As of March 31, 2023, we had $380.5 million of cash and cash equivalents, $569.4 million in investments and an accumulated deficit of $582.6 million.

On July 2, 2021, we filed a shelf registration statement on Form S-3ASR, or the Shelf Registration Statement, under which we may, from time to time, sell securities in one or more offerings of our common stock, preferred stock, debt securities or warrants. The Shelf Registration Statement became automatically effective upon the filing of the Form S-3ASR on July 2, 2021.

In July 2021, we entered into an Open Market Sales Agreement[SM], or the Original ATM Sales Agreement, with Jefferies LLC, or Jefferies, which provided that, upon the terms and subject to the conditions and limitations set forth in the Original ATM Sales Agreement, we may elect 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 an 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, which is in addition to the $150.0 million aggregate offering price under the Original ATM Sales Agreement. The material terms and conditions of the Original ATM Sales Agreement otherwise remain unchanged. Under the Amended ATM Sales Agreement, Jefferies may sell the shares of common stock by any method permitted by law deemed to be an “at-the-market offering” as defined under the Securities Act of 1933, as amended, in block transactions or in privately-negotiated transactions with our consent. Jefferies will use commercially reasonable efforts to sell the shares of common stock subject to the Amended ATM Sales Agreement from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions that we may impose). 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 March 31, 2023, we have sold 534,400 shares of our common stock under the Amended ATM Sales Agreement at an average price of $37.42 per share for aggregate gross proceeds of $20.0 million ($19.6 million net of commissions and offering expenses).

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. In February 2022, the underwriters exercised their option to purchase an additional 750,000 shares of common stock. In aggregate, we received approximately $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.

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. 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.

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. In aggregate, we received $545.1 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.

Future Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to advance our vaccine candidates, expand our corporate infrastructure, including the costs associated with being a public company, further our research and development initiatives for our vaccine candidates 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 Quarterly Report on Form 10-Q will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months from the filing date of this Quarterly Report on Form 10-Q. We have raised substantial capital, however, we will need to raise substantial additional capital to complete development 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 initial commercial launch of VAX-24;
- our potential exercise of the Option with Sutro Biopharma;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies for our PCV candidates, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the cost of building a sales force in anticipation of any product commercialization;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our vaccine candidates for which we receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the 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;
- the costs of operating as a public company; and
- the impact of the COVID-19 pandemic and rising inflation which may impact labor costs, research and development costs 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:

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (47,690)	$ (27,702)
Net cash (used in) provided by investing activities	(448,101)	49,666
Net cash provided by financing activities	41,562	111,019
Effect of exchange rate changes on cash and cash equivalents	23	(227)
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (454,206)	$ 132,756

Cash Flows from Operating Activities

Net cash used in operating activities for the three months ended March 31, 2023 was $47.7 million, which primarily resulted from a net loss of $60.5 million, partially offset by non-cash charges of $6.0 million and a net change in our operating assets and liabilities of $6.8 million. Non-cash charges primarily consisted of $9.6 million in stock-based compensation expense, $1.6 million in amortization of right-of-use, or ROU, assets and $0.7 million in depreciation and amortization, partially offset by a decrease of $6.0 million in net amortization of premiums on investments. The net change in operating assets and liabilities of $6.8 million was primarily due to increases (i) in accrued manufacturing expenses of $6.7 million resulting from increased outsourced manufacturing activities, (ii) in accounts payable and accrued expenses of $4.8 million resulting from the timing of payments and (iii) in accrued compensation of $0.7 million related to higher headcount. These increases were partially offset by (i) an increase in prepaid and other assets of $4.1 million related to prepaid insurance and research costs and (ii) a decrease in operating lease liabilities of $1.4 million related to our San Carlos office.

Net cash used in operating activities for the three months ended March 31, 2022 was $27.7 million, which primarily resulted from a net loss of $39.0 million, partially offset by non-cash charges of $6.9 million and a net change in our operating assets and liabilities of $4.4 million. Non-cash charges primarily consisted of $4.1 million in stock-based compensation expense, $1.8 million in amortization of ROU assets and $0.6 million in depreciation and amortization. The net change in operating assets and liabilities of $4.4 million was primarily due to (i) an increase in operating lease liabilities of $5.6 million related to the San Carlos office, (ii) a decrease in prepaid and other current assets of $2.8 million related to reduced prepaid insurance and prepaid research costs, and (iii) an increase in accrued manufacturing expenses of $2.4 million resulting from increased outsourced manufacturing activities. These changes were partially offset by (i) a decrease in accrued compensation of $2.2 million related to a 2021 accrued bonus payout in March 2022, (ii) a decrease in accounts payable of $1.9 million resulting from the timing of payments and (iii) an increase in other assets of $1.6 million related to purchases of equipment for the transfer of technology in the manufacturing extracts and reagents from Sutro Biopharma to other manufacturers.

Cash Flows from Investing Activities

Cash used in investing activities for the three months ended March 31, 2023 was $448.1 million, which was attributable primarily to $483.8 million in purchase of investments and $5.6 million of purchases of lab equipment and leasehold improvements, partially offset by $40.2 million in maturities of investments and $1.1 million in sales of investments.

Cash used in investing activities for the three months ended March 31, 2022 was $49.7 million, which related primarily to $59.6 million in maturities of investments, partially offset by $7.0 million in purchases of investments and $2.9 million of purchases of lab equipment.

Cash Flows from Financing Activities

Cash provided by financing activities for the three months ended March 31, 2023 was $41.6 million, which primarily consisted of net proceeds from our Original and Amended ATM Sales Agreements of $41.8 million.

Cash provided by financing activities for the three months ended March 31, 2022 was $111.0 million, which primarily consisted of net proceeds from shares issued for our follow-on public offering in January 2022 of $107.6 million and under our Original ATM Sales Agreement of $3.1 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 March 31, 2023, we had total lease payment obligations of $18.3 million, of which $6.2 million is payable within one year.

Option Agreement

Pursuant to the Option Agreement, we and Sutro Biopharma have agreed to negotiate the terms and conditions of the Form Definitive Agreement. Within five business days after we and Sutro Biopharma mutually agree in writing upon the Form Definitive Agreement, we have agreed to pay Sutro Biopharma $5.0 million. Additionally, in the event that we elect to exercise the Option, we would pay Sutro Biopharma an aggregate Option exercise price of $75.0 million in cash in two installments and, upon the occurrence of certain regulatory milestones, 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 condensed balance sheets as of March 31, 2023 or December 31, 2022.

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 March 31, 2023, 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)**
Remainder of 2023	$ 97,648
2024	47,478
Total non-cancelable purchase commitments due to our key manufacturing partners	$ 145,126

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.

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 condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these condensed 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 condensed financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and 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 financial statements included elsewhere in this Quarterly Report on Form 10-Q, 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 financial statements, we are required to estimate our accrued research and development expenses, including accrued 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

Stock-based compensation expense related to awards to employees is measured at the grant date based on the fair value of the award. The fair value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period, net of the impact of actual forfeitures recorded in the period in which they occur.

Stock-based compensation expense related to awards to non-employees is recognized based on the then-current fair value at each measurement date over the associated service period of the award, which is generally the vesting term, using the straight-line method. The fair value of non-employee stock options is estimated using the Black-Scholes valuation model with assumptions generally consistent with those used for employee stock options, with the exception of the expected term, which is the remaining contractual life at each measurement date. Refer to Note 2, “Basis of Presentation and Summary of Significant Accounting Policies” and Note 9, “Equity Incentive Plans,” to our condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information on assumptions used in estimating stock-based compensation expense.

The Black-Scholes option-pricing model requires the use of subjective assumptions, such as volatility, which determine the fair value of stock-based awards. The assumptions utilized in the Black-Scholes option-pricing model are expected term, expected volatility, expected dividend, risk-free interest rate and fair value of common stock.

Leases

We adopted Accounting Standards Update, or ASU 2016-02, *Leases* (*Topic 842*) on January 1, 2021, using the modified retrospective transition approach. There was no cumulative-effect adjustment recorded to retained earnings upon adoption.

Under ASC 842, we assess all arrangements that convey the right to control the use of property, plant and equipment, at inception, to determine if it is, or contains, a lease based on the unique facts and circumstances present in the arrangements. In addition, we determine whether leases meet the classification criteria of a finance or operating lease at the lease commencement date considering: (i) whether the lease transfers ownership of the underlying asset to the lessee at the end of the lease term, (ii) whether the lease contains a bargain purchase option, (iii) whether the lease term is for a major part of the remaining economic life of the underlying asset, (iv) whether 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) whether the underlying asset is of 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 March 31, 2023, our lease population consisted only of operating real estate leases.

Once a lease is identified and its classification determined, we recognize a ROU asset and a corresponding lease liability. Lease liabilities are recorded based on the present value of lease payments over the expected least term. The corresponding ROU asset is measured from the initial lease liability, adjusted by (i) accrued or prepaid rents, (ii) remaining unamortized initial direct costs and lease incentives, and (iii) any impairments of the ROU asset.

Significant assumptions utilized in recognizing the ROU assets and corresponding lease liabilities included the expected lease term and the incremental borrowing rate. The expected lease term includes both contractual lease periods and, as applicable, extensions of the lease term when we have determined the exercise of the option to extend is reasonably certain to occur. The incremental borrowing rate was utilized to discount lease payments over the expected term given our operating leases do not provide an implicit rate. We estimated 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.

For additional details regarding the impact of adoption and disclosure, see Note 5, “Leases,” to our condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Recently Adopted Accounting Pronouncements

There were no applicable recent accounting pronouncements, and we did not adopt any new accounting standards during the quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our cash and cash equivalents as of March 31, 2023 and December 31, 2022 consisted of readily available checking and money market funds. As of March 31, 2023, 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 March 31, 2023 and December 31, 2022, we had approximately $949.9 million and $957.9 million in cash and investments. For the three months ended March 31, 2022, we had interest income of 10.4 million. The following table shows the impact of a hypothetical 10% increase or decrease in interest rates on our net assets as of March 31, 2023 and our net loss for the three months ended March 31, 2023:

Hypothetical Change in Interest Rates	Impact on Net Assets as of March 31, 2023	Impact on Net Loss for the Three Months Ended March 31, 2023
	(in thousands)	
10% increase	$ 3,742	$ 990
10% decrease	$ (3,742)	$ (990)

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 condensed balance sheets. For example, on March 10, 2023, the California Department of Financial Protection and Innovation took control of Silicon Valley Bank, or SVB, and appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. While SVB was our primary bank at the time, we maintained banking relationships with other major banks. The substantial majority of funds we held at SVB, which included cash, cash equivalents and investments were held in custodial accounts of a third-party institution for which SVB Asset Management was the advisor, or SVB Custodial Accounts. On March 12, 2023, the FDIC confirmed that depositors of SVB would have access to all of their money and, as a result, we regained access to all of our funds deposited with SVB. The FDIC subsequently transferred SVB's deposits and loans to a newly created bridge bank, named Silicon Valley Bridge Bank, N.A., or Silicon Valley Bridge Bank. On March 26, 2023, the FDIC announced that First Citizens Bank & Trust Company, or First Citizens Bank, had agreed to purchase and assume all deposits and loans of Silicon Valley Bridge Bank. Management believes that we are not exposed to significant credit risk as our deposits are held at First Citizens Bank, and our investments are held under separate financial institution custodial accounts, each of which management continues to believe to be of high credit quality. We have not experienced any losses on these deposits or investments as a result of this market event. 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. 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 contract with Lonza, our CMO in Switzerland. We have also entered into a limited number of contracts with other parties with payments denominated in foreign currencies. Payments under these contracts are made in foreign currencies and are subject to fluctuations in foreign currency rates. We do not currently have a formal program in place to hedge foreign currency risks. However, from time to time, we buy Swiss Francs, or CHF, which is the majority of our foreign currency exposure, at market and are holding CHF in our bank accounts. As of March 31, 2023 and December 31, 2022, we had approximately $18.2 million and $21.8 million of CHF cash and cash equivalents, respectively, held at one financial institution. As of March 31, 2023 and December 31, 2022, we had foreign currency denominated accounts payable and accrued expenses of $20.3 million and $13.9 million, respectively. For the three months ended March 31, 2023, we had foreign currency transaction losses of $0.3 million. The following table shows the impact of a hypothetical 10% increase or decrease in current exchange rates on our net assets as of March 31, 2023 and our net loss for the three months ended March 31, 2023:

Hypothetical Change in Currency Exchange Rates	Impact on Net Assets as of March 31, 2023	Impact on Net Loss for the Three Months Ended March 31, 2023
	(in thousands)	
10% increase	$ 212	$ 3,162
10% decrease	$ (212)	$ (3,162)

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

Recently, 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 further increase, neither of which we are able to predict. If elevated levels of inflation were to persist or if the rate of inflation were to accelerate, 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 results of operations during the periods presented.

Item 4. Controls and Procedures.

Evaluation 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 Officer, or CEO, and our Chief Financial Officer, or CFO, our principal executive officer and principal financial officer, respectively, has 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, or the Exchange Act, as of March 31, 2023. Based on this evaluation, our CEO and CFO have concluded that our disclosure controls and procedures as of March 31, 2023 were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, that occurred during the quarter ended March 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. 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 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 Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q.

Risks Related to Our Financial Position and Capital Needs

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

To date, we have devoted substantially all of our resources to performing research and development, undertaking preclinical studies, 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 these activities on our behalf. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

We have incurred significant net losses since inception and anticipate that we will continue to incur substantial net losses for the foreseeable future. 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 $223.5 million and $100.1 million for the years ended December 31, 2022 and 2021, respectively, and $60.5 million and $39.0 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of $582.6 million.

We expect to continue to spend significant resources to fund research and development of, and seek regulatory approvals for, our vaccine candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, manufacturing, preclinical testing and clinical trial activities increase. As a result, our accumulated deficit will also increase significantly. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. However, we do not expect to generate any revenue from commercial product 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 March 31, 2023, we had cash, cash equivalents and investments of $949.9 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 Quarterly Report on Form 10-Q. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. We have raised substantial capital, however, we will need to raise substantial additional capital to complete the development 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.

In July 2021, we entered into an Open Market Sales Agreement[SM], or the Original ATM Sales Agreement with Jefferies LLC, or Jefferies, which provided that, upon the terms and subject to the conditions and limitations set forth in the Original ATM Sales Agreement, we may elect 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 to the Original ATM Sales Agreement at an 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, which is in addition to the $150.0 million aggregate offering price under the Original ATM Sales Agreement. The material terms and conditions of the Original ATM Sales Agreement otherwise remain unchanged. As of March 31, 2023, we have sold 534,400 shares of our common stock under the Amended ATM Sales Agreement at an average price of $37.42 per share for aggregate gross proceeds of $20.0 million ($19.6 million net of commissions and offering expenses).

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. In aggregate, we received approximately $545.1 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.

Our ability to raise additional capital may be adversely impacted by potential worsening 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, including the trading price of common stock, resulting from the ongoing COVID-19 pandemic and 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;
- our potential exercise of the Option (as described below) with Sutro Biopharma, Inc., or Sutro Biopharma;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the U.S. Food and Drug Administration, or FDA, and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies for our pneumococcal conjugate vaccine, or PCV, candidates, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;

- the costs of establishing additional manufacturing capacity to meet potential incremental supply requirements following the initial commercial launch of VAX-24;
- 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;
- 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;
- the costs of operating as a public company; and
- the impact of the COVID-19 pandemic, which 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. Similarly, our potential decisions to delay, terminate, license or collaborate with third parties in respect of certain vaccine candidates may subsequently also prove to be less than optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our vaccine candidates or misread trends in the biopharmaceutical industry, in particular for vaccines, our business could be seriously harmed. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other vaccine candidates that may later prove to have greater commercial potential than those we choose to pursue or relinquish valuable rights to such vaccine candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

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, and our proprietary know-how for vaccine applications against infectious disease, and our future success depends on the successful application of this approach to vaccine development. We are in the clinical or preclinical stages of developing our vaccine candidates and there can be no assurance that any development problems

we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be overcome. For example, although we have achieved proof-of-concept for our carrier-sparing approach with VAX-24, our approach may not be validated for our other vaccine candidates or subsequent trials of 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, we do not know the specific doses that may be effective in the clinic or, if approved, commercially. Finding a suitable dose may delay our anticipated clinical development timelines.

Furthermore, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our vaccine candidates and understand these critical factors. Conjugate vaccine development is highly complex, and development of broad-valency PCVs is further complicated by the number of components, analytical assays and potential for adjustments, including but not limited to changes in raw materials, composition, formulation, manufacturing methods and dosing, which could result in drug substances and/or drug product that may vary between preclinical and clinical studies over time. Over the course of the development and manufacturing of VAX-24, we have encountered process-related matters that have required us to make adjustments to our processes. We encountered such process-related matters during our drug substance manufacturing campaign for VAX-24 at Lonza, Ltd., or 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, or IND, application timelines in the past and future changes or delays could impact future timelines for VAX-24 or for our other product candidates.

In addition, the preclinical and clinical trial requirements of the FDA, European Medicines Agency, or EMA, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a vaccine candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. Approvals by the FDA and EMA for existing pneumococcal vaccines, such as Pfizer Inc.'s, or Pfizer's, Prevnar 13, or PCV13, Prevnar 20®, or PCV20 and Merck & Co., Inc.'s, or Merck's, Vaxneuvance, or PCV15 and Pneumovax 23, or PPSV23, may not be indicative of what these regulators may require for approval of our vaccine candidates. For example, we have used opsonophagocytic activity, or OPA, titers as the primary immunogenicity surrogate endpoint for the VAX-24 program in adults because PCV13 and PCV20 were approved based on the establishment of non-inferiority of serotype-specific OPA responses relative to PPSV23 and PCV13 respectively; however, there can be no assurance that this streamlined non-inferiority approach will be sufficient for regulatory approval or that regulators will not require field efficacy trials. Furthermore, while there have been approvals granted for both PCVs and meningococcal conjugate vaccines based on surrogate immune endpoints rather than field efficacy studies, we will not be able to confirm this approach’s applicability for our vaccines until we complete our Phase 2 clinical development program. Additionally, novel aspects of our vaccine candidates and manufacturing processes may create further challenges in obtaining regulatory approval. The regulatory approval process for our novel vaccine candidates can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other vaccine candidates. More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new vaccine candidates. Moreover, our vaccine candidates may not perform successfully in clinical trials.

Our vaccine candidates 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.

None of our vaccine candidates have been the subject of late-stage or pivotal clinical trials. On October 24, 2022, we announced positive topline results from our Phase 1/2 clinical proof-of-concept study of VAX-24 in adults ages 18 to 64. On April 17, 2023, we announced positive results from the VAX-24 Phase 2 study 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. Regulatory interactions to inform the Phase 3 program are anticipated in the second half of 2023, and topline safety, tolerability and immunogenicity data from the pivotal Phase 3 non-inferiority study in adults are expected in 2025. With regard to our VAX-24 pediatric program, in March 2023, we announced that the first participants were dosed in the Phase 2 study of VAX-24 in healthy infants, after the FDA cleared our IND application in February 2023. We expect to share topline safety, tolerability and immunogenicity data following the primary three-dose immunization series by 2025. We anticipate the submission of the VAX-31 adult IND application to the FDA and announcement of subsequent FDA clearance in the second half of 2023. We expect topline safety, tolerability and immunogenicity data from a Phase 1/2 study in adults in 2024. In addition to our PCV franchise, our pipeline includes VAX-A1, a novel conjugate vaccine candidate designed to prevent disease caused by Group A Strep; VAX-PG, a novel protein vaccine candidate targeting the keystone pathogen responsible for periodontitis; VAX-GI, a vaccine designed to prevent Shigella; and other discovery-stage programs. Our ability to achieve and sustain profitability depends on obtaining

regulatory approvals for and successfully commercializing our vaccine candidates, either alone or with third parties, and we cannot guarantee that we will ever obtain regulatory approval for any of our vaccine candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. Before obtaining regulatory approval for the commercial distribution of our vaccine candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of our vaccine candidates.

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

- negative or inconclusive results from our preclinical or clinical trials, leading to a decision or requirement to conduct additional preclinical 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 compatible foreign applications or delays or failures in obtaining necessary approvals from regulators to commence a clinical trial, or suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or similar foreign authorities regarding the scope or design of our clinical trials, including any requirements to perform field efficacy studies;
- 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 chemistry, manufacturing and controls, or CMC, activities related to our clinical trials;
- harmful side effects or inability of our vaccine candidates to meet efficacy endpoints;
- unfavorable FDA or other regulatory agency inspection and review of one or more of our clinical trial sites or our contract manufacturers' facilities;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology or vaccine candidates in particular; or
- varying interpretations of our data by the FDA and comparable foreign regulatory authorities.

In particular, while we believe our PCVs could receive regulatory approval based on well-defined surrogate immune endpoints, consistent with how other PCVs have obtained regulatory approval in the past, rather than requiring clinical field efficacy

studies, there can be no assurance that the FDA or comparable foreign regulatory authorities will provide approvals on such basis. In addition, changes to the standard of care or the approval of new vaccines could change the threshold for achievement of non-inferiority using the established surrogate immune endpoints that our PCVs will need to meet in our clinical trials.

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

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

Our business is highly dependent on the success of our PCV Candidates –VAX-24, which is in clinical development, and VAX-31, which is in preclinical development. If we are unable to successfully develop, obtain approval for and effectively commercialize VAX-24 or VAX-31, 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-24, our most advanced vaccine candidate, and VAX-31, our preclinical PCV candidate. Although VAX-24 has produced positive topline results in a Phase 1/2 clinical study in adults aged 18-64, positive results from a Phase 2 study in adults aged 65 and older, and 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, it may not demonstrate the same results in future pivotal studies. Past and future VAX-24 results may not be indicative of future VAX-31 results. We anticipate the submission of the VAX-31 adult IND application to the FDA and announcement of subsequent FDA clearance in the second half of 2023. We expect topline safety, tolerability and immunogenicity data from a Phase 1/2 study in adults in 2024. VAX-24 and VAX-31will require additional preclinical, 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 VAX-24 or VAX-31 through the development process.

The clinical and commercial success of VAX-24, VAX-31 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, or 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, or other studies beyond those planned to support the approval and commercialization of our vaccine candidates or any future vaccine candidates;
- acceptance of our proposed indications and primary surrogate endpoint assessments for our PCV candidates by the FDA and similar foreign regulatory authorities;
- any changes to the required threshold for the achievement of non-inferiority using established surrogate immune endpoints that our PCVs will need to meet in our clinical trials;

- our ability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of VAX-24, VAX-31 or any future vaccine candidates;
- the pace and prevalence of serotype replacement following the introduction of VAX-24 or VAX-31 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 an Advisory Committee on Immunization Practices, or ACIP, preferred recommendation or comparable foreign regulatory authority's recommendation of our vaccine candidates and the willingness of physicians, operators of clinics and patients to utilize or adopt any of our future vaccine candidates to prevent or treat age-associated diseases;
- our ability to successfully develop a commercial strategy and thereafter commercialize our vaccine candidates or any future vaccine candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- the convenience of our treatment or dosing regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our vaccine candidates or any future vaccine candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our vaccine candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our vaccine candidates or any future vaccine candidates;
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims; and
- the impact of the COVID-19 pandemic, which 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 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, or 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 for their products. For example, PCV13 obtained FDA approval for the prevention of invasive pneumococcal disease, or IPD, in infants based on non-inferior IgG antibody responses relative to Prevnar, using the surrogate immune endpoints established by the prior Prevnar field efficacy study. Pfizer implemented a similar approach to 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. 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 April 2022 that V116, the company's investigational 21-valent PCV for adults, received Breakthrough Therapy designation from the FDA, and later announced that it enrolled the first patient in their Phase 3 clinical trial. In June 2022, Merck announced positive results from its Phase 1/2 study evaluating the safety, tolerability and immunogenicity of V116 in pneumococcal vaccine-naïve adults 18-49 years of age (Phase 1) and 50 years of age and older (Phase 2). In addition, Sanofi and SK Chemicals have partnered to develop a PCV, and GSK, which recently acquired Affinivax, is developing a 24-valent affinity-bound pneumococcal vaccine. Affinivax also has a 30-plus valent pneumococcal candidate vaccine in preclinical development.

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 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 chemistry, manufacturing and controls requirements imposed by the FDA and comparable foreign regulatory authorities. To date, no product developed using a cell-free manufacturing platform has received approval from the FDA or been commercialized.

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

- manufacturing our vaccine candidates to our specifications, including process development, analytical development and quality control testing, and in a timely manner to support our preclinical and clinical trials and, if approved, commercialization;
- 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, or EU, a manufacturing authorization must be obtained from the appropriate EU regulatory authorities. Because no product manufactured on a

cell-free manufacturing platform has been approved in the United States, there is no manufacturing facility that has demonstrated the ability to comply with FDA requirements, and, therefore, the timeframe for demonstrating compliance to the FDA's satisfaction is uncertain. Delays in establishing that our manufacturing process and the facilities we utilize for manufacturing comply with cGMP or disruptions in our manufacturing processes, implementation of novel technologies or scale-up activities, may delay or disrupt our development efforts.

Even if we obtain regulatory approval of our vaccine candidates, the products may not gain market acceptance among regulators, advisory boards, physicians, patients, third-party payors and others in the medical community 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 Centers for Disease Control and Prevention, or CDC, and ACIP recommendations for use, as well as recommendations of comparable foreign regulatory and advisory bodies;
- prevalence and severity of the disease targets for which our vaccine candidates are approved;
- physicians, hospitals, third-party payors and patients considering our vaccine candidates as safe and effective;
- the potential and perceived advantages of our vaccine candidates over existing vaccines, including with respect to spectrum 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 similar agencies around the world. To develop its recommendations, ACIP forms working groups that gather, analyze and prepare scientific information. The ACIP also considers many of the factors above, as well as myriad additional factors such as the value of vaccination for the target population regarding the outcomes, health economic data and implementation issues. ACIP recommendations are also made within categories, such as in an age group or a specified risk group. For example, the ACIP may determine that a preferred recommendation in a smaller child population may be more economical than recommending vaccinations for a larger adult population, which could adversely impact our market opportunity.

New pediatric vaccines that receive an ACIP preferred recommendation are almost universally adopted, and adult vaccines that receive a preferred recommendation are widely adopted. For example, in 2014, the ACIP voted to recommend PCV13 for routine use to help protect adults aged 65 years and older against pneumococcal disease, which caused PCV13 to become the standard of care along with continued use of PPSV23. ACIP can also modify its preferred recommendation. For instance, in June 2019, the ACIP voted to revise the pneumococcal vaccination guidelines and recommend PCV13 for adults 65 and older based on the shared clinical decision making of the provider and patient, rather than a preferred use recommendation, which means the decision to vaccinate should be made at the individual level between health care providers and their patients. In October 2021, the ACIP voted to recommend the use of either Pfizer's PCV20, or Merck's 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. In June 2022,

ACIP voted to recommend that Merck's PCV15 may be used as an option to the currently available PCV13 for children aged under 19 years according to currently recommended PCV13 dosing and schedules.

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

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

The success of our business depends in large part upon our ability to identify, develop and commercialize products based on our cell-free protein synthesis platform. We intend to pursue clinical development of additional vaccine candidates beyond VAX-24, including VAX-31 for PCV, VAX-A1 for Group A Strep, VAX-PG for periodontitis and VAX-GI for Shigella. Our research programs may fail to identify potential vaccine candidates for clinical development for a number of reasons or we may focus our efforts and resources on potential programs or vaccine candidates that ultimately prove to be unsuccessful. In addition, we cannot provide any assurance that we will be able to successfully advance any of our existing or future vaccine candidates through the development process.

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

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

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

We currently rely on third-party manufacturing and supply partners, including Lonza and Sutro Biopharma, to supply raw materials and components for, and manufacture 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 currently do not own or operate any manufacturing facilities. We are designing and developing a manufacturing process that we believe can scale to address clinical and commercial vaccine supply. However, our assumptions as to our ability and our CMOs' ability to produce vaccines at the scale needed for clinical development and commercial demand, in particular for our PCVs, may prove to be wrong. If we encounter 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 have encountered process-related matters that have required us to make adjustments to our processes. 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-24 or for our other product candidates. As a third-party manufacturer, we are also subject to Lonza's scheduling commitments for its 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. In addition, certain aspects of our manufacturing process for our clinical trial product materials and supplies were adversely affected by the COVID-19 pandemic, and could be adversely affected by the ongoing COVID-19 pandemic, earthquakes and other natural or man-made disasters, equipment failures, labor shortages, power failures and numerous other factors in the future. Please see the risk factor titled *"Health epidemics, including the effects of the ongoing COVID-19 pandemic, have impacted and could continue to impact our business, including in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations."*

The manufacturing process for a vaccine candidate is subject to FDA or comparable foreign regulatory authority review. Our suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs.

If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our vaccine candidates. Moreover, we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills, raw materials or technology required to manufacture our vaccine candidates may be unique or proprietary to the original manufacturer or supplier, and we may have difficulty applying such skills or technology or sourcing such raw materials ourselves, or in transferring such skills, technology or raw materials to another third party, or such transfer may be subject to certain consent obligations and payment terms to Lonza. 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. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop vaccine candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers and suppliers, including Lonza, if we receive regulatory approval for any PCV or any other vaccine candidates. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. 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. In December 2022, we entered into an option agreement with Sutro Biopharma, or the Option Agreement, pursuant to which we acquired, among other thing, 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. If we are unable to obtain or maintain third-party manufacturing for vaccine candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our vaccine candidates successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMPs could adversely affect our business in a number of ways, including:

- an inability to initiate or complete clinical trials of vaccine candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for our vaccine candidates;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our vaccine candidates; and

- in the event of approval to market and commercialize a vaccine candidate, an inability to meet commercial demands for our products.

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

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

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

Adverse effects or other undesirable or unacceptable side effects caused by our vaccine candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. 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. A data safety monitoring board 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 new technologies on which we rely may damage public perception of our vaccine candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our vaccine candidates.

Negative developments and negative public opinion of new or existing technologies on which we rely may damage public perception of our vaccine candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our vaccine candidates. Public perception may be influenced by claims that vaccines are unsafe, and products incorporating new vaccine technology may not gain the acceptance of the public or the medical community. Adverse public attitudes may negatively impact our ability to enroll 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. Any increase in negative perceptions of the technologies that we rely on may result in fewer physicians prescribing our products or may reduce the willingness of patients to utilize our products or participate in clinical trials for our vaccine candidates.

We may not be able to file 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 such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

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

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

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in reaching a consensus with regulatory agencies on study design;
- 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, or IRB, approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology that 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;
- disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned clinical trials;
- 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, or GCP, requirements or applicable regulatory guidelines in other jurisdictions;
- transfer of manufacturing processes to any new CMO or our own manufacturing facilities or any other development or commercialization partner for the manufacture of vaccine candidates;
- delays in having 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.

For example, based on the positive topline results from the VAX-24 Phase 1/2 proof-of-concept study, which evaluated the safety, tolerability and immunogenicity of VAX-24 in adults 18-64 years of age, the FDA supported the initiation of a pediatric

study in infants. This study could uncover risks in this study population that could have potentially been discovered during a child and/or toddler study, which could then delay completion of clinical development. 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:

- 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 caused by the COVID-19 pandemic related to patient and physician investigator recruitment and retention and study site initiation and clinical trial activities.

To the extent we are required to conduct any field efficacy studies, 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. For instance, on October 24, 2022, we announced positive topline results from the Phase 1/2 clinical proof-of-concept study evaluating the safety, tolerability and immunogenicity of VAX-24 in healthy adults aged 18-64. 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.

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 may seek Breakthrough Therapy designation or Fast Track designation by the FDA for one or more of our vaccine candidates, but we may not receive such designation, 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 may seek Breakthrough Therapy 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 and, in January 2023, we announced that the FDA granted Breakthrough Therapy designation for VAX-24 for the prevention of IPD 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. For instance, although the FDA has granted Fast Track designation to VAX-24 in adults, we may not experience a faster development, review or approval process compared to the conventional process. In addition, the FDA may withdraw Fast Track designation from VAX-24, or from any other 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 Breakthrough Therapy or Fast Track designations are 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 if 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 capital expenditures, management resources and time, and we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

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

and marketing efforts of our vaccine candidates.

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

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

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

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping vaccine candidates abroad;
- import and export requirements and restrictions;
- 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.

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, or 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 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:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our vaccine candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our vaccine candidates will depend, in part, on our ability to effectively manage our growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

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

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

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

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of vaccine candidates with which we must comply prior to marketing in those

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

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

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our discovery, development and commercialization efforts with respect to our vaccine candidates and any future vaccine candidates that we may seek to develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our vaccine candidates because they may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view our vaccine candidates as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new strategic partnership agreements related to our vaccine candidates could delay the development and commercialization of our vaccine candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

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

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

We intend to initially seek approval of our VAX-24 vaccine candidate in adults. If approved, we believe it may have the potential to serve as a "catch up" or booster to those adults who have previously received 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 security measures, or those maintained on our behalf by CROs, service providers or other third parties, are compromised now, or in the future, or the security, confidentiality, integrity or availability of our information technology, software, services, networks, communications or data is compromised, limited or fails, this could result in significant fines or other liability, interrupt our development programs, harm our reputation, or otherwise adversely affect our business.

In the ordinary course of our business, we collect, use, retain, safeguard, disclose, share, transfer 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, or 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 security incident or other interruption, 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.

Cyberattacks, malicious internet-based activity and online and offline fraud are prevalent and continue to increase. In addition to traditional computer "hackers"; threat actors; software bugs; malicious code (such as viruses and worms); employee error, theft or misuse; denial-of-service attacks (such as credential stuffing); advanced persistent threat intrusions; natural disasters; terrorism; war; telecommunication and electrical failures; and ransomware attacks, sophisticated nation-state and nation-state

supported actors are threats to our information technology assets and data. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, 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. Any of the previously identified or similar threats could cause a security incident or other interruption. A security 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.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. While we take steps to detect and remediate vulnerabilities, we may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature and may not be detected until after a security incident has occurred. 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. These vulnerabilities pose material risks to 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 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. While we have not experienced any such material system failure or security breach to date, if we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, including interruptions in our operations, which could result in a material 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 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. Security 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 protection requirements, 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 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 use 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.

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, including the COVID-19 pandemic. 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.

Health epidemics, including the effects of the ongoing COVID-19 pandemic, have impacted and could continue to impact our business, including in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations.

Health epidemics could adversely impact our business, including in regions where we have concentrations of potential clinical trial sites or other business operations, and cause significant disruption in the operations of our contract manufacturer and other third parties upon whom we rely. For example, the COVID-19 pandemic has presented a substantial public health and economic challenge around the world and has affected and could continue to affect employees, patients, communities and business operations, as well as the U.S. economy and financial markets. Our headquarters is located in the San Francisco Bay Area, and our contract manufacturer, Lonza, is located in Switzerland. Many geographic regions imposed and in the future may impose, "shelter-in-place" orders, quarantines or similar orders or restrictions to control the spread of COVID-19. The effects of these orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In connection with these measures, we may be subject to claims based upon, arising out of or related to COVID-19 and our actions and responses thereto, including any determinations that we may make to continue to operate or to re-open our facilities where permitted by applicable law. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, financial condition, results of operations and growth prospects.

Moreover, we rely on third parties to supply raw materials and manufacture our preclinical and clinical product supplies of our vaccine candidates, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic. In addition, public health guidelines could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. For example, the COVID-19 pandemic slowed raw material supply chains and travel restrictions delayed the qualification of key analytical equipment used in manufacturing and curtailed in-person CMO oversight of manufacturing.

Some of our suppliers of certain materials used in the production of our vaccine candidates are located in Europe. Any manufacturing supply interruption at Lonza's facilities in Switzerland could adversely affect our ability to produce our vaccine candidates for use in the conduct of our preclinical studies or clinical trials. In any event, if the COVID-19 pandemic continues and persists for an extended period of time or more acutely impacts geographies with particular impact on our business, we could experience significant disruptions to our preclinical and clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

In addition, our planned clinical trials may be affected by the COVID-19 pandemic. Site initiation and subject enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some subjects may not be able to comply with clinical trial protocols if quarantines impede their movement or interrupt healthcare services. Similarly, our ability to recruit and retain subjects and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may adversely impact our planned clinical trial operations. Additionally, our clinical trial vendors, including testing labs, may experience short interruptions, delays or reductions in capacity as a result of staff exposure to COVID-19, which could adversely

affect our timelines for planned clinical operations.

Furthermore, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic resulted in significant and prolonged disruption of global financial markets, which may reduce our ability to access capital, which could in the future negatively affect our liquidity.

While the ultimate impact of the COVID-19 pandemic on our business is highly uncertain, any negative impacts that materialize could materially adversely affect our clinical development and operations, financial performance and stock price. In addition, to the extent the evolving effects of the COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this "Risk Factors" section.

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.

In December 2017, the Tax Cuts and Jobs Act, or Tax Act, was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) changes to the expensing of research and development expenses for tax years beginning after December 31, 2021, (ii) reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (iii) limitation of the tax deduction for interest expense to 30% of adjusted earnings (with certain exceptions, including for certain small businesses), (iv) limitation of the deduction for post-2017 net operating losses, or NOLs, to 80% of current-year taxable income and elimination of net operating loss carrybacks for post-2017 NOLs, (v) immediate deductions for certain new investments instead of deductions for depreciation expense over time and (vi) modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as orphan drugs). Effective January 1, 2022, we are also subject to mandatory capitalization of Section 174 research and development expenditures. The capitalized expenses are subject to amortization over five and fifteen years for expenses incurred within the U.S. and outside of U.S., respectively.

In March 2020, the Coronavirus Aid, Relief, and Economic Security, or CARES, Act was signed into law. The CARES Act changed certain provisions of the Tax Act. Under the CARES Act, NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminated the limitation on the deduction of NOLs to 80% of current year taxable income for taxable years beginning before January 1, 2021, and increased the amount of interest expense that may be deducted to 50% of adjusted taxable income for taxable years beginning in 2019 or 2020. Notwithstanding the reduction in the corporate income tax, these benefits do not impact our current tax provision.

On December 21, 2020, the President of the United States signed into law the “Consolidated Appropriations Act, 2021,” which includes further COVID-19 economic relief and extension of certain expiring tax provisions. The relief package includes a tax provision clarifying that businesses with forgiven Paycheck Protection Program, or PPP, loans can deduct regular business expenses that are paid for with the loan proceeds. Additional pandemic relief tax measures include an expansion of the employee retention credit, enhanced charitable contribution deductions and a temporary full deduction for business expenses for food and beverages provided by a restaurant for tax years 2021 and 2022.

The Infrastructure Investment and Jobs Act was signed on November 15, 2021, and it contained several tax provisions including changes to the Employee Retention Tax Credit and changes to excise taxes. These provisions do not have a material impact on our current tax provision.

In accordance with the 2017 Tax Act, research and experimental (R&E) expenses under Internal Revenue Code Section 174 are required to be capitalized beginning in 2022. R&E expenses are required to be amortized over a period of five years for

domestic expenses and 15 years for foreign expenses. We have capitalized research and experimental expenditures in our current tax provision as a result.

The Inflation Reduction Act of 2022 specifically introduces the topic of corporate alternative minimum tax, or CAMT, on adjusted financial statement income on applicable corporations for taxable years beginning after December 31, 2022. There is no impact to our current tax provision.

The American Rescue Plan Act was signed on March 11, 2021. One of the provisions of the Act included expanding the definition of covered employees subject to IRC 162(m) to include an additional top five highest compensated officers beyond the CEO, CFO, and three highest paid employees currently covered under IRC 162(m). This expanded provision is applicable for tax years beginning after December 31, 2026. The Company does not believe that this update to IRC 162(m) would have a material impact on its income tax provision currently and will continue to monitor this.

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 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, 2022, we had federal and state NOL carryforwards of $340.2 million and $453.1 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, 2022, we also had federal and state research credit carryforwards of $4.4 million and $2.8 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, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, a corporation that undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We have experienced ownership changes in the past. There were no ownership changes identified in 2022, as such we have determined that no federal research credits will expire unutilized or are excluded from our research carryforwards as of December 31, 2022. We do not expect any ownership changes during the year ended December 31, 2022 to result in a limitation that would materially reduce the total amount of net operating loss carryforwards and credits that can be utilized. 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, including Sutro Biopharma and Lonza, to supply raw materials and manufacture our preclinical and clinical product supplies of our vaccine candidates, and expect to rely on third parties to supply raw materials and produce and process our vaccine candidates, if approved. The loss of these suppliers or their failure to comply with applicable regulatory requirements or provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

We do not have the infrastructure or capability internally to manufacture supplies for our vaccine candidates or the materials necessary to produce our vaccine candidates for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our vaccine candidates on a preclinical, clinical or commercial scale. We have entered into an agreement with Sutro Biopharma to supply us with extract and custom reagents for use in manufacturing non-clinical and certain clinical supply of vaccine compositions. Pursuant to the Option Agreement, we also acquired, among other things, 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, or the Option. The Option period is five years from the date of the agreement, and we have not yet exercised the Option and we may never exercise the Option. We have engaged Lonza to perform manufacturing process development and clinical manufacture and supply of components for VAX-24, including the manufacture of polysaccharide antigens, our proprietary eCRM protein carrier and conjugated

drug substances. We also engaged Lonza to perform manufacturing process development and clinical manufacture and supply of VAX-24 finished drug product. Our agreements with Lonza are denominated in Swiss Francs. Fluctuations in the exchange rate for Swiss Francs may increase our costs and affect our operating results.

Lonza is currently in the process of manufacturing our vaccine candidates on a clinical scale. 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:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any.
- Our third-party suppliers and manufacturers might be unable to timely formulate and manufacture or supply raw materials for our vaccine candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.
- Our third-party suppliers and manufacturers could breach or terminate their agreement with us.

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

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

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

Risks Related to Government Regulation

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

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our vaccine candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of 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 or efficacy results between different clinical trials of the same vaccine candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Vaccine candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most vaccine candidates that begin clinical trials are never approved by regulatory authorities for commercialization. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit a BLA or other marketing application.

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

- obtaining regulatory authorization to begin a trial, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent IRB;
- recruiting suitable 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 encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our vaccine candidates in lieu of using existing vaccines that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a vaccine candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial or based on a recommendation by the data safety monitoring board. If we experience termination of, or delays in the completion of, any clinical trial of our vaccine candidates, the commercial prospects for our vaccine candidates will be

harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

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

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

The general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from two Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and are time consuming. While we have not had extensive discussions with the FDA regarding our regulatory plan, as a prerequisite for FDA approval, we believe that any new PCV, such as VAX-24, will have to be compared to the current standard of care, PCV13 and PCV15 in infants and PCV20 in adults. We believe that a successful comparison for an adult study would be based on demonstrating clinical non-inferiority of the immune response to PCV20 for common serotypes. In addition, we expect to use OPA titers as the primary immunogenicity surrogate endpoint for the VAX-24 program in adults because PCV13 was approved based on the establishment of non-inferiority of OPA responses relative to PPSV23, on a strain-by-strain basis. On October 24, 2022, we announced positive topline results from the Phase 1/2 clinical proof-of-concept study evaluating the safety, tolerability and immunogenicity of VAX-24 in healthy adults aged 18-64. In this study, VAX-24 met the primary safety and tolerability objectives, demonstrating a safety profile similar to PCV20 for all doses studied. In this study, VAX-24 met or exceeded the established regulatory immunogenicity standards for all 24 serotypes at the conventional 2.2mcg dose, which we intend to move forward into a Phase 3 program. At this dose, VAX-24 met the standard OPA response non-inferiority criteria for all 20 serotypes common with PCV20, of which 16 achieved higher immune responses. Additionally, at all three doses, VAX-24 met the standard superiority criteria for all four serotypes unique to VAX-24. VAX-24 has the potential to cover an additional 10-28 percent of strains causing IPD in adults over the current standard-of-care PCVs. We believe these topline results support clinical non-inferiority to PCV20, but there can be no assurance that this approach in pivotal studies will be sufficient for regulatory approval or that regulators will not require field efficacy trials.

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our vaccine candidates are safe and effective;
- 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;
- product seizure or detention, or refusal to permit the import or export of our vaccine candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our vaccine candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive

actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

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

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

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

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

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 arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws.

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which prohibit, among other

things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or 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, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information for or on their behalf, as well as their covered subcontractors;
- the Federal Food Drug or Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), 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, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- 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, or 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. Certain 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 other health insurance coverage may be eligible to receive such vaccinations free-of-charge through the CDC's Vaccines for Children Program, or 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. If our vaccine candidates, once approved, are covered only under the Part D program, physicians may be less willing to use our products because of the claims adjudication costs and time related to the claims adjudication process and collection of co-payments associated with the Part D program.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. 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 ACA was passed, which substantially changed the way healthcare is financed by both governmental and private payors in the United States. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include:

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

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

There have been executive, judicial and Congressional challenges to the ACA. 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 United States 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. Moreover, prior to the United States Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how additional healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2015and the Consolidated Appropriations Act of 2023, will remain in effect until 2032 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which ended the use of the statutory formula for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, the full impact of the introduction of the Medicare quality payment program on overall physician reimbursement remains unclear. 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. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services, or HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, the IRA will, among other things, (i) allow HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) impose rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. However, the IRA does not change either the VFC or the 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. The IRA did help with vaccine access by eliminating cost sharing for adult vaccines covered under Medicare Part D and mandating that all state Medicaid programs cover many adult vaccines and their administration without cost sharing. Further, many vaccines are excluded from Medicare Part B rebate requirements. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs, biological products and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future vaccine candidates or additional pricing pressures. Further, it is possible that additional governmental action is taken in response to the ongoing COVID-19 pandemic. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing or new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future vaccine candidates we may develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, which could have an adverse effect on demand for our vaccine candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

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

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

and unpredictable.

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

Separately, in response to the global COVID-19 pandemic, the FDA has adopted a risk-based system for the conduct of inspections of manufacturing facilities. Additionally, the FDA is conducting voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. Regulatory authorities outside the United States have adopted similar restrictions and policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We are subject to increasingly stringent and rapidly changing laws and regulations related to privacy and data security. The restrictions and costs imposed by these requirements, or our actual or perceived failure to comply with them, could harm our reputation, subject us to significant fines and liability, and adversely affect our business.

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 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 on health plans, healthcare clearinghouses and certain healthcare providers, and 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 comparable to HIPAA, some of which may 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.

Domestic privacy and data security laws beyond HIPAA and other healthcare privacy laws are also changing rapidly and becoming more complex. For example, the CCPA imposes obligations on businesses to which it applies. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for administrative fines for noncompliance (up to $7,500 per violation). In addition, the CPRA expanded the CCPA's requirements, including by adding a new right of individuals to correct their personal data and establishing a new California Privacy Protection Agency to implement and enforce the CCPA. Other states have enacted data privacy laws that become operative in 2023, such as Virginia and Colorado, and other local, state, and federal laws are under consideration. 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 whom 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 may also 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. Under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals or consumer protection organizations may initiate

litigation related to our processing of their personal data.

In addition, many jurisdictions have enacted data localization laws and cross-border personal data transfer laws. These laws may make it more difficult for us to transfer personal data across jurisdictions, which could impede our business. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the EEA, such as the United States, which the European Commission does not consider to be providing an adequate level of data privacy and security. The European Commission released a set of "Standard Contractual Clauses" that are designed to be a valid mechanism by which entities can transfer personal data out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, these Standard Contractual clauses are a valid mechanism to transfer personal data outside of the EEA, but are subject to legal challenges. Due to these legal challenges, there exists some uncertainty regarding whether the Standard Contractual Clauses will remain a valid mechanism for transfers of personal data out of the EEA. In addition, laws in Switzerland and the UK similarly restrict transfers of personal data outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection. If we need but cannot implement a valid compliance mechanism for cross-border privacy and security transfers, 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.

Our obligations related to data privacy and security 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). These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. 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 whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others. If we 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); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. 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 VAX-24 and any future vaccine candidates, as well as methods of making our vaccine candidates and components thereof. We seek to protect our proprietary position by filing patent applications in the 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 VAX-24 or any future vaccine candidate in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing

from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover VAX-24 or any future vaccine candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any vaccine candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a vaccine candidate under patent protection could be reduced.

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future vaccine candidates.

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

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

We have licensed certain intellectual property rights related to the XpressCF platform, components of our PCV candidates, and methods of making components of VAX-24 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 VAX-24 or any future vaccine candidate, or the XpressCF platform, our competitors might be able to enter the market, which would have an adverse effect on our business.

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

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

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

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon 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. 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 takes 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 will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national 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 in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

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

The ongoing conflict in Ukraine and related sanctions could significantly devalue our Eurasian patent applications. Recent 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 expect to rely on third parties to manufacture VAX-24 and any future vaccine candidates, and we expect to collaborate with third parties on the development of VAX-24 and any 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 may be volatile, and the value of our common stock may decline.

The market price of our common stock may 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 particular, the COVID-19 pandemic has further heightened the volatility of the stock market for biopharmaceutical companies. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- the commencement, enrollment or results of our planned or future preclinical studies or clinical trials of our vaccine candidates and those of our competitors;
- regulatory or legal developments in the United States and abroad;
- the success of competitive vaccines or technologies;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the level of expenses related to our vaccine candidates or preclinical and clinical development programs;
- the results of our efforts to develop additional vaccine candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations or reports by securities analysts;
- the level of expenses and capital investment related to manufacturing 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 higher inflation rates, bank failures, changes in interest rates and the Russia-Ukraine war, 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, including in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many 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.

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

Our executive officers, directors and principal stockholders beneficially own a significant portion of our common stock. Accordingly, these stockholders have the ability to influence us through this ownership position and significantly affect the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to significantly affect the outcome of elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC, or Nasdaq, and other applicable securities rules and regulations.

Sarbanes-Oxley as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. We cannot assure you that we will satisfy our obligations as a public company on a timely basis.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If we are unable to comply with these requirements on a timely basis or if the attention of our management and personnel is diverted from other business concerns, it could have a material adverse effect on our business, financial condition and results of operations. The increased costs will increase our net loss or decrease our net income, and may require us to reduce costs in other areas of our business. In addition, as we expand, it may be more difficult

or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers.

We are also subject to more stringent state law requirements. Compliance costs and penalties or other adverse impacts as a result of non-compliance (including reputational impacts) may adversely affect our business.

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

There is an increasing focus from certain investors and other key stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. As a result, there is 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. We risk damage to our brand and reputation if our corporate responsibility procedures or standards do not meet the standards set by various constituencies. We may be required to make investments in matters related to ESG, 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, 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 is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

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

- require the approval of the holders of at least 66 $^{2}/_{3}$% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

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

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, or 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 in the past several years, including as a result worsening global economic conditions, including higher inflation rates and changes in interest rates, and the COVID-19 pandemic 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, or SVB, and appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. While SVB was our primary bank at the time, we maintained banking relationships with other major banks. The substantial majority of funds we held at SVB, which included cash, cash equivalents and investments were held in custodial accounts of a third-party institution for which SVB Asset Management was the advisor, or SVB Custodial Accounts. On March 12, 2023, the FDIC confirmed that depositors of SVB would have access to all of their money and, as a result, we regained access to all of our funds deposited with SVB. The FDIC subsequently transferred SVB's deposits and loans to a newly created bridge bank, named Silicon Valley Bridge Bank, N.A., or Silicon Valley Bridge Bank. On March 26, 2023, the FDIC announced that First Citizens Bank & Trust Company, or First Citizens Bank, had agreed to purchase and assume all deposits and loans of Silicon Valley Bridge Bank. We have not experienced any losses on these deposits or investments 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 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.

An active trading market for our common stock may never develop or be sustained.

Our common stock is currently listed on the Nasdaq Global Select Market under the symbol "PCVX." However, we cannot assure you that an active trading market for our shares will develop or be sustained. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

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

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

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

As a public company, we will incur significant legal, accounting, investor relations and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Stockholder activism, the current political environment and the current high level of U.S. government intervention and regulatory reform may also lead to substantial new regulations and disclosure obligations, which may in turn lead to additional compliance costs and impact the manner in which we operate our business in ways we do not currently anticipate. Our management and other personnel will need to devote a substantial amount of time to comply with these requirements. Moreover, these requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by management related to the internal control over financial reporting in our Form 10-K for the year ended December 31, 2022 and we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the Sarbanes-Oxley Act, the requirements of

being a reporting company under the Exchange Act and any complex accounting rules in the future, we may need to upgrade our information technology systems, implement additional financial and management controls, reporting systems and procedures, and hire additional accounting and finance staff. We are currently in the process of hiring additional accounting and finance staff as we grow our business. If we are unable to hire the additional accounting and finance staff necessary to comply with these requirements, we may need to retain additional outside consultants. If we or, if required, our auditors, are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

There can be no assurance that there will not be material weaknesses in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines that we have a material weakness in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over 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 2. Unregistered Sales of Equity Securities and Use of Proceeds.

(a) **Recent Sales of Unregistered Equity Securities**

None.

(b) **Use of Proceeds**

In June 2020, we closed our IPO of 17,968,750 shares of our common stock, including shares issued upon the exercise in full of the underwriters' option to purchase 2,343,750 additional shares of common stock, at a public offering price of $16.00 per share. We received gross proceeds to us of $287.5 million. All of the shares issued and sold in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-238630), which was declared effective by the SEC on June 11, 2020. BofA Securities, Inc., Jefferies LLC and Evercore Group L.L.C. acted as joint book-running managers for the offering. Cantor Fitzgerald & Co. and Needham & Company, LLC acted as co-managers for the offering. Shares of our common stock began trading on the Nasdaq Global Select Market on June 12, 2020 and, following the sale of all the shares upon the closing of the IPO, the offer terminated. The net proceeds to us, after deducting underwriting discounts and commissions of $20.1 million and net offering expenses of $3.4 million, were $264.0 million.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

There has been no material change in the planned use of proceeds from our IPO from those disclosed in the prospectus for our IPO dated as of June 11, 2020 and filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on June 15, 2020.

(c) **Issuer Purchases of Equity Securities**

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Schedule Form	File Number	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Vaxcyte, Inc., as amended.	8-K	001-39323	3.1	June 16, 2020
3.2	Amended and Restated Bylaws of Vaxcyte, Inc.	8-K	001-39323	3.2	June 16, 2020
4.1	Form of Common Stock Certificate of the Registrant.	S-1/A	333-238630	4.1	June 8, 2020
4.2	Form of Pre-Funded Warrant	8-K	001-39323	4.1	January 13, 2022
4.3	Form of Pre-Funded Warrant	8-K	001-39323	4.1	October 27, 2022
4.4	Form of Pre-Funded Warrant	8-K	001-39323	4.1	April 20, 2023
10.1#+*	Development and Manufacturing Services Agreement by and between the Registrant and Lonza Ltd., dated March 1, 2023.				
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 Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1†*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document: the instance document does not appear in the interactive Data File because its XBRL tags are embedded within the Inline XBRL document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Inline XBRL for the cover page of the Quarterly Report on Form 10-Q included in the Exhibit 101 Inline XBRL Document Set.				

* Filed herewith.

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 SEC upon request; provided, however, that we may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any schedule or exhibit so furnished.

† The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q 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 Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Vaxcyte, Inc.

Date: May 8, 2023 By: /s/ Grant E. Pickering
Grant E. Pickering
Chief Executive Officer

Date: May 8, 2023 By: /s/ Andrew Guggenhime
Andrew Guggenhime
President and Chief Financial Officer

Date: May 8, 2023 By: /s/ Elvia Cowan
Elvia Cowan
Senior Vice President, Finance

CONFIDENTIAL

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Development and Manufacturing Services Agreement

(the “Agreement”)

by and between

Lonza Ltd
Münchensteinerstrasse 38
CH-4002 Basel
Switzerland

- hereinafter “Lonza” -

and

Vaxcyte, Inc.

825 Industrial Road
Suite 300
San Carlos, CA 94070
U.S.A.

- hereinafter “Customer” -

Effective as of March 1, 2023 (the “Effective Date”)

Table of Contents

Recitals

WHEREAS, Customer is engaged in the development and research of certain products and requires assistance in the development and manufacture of product;

WHEREAS, Lonza and its Affiliates have expertise in the evaluation, development and manufacture of products;

WHEREAS, the Parties have entered into a development and manufacturing services agreement, dated 21 October 2016, as amended from time to time relating to the manufacture of product, which is currently set to expire on 31 March 2023 ("Original Agreement"); and

WHEREAS, Customer wishes to engage Lonza for new Services relating to the expansion of development and manufacture of the Product as described in this Agreement;

WHEREAS, the Parties have entered into a development and manufacturing services agreement, dated 2 March 2022, for manufacturing services related to drug product;

WHEREAS, this Agreement relates to development and manufacturing services for conjugated polysaccharide drug substances and microbial products; and

WHEREAS, Lonza, or its Affiliate, is prepared to perform such Services for Customer on the terms and subject to the conditions set out herein.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the parties intending to be legally bound, agree as follows:

1 Definitions and Interpretation

“Affiliates” means any company, partnership or other entity which directly or indirectly Controls, is Controlled by or is under common Control with the relevant Party. “Control” means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of the relevant Party.

“Agreement” means this agreement incorporating all Appendices, as amended from time to time by written agreement of the Parties.

“Applicable Laws” means all relevant U.S., Swiss and European Union federal, state and local laws, statutes, rules, and regulations which are applicable to a Party’s activities hereunder, including, without limitation, the applicable regulations and guidelines of any Governmental Authority and all applicable cGMP together with amendments thereto.

“Approval” means the first marketing approval by the FDA or EMA of Product from the Facility for commercial supply.

“Background Intellectual Property” means any Intellectual Property either [***].

“Batch” means, as the context dictates, [***].

“Batch Price” means the Price of each Batch.

“BLA Services” means pre biologics license application activities services to be performed in respect of the Product to support a License application.

“Campaign” means a series of no less than [***] cGMP Batches manufactured consecutively.

“Cancellation Fee” has the meaning given in Clause 6.3.

“Capital Equipment“ means those certain pieces of equipment described in the Project Plan: [***].

“Certificate of Analysis” means a document prepared by Lonza listing tests performed by Lonza or approved External Laboratories, the Specifications and test results.

“cGMP” means those laws and regulations applicable in the U.S. and Europe, relating to the manufacture of medicinal products for human use, including, without limitation, current good manufacturing practices as specified in the ICH guidelines, including without limitation, ICH Q7A “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients”, US Federal Food Drug and Cosmetic Act at 21CFR (Chapters 210, 211, 600 and 610) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC. For the avoidance of doubt, Lonza’s operational quality standards are defined in internal cGMP policy documents.

“cGMP Batches” means any Batches which are required under the Project Plan to be manufactured in accordance with cGMP.

“Change” means any change to the Services, pricing or Scope of Work incorporated into a written amendment to the Agreement in accordance with clause 16.2 or effected in accordance with the Quality Agreement.

“Commencement Date” means the date of commencement of the Services [***] hereunder.

“Confidential Information” means Customer Information and/or Lonza Information.

"Conjugated Drug Substance Batch" means a batch of conjugated drug substance manufactured at the Facility.

“Customer Information” means [***].

“Customer Product Components” means, as the context dictates, any components of (bioconjugate) Product such as eCRM Intermediate or any of the Polysaccharide Intermediates that comprise the Conjugated Drug Substances found in VAX-24 or VAX-XP.

“Customer Supplied Raw Materials” means [***].

"eCRM Intermediate Batch" means a batch of eCRM manufactured at the Facility.

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

“Engineering Batches” means a Batch that is intended to demonstrate the transfer of the Manufacturing Process to the Facility.

“External Laboratories” means any Third Party instructed by Lonza, with Customer’s prior consent, which is to conduct activities required to complete the Services.

“Facility” means [***].

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

“Governmental Authority” means any Regulatory Authority and any national, multi-national, regional, state or local regulatory agency, department, bureau, or other governmental entity in the U.S., Switzerland or the European Union.

“Intellectual Property” means: [***].

“Lonza Information” means [***].

“Manufacturing Process” means [***].

“Master Batch Record” means the document, proposed by Lonza and approved by Customer, which defines the manufacturing methods, test methods and other procedures, directions and controls associated with the manufacture and testing of Product.

“New Customer Intellectual Property” has the meaning given in Clause 10.2

“New General Application Intellectual Property” has the meaning given in Clause 10.3.

“Party” means each of Lonza and Customer and, together, the “Parties”.

"Polysaccharide Intermediate Batch" means a batch of polysaccharide intermediate manufactured at the Facility.

“Price” means the price for the Services and Products as set out in the applicable Project Plan.

“Process Validation Batch” means a Batch that is produced with the intent to show reproducibility of the Manufacturing Process and is required to complete process validation studies.

“Product” means the proprietary molecule identified by Customer in the applicable Project Plan, including but not limited to [***].

“Project Plan” or “Project Plans” means the plans describing the Services to be performed by Lonza under this Agreement, including any update and amendment of the Project Plan to which the Parties may agree from time to time.

“Quality Agreement” means the quality agreement, attached hereto as Appendix B, setting out the responsibilities of the Parties in relation to quality as required for compliance with cGMP.

“Raw Materials” means all ingredients, solvents, consumables (including Resins), and other components of the Product required to perform the Manufacturing Process or Services and to be procured by Lonza, as further set forth in the bill of materials detailing the same. For the avoidance of doubt, Customer Product Components and Customer Supplied Raw Materials are not considered to be Raw Materials.

“Raw Materials Fee” means the procurement and handling fee of [***] of the acquisition cost of Raw Materials by Lonza that is charged to the Customer in addition to the cost of such Raw Materials.

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“Regulatory Authority” means the FDA, Swissmedic, EMA and any other similar regulatory authorities as may be agreed upon in writing by the Parties.

“Release” has the meaning given in Clause 7.1.

"Resins” means the chromatographic media and/or UF membranes [***], as specified in the Master Batch Record.

"Services" means all or any part of the services to be performed by Lonza under this Agreement (including, without limitation, process and analytical method transfer, process development, process optimization, validation, clinical and commercial manufacturing, as well as quality control and quality assurance activities), particulars of which are set out in a Project Plan.

"Specifications" means the specifications of the Product as specified in Appendix C, which may be amended from time to time in accordance with this Agreement.

"Term" has the meaning given in Clause 14.1.

"Third Party" means any party other than Customer, Lonza and their respective Affiliates.

In this Agreement references to the Parties are to the Parties to this Agreement, headings are used for convenience only and do not affect its interpretation, references to a statutory provision include references to the statutory provision as modified or re-enacted or both from time to time and to any subordinate legislation made under the statutory provision, references to the singular include the plural and vice versa, and references to the word "including" are to be construed without limitation.

2 Performance of Services

2.1 Performance of Services. Subject to Clause 2.3, Lonza shall itself and through its Affiliates, diligently carry out the Services in accordance with the prevailing industry standards as provided in the Project Plan and according to the estimated timelines as set forth in the Project Plan. Lonza shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform the Services in accordance with this Agreement. Lonza may subcontract or delegate any of its rights or obligations under this Agreement to perform the Services to External Laboratories with prior notice to and approval of Customer; provided, that any External Laboratories shall be subject to the same obligations and other provisions contained in this Agreement or any applicable Project Plan, including obligations of confidentiality at least as stringent, and as protective of Customer, as those obligations of confidence and non-use imposed upon Lonza and provided that such External Laboratories shall be subject to obligations to act diligently. Lonza shall not be responsible for analytical lab services performed by External Laboratories.

2.2 Technology Transfer. The Parties expressly agree that they shall work together to transfer the Manufacturing Process to the Facility, including implementing the technology transfer plan set forth in Project Plan. Customer shall fully support such technology transfer as reasonably requested by Lonza. Customer shall (by such date as agreed between the Parties) supply to Lonza all such Customer Information, Customer Supplied Raw Materials, Customer Product Components and other information or materials that are listed in each Project Plan and may be reasonably required by Lonza to perform the Services. Lonza shall not be responsible for any delays arising out of Customer's failure to provide such Customer Information, Customer Supplied Raw Materials, Customer Product Components and/or other information and/or materials reasonably required to perform the Services to Lonza.

2.3 Engineering Batches. Lonza shall manufacture Engineering Batches in accordance with the Project Plan(s) and batch records. Customer shall have the right to make whatever further use of the non-cGMP Engineering Batches as it shall determine, provided that Customer pays for such Batches, such use is not for human use and does not violate any Applicable Laws. While Lonza makes absolutely no warranty that Engineering Batches will meet cGMP or the Specifications, Lonza will manufacture the Engineering Batches under cGMP conditions. Accordingly, if Lonza determines that an Engineering Batch does meet cGMP and the Specifications, it will release such Engineering Batch as a cGMP Batch. Regardless of whether any Engineering Batch meets cGMP or the Specifications and provided that the Engineering Batch was executed in accordance with the Project Plan and batch records, Customer shall pay to Lonza the Price for such Engineering Batch plus the Raw Materials Fee associated with such Engineering Batch. In the event Customer requests a material change to the Manufacturing Process or Specifications, Lonza and Customer shall discuss in good faith modifications and written amendments to the applicable Project Plan, including potential manufacture of additional Engineering Batches utilizing the modified process or specifications and adjustments (up or down) to Batch Price to reflect changes in cost resulting from such material change.

2.4 cGMP Batches. Lonza will, in accordance with the terms of this Agreement and Quality Agreement, manufacture at the Facility and Release to Customer, cGMP Batches that comply with the Manufacturing Process, cGMP and the Specifications, together with a Certificate of Analysis. [***].

2.5 Process Validation Batches. Lonza shall manufacture and deliver Process Validation Batches as mutually agreed by Parties sufficient to document the operability and reproducibility of the Manufacturing Process and permit the Parties to complete and file the necessary regulatory documents.

2.5.1 Prior to commencement of Process Validation Batches, Lonza and Customer shall agree a process validation plan identifying the validation requirements of the Manufacturing Process. All process validation activities are excluded from the Price of Process Validation Batches shall be approved by the Customer in advance and shall be paid for by the Customer at the Price set out in the applicable Project Plan.

2.5.2 Any regulatory support activities (including pre-Approval inspection) required and agreed to by Customer to support the Approval of the Product from the Facility shall be performed and supported by Lonza as reasonably requested by Customer. All such regulatory support activities are excluded from the Price of Process Validation Batches, shall be approved by the Customer in advance, and shall be paid for by the Customer at the Price set out in the applicable Project Plan.

For the sake of clarity, the Parties agree that Lonza shall provide regulatory review, at the agreed hourly rate/day rate, with respect to all documents related to any regulatory submission. Lonza shall exercise reasonable commercial efforts to review the documents and provide input in accordance with Customer's reasonably requested timeline.

2.6 Supply of Customer Information and Customer Supplied Raw Materials. Customer shall supply to Lonza all Customer Information and Customer Supplied Raw Materials and other information that may be reasonably required by Lonza to perform the Services. Lonza hereby undertakes not to use the Customer Supplied

Raw Materials or Customer Information (or any part thereof) for any purpose other than the performance of the Services under this Agreement. With respect to any Customer Supplied Raw Materials, title shall remain with the Customer and shall not transfer to Lonza. Lonza shall provide quarterly reporting of cGMP inventory of Customer Supplied Raw Materials and Customer Product Components levels by SKU, with actual utilization/ending balances provided, within [***] business days from the end of the calendar quarter.

Timelines for delivery of critical Customer Information, Customer Supplier Raw Materials and Customer Product Components shall be set forth in the applicable Project Plan/Scope Change. [***]. Lonza shall have an obligation to mitigate damages related to such idle manufacturing suite capacity and shall use utmost commercially reasonable efforts to reduce Customer cycle times, secure a new project or shift any existing projects then under contract with Lonza for the same dates and duration that would have been utilized by Customer. For clarity, no compensation shall be due with respect to any losses caused in whole or in part by action or omission by Lonza or its Affiliates or External Laboratories or Force Majeure event.

2.7 Raw Materials. Lonza shall procure all Raw Materials. Customer shall be responsible for payment for all consumables and Raw Materials ordered or irrevocably committed to be procured by Lonza hereunder. [***].

2.7.1 [***].

3 Project Management / Steering Committee

3.1 Project Plans. With respect to a new project to be governed by this Agreement, a new Project Plan shall be added by agreement in a writing signed by the Parties and appended to Appendix A. Each Project Plan shall include a description of the Services to be provided, the Product to be manufactured, Specifications, a schedule for completion of the Project Plan, pricing details, and such other information as is necessary for relevant Services. In the event of a conflict between the terms of a Project Plan and this Agreement, the terms of the Agreement will govern unless explicitly stated otherwise in the Project Plan.

3.2 Project Management. With respect to each Project Plan, each party will appoint a project manager who will be the party responsible for overseeing the Project Plan.

3.3 Steering Committee. Each Party shall name a mutually agreed upon equal number of representatives for the Steering Committee, which shall meet twice per calendar year, or as otherwise mutually agreed by the Parties. In the event that a Steering Committee dispute cannot be resolved, such dispute shall be escalated to a senior executive of each of Customer and Lonza.

The primary function of the Steering Committee is to ensure the ongoing communication between the Parties and discuss and resolve any issues arising under this Agreement. In addition to the primary function described above, the Steering Committee shall also take on the following responsibilities:

3.3.1 discuss and seek resolution of issues around management of the Services;

3.3.2 agree and monitor deadlines and milestones for the Services; and

3.3.3 discuss and recommend any changes to the Services (although such changes will not take effect until they have been incorporated into a written amendment to the Project Plan which has been signed by the Parties).

3.4 Person in Plant. Customer shall be permitted to have [***] at the Facility as reasonably requested by Customer, [***] for the purpose of observing, reporting on, and consulting as to the performance of the Services. Such [***] shall be subject to and agree to abide by confidentiality obligations to Third Parties and Lonza's customary practices and operating procedures regarding persons in plant, and such [***] agrees to comply with all instructions of Lonza's employees at the Facility. Lonza shall have the right to postpone a request from Customer in the event of a significant spike in the Covid pandemic impacting the Facility.

4 Quality

4.1 Responsibility for quality assurance and quality control of Product shall be allocated between Customer and Lonza as set forth in the Quality Agreement and in Lonza standard operating procedures. If there is a conflict between the terms and conditions of this Agreement and the Quality Agreement, the terms and conditions of the Quality Agreement shall prevail with respect to quality matters and this Agreement shall prevail with respect to all other matters. If the Quality Agreement is not in place at the Effective Date, Lonza and Customer commit to enter into the Quality Agreement in a timely manner, but in no event later than the commencement of cGMP manufacturing.

4.2 Provisions regarding inspections by Regulatory Authorities and audits shall be set out in the Quality Agreement.

5 Insurance

5.1 Each Party shall, during the Term and for [***] after delivery of the last Product manufactured or Services provided under this Agreement, obtain and maintain at its own cost and expense from a qualified insurance company, comprehensive general liability insurance including, but not limited to product liability coverage in the amount of at least [***]. Each Party shall provide the respective other Party with a certificate of such insurance upon reasonable request.

6 Forecasting, Ordering and Cancellation

Forecasting and Ordering.

6.1.1 [Intentionally Deleted].

6.1.2 Parties shall agree upon Services to be provide by Lonza in the Project Plan and/or a separate scope change/scope of work. Upon execution of such document by both Parties, the Services shall be binding on both Parties. [***].

6.2 Rescheduling.

6.2.1 After good faith discussion between the Parties, Lonza may reschedule a Commencement Date of any Batch or Campaign, provided that the rescheduled Commencement Date is no earlier or no later than [***] from the Commencement Date originally estimated at the time of Lonza's acceptance of the binding purchase order. For clarity, prior written consent of Customer shall be required to reschedule the Commencement Date by more than [***] from the

Commencement Date originally estimated at the time of Lonza's acceptance of the binding purchase order, whereas failure to obtain such consent shall be deemed a material breach. If the Customer requests to change the Commencement Date, Lonza will make all reasonable attempts to accommodate the request; provided, however, in the event that this change would impact other projects scheduled for occupancy in the designated suite or suites, manufacture of the Customer's Batch or Campaign may be delayed until an adequate time period is available in the Facility schedule. Any delay requested by Customer of more than [***] and not replaced by other Customer Batches for the cGMP manufacturing space, for the same dates and duration that would have been occupied by Customer's rescheduled Batches, may be considered a cancellation pursuant to Section 6 and subject to Section 6.5. For clarity, no Cancellation Fees shall be due with respect to any delays caused in whole or in part by action or omission by Lonza or its Affiliates or External Laboratories.

6.2.2 Upon prior consent of Customer after good faith discussion between the Parties, which may not be unreasonably withheld or delayed, Lonza may reschedule a Commencement Date of any Service, provided that the rescheduled Commencement Date is no earlier or no later than [***] from the Commencement Date originally estimated at the time of Lonza's acceptance of the binding purchase order. If the Customer requests to change the Commencement Date, Lonza will make all reasonable attempts to accommodate the request. Any delay requested by Customer whereas such human and capital resources cannot be reutilized by Lonza for Customer or other customers shall be subject to a rescheduling fee. Rescheduling fee shall equal [***]. Notwithstanding the foregoing, Lonza shall have an obligation to mitigate damages related to such rescheduling of Services by Customer leading to rescheduling fees. Lonza shall use utmost commercially reasonable efforts to secure a new project or shift any existing projects then under contract with Lonza for the same dates and duration that would have been utilized by Customer. For clarity, no rescheduling fees shall be due with respect to any delays caused in whole or in part by action or omission by Lonza or its Affiliates or External Laboratories.

6.3 Cancellation of a Purchase Order. Customer may cancel a binding purchase orders upon written notice to Lonza, subject to the payment of a cancellation fee as calculated below (the "Cancellation Fee"):

Development Services

6.3.1 In the event that Customer provides written notice of cancellation to Lonza less than or equal to [***] prior to the Commencement Date of one or more development Services, then [***] of the development Services cancelled under a purchase order is payable; and

6.3.2 In the event that Customer provides written notice of cancellation more than [***] prior to the Commencement Date of one or more development Services, then [***] is payable.

BLA Services

6.3.3 In the event that Customer provides written notice of cancellation to Lonza less than or equal to [***] prior to the Commencement Date of one or more BLA Services, then [***] of the BLA Services cancelled under a purchase order is

payable;

6.3.4 In the event that Customer provides written notice of cancellation to Lonza more than [***] but less than or equal to [***] prior to the Commencement Date of one or more BLA Services, then [***] of the Price of each such BLA Services cancelled is payable; and

6.3.5 In the event that Customer provides written notice of cancellation more than [***] prior to the Commencement Date of one or more BLA Services, then [***] is payable.

Bioconjugates PCP Asset, Microbial L2, Microbial 70L Asset and BPMSS 1k Asset

6.3.1 In the event that Customer provides written notice of cancellation to Lonza less than or equal to [***] prior to the Commencement Date of one or more Batches, then [***] of the Price of each such Batches cancelled is payable; and

6.3.2 In the event that Customer provides written notice of cancellation to Lonza more than [***] but less than or equal to [***] prior to the Commencement Date of one or more Batches, then [***] of the Price of each such Batches cancelled is payable.

6.3.1 In the event that Customer provides written notice of cancellation to Lonza more than [***] prior to the Commencement Date of one or more Batches, then [***] is payable.

Microbial P2/15k Asset

6.3.2 In the event that Customer provides written notice of cancellation to Lonza less than or equal to [***] prior to the Commencement Date of one or more Batches, then [***] of the Price of each such Batches cancelled is payable;

6.3.3 In the event that Customer provides written notice of cancellation to Lonza more than [***] but less than or equal to [***] prior to the Commencement Date of one or more Batcheses, then [***] of the Price of each such Batches cancelled is payable;

6.3.4 In the event that Customer provides written notice of cancellation to Lonza more than [***] prior to the Commencement Date of one or more Batches, then [***] is payable.

6.4 Payment of Cancellation Fee. Any Cancellation Fee shall be payable within [***] following the written notice of cancellation associated with the cancelled Batch.

6.5 Replacement Project. Notwithstanding the foregoing, Lonza shall have an obligation to mitigate damages related cancelation, rescheduling and delays to Services by Customer leading to Cancellation Fees. [***].

6.6 Delays. In the event of a delay [***]:

Development Services

6.6.1 [***].

BLA Services

6.6.2 [***].

Manufacturing Services

6.6.3 [***].

7 Delivery and Acceptance

7.1 Delivery. All Product shall be delivered [***] (as defined by Incoterms® 2020). Lonza shall deliver to Customer the Certificate of Analysis and such other documentation as is reasonably required to meet all applicable regulatory requirements of the Governmental Authorities not later than the date of delivery of Batches (the "Release"). [***]. In addition, Lonza shall exercise reasonable commercial efforts and customary due diligence and care to ensure that Customer Supplier Raw Materials and Customer Product Components are stored in accordance with the Specifications, cGMPs, Quality Agreement and Customer's instructions and protect these from theft, casualty, or other damage within Lonza's reasonable control.

7.2 Storage. CRM12 Intermediate Batches and Polysaccharide Intermediate Batches (required intermediates for the production of Conjugate Drug Substances) will be stored [***] until the CRM12 Intermediate Batches and Polysaccharide Intermediate Batches are used for the manufacturing of Conjugate Drug Substances; [***].

Customer shall arrange for shipment and take delivery of Conjugate Drug Substances Batches from the Facility, at Customer's expense, within [***] after Release or pay applicable storage costs, unless otherwise agreed to by the Parties. [***]. In addition to Section 8.2, Customer shall be responsible for all value added tax ("VAT") and any other applicable taxes, levies, import, duties and fees of whatever nature imposed as a result of any storage. Within [***] following a written request from Lonza, Customer shall provide Lonza with a letter in form satisfactory to Lonza confirming the bill and hold status of each stored Batch.

7.3 Acceptance/Rejection of Product.

7.3.1 Promptly following Release of Batches, Customer shall inspect such Batches and shall have the right to test such Batches to determine compliance with the Specifications. Customer shall notify Lonza in writing of any rejection of a Batch based on any claim that it fails to meet Specifications within [***] of Release, after which time all unrejected Batches shall be deemed accepted. Customer shall inform Lonza in writing in case of concealed or latent defects (i.e. not discovered by routine quality control means), promptly upon discovery of such defects but no later than [***] after initial discovery of the defect and in no event after [***] from Release of the Batch.

7.3.2 In the event that Lonza believes that a Batch has been incorrectly rejected, Lonza may require that Customer provide to it Batch samples for testing. Lonza may retain and test the samples of such Batch. In the event of a discrepancy between Customer's and Lonza's test results such that Lonza's test results fall within relevant Specifications, or there exists a dispute between the Parties over the extent to which such failure is attributable to a given Party, the Parties shall cause an independent laboratory promptly to review records, test data and perform comparative tests and/or analyses on samples of the Product that

allegedly fails to conform to Specifications. Such independent laboratory shall be mutually agreed upon by the Parties and shall be located in either the United States or the European Union. The independent laboratory's results shall be in writing and shall be final and binding save for manifest error. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules.

Lonza may, upon written approval of Customer, reprocess any cGMP Batch or, if reprocessing is not possible or Customer does not consent, Lonza shall replace any cGMP Batch that failed to conform with the Specifications, where such cGMP Batch was required to conform with the Specification (a "Failed Batch"), in the event that it is determined (by the Parties or the independent laboratory) that such failure was [***] ("Lonza Responsibility"). [***].

With respect to the loss of Customer Supplied Raw Materials and/or Customer Product Components (as applicable) used in the Failed Batch, the Parties agree that for the replacement Batch [***].

Lonza shall exercise best commercial efforts to immediately reprocess or replace the Failed Batch.

7.3.3 Customer acknowledges and agrees that [***] with respect to a Failed Batch that is a Lonza Responsibility [***], and in furtherance thereof, [***].

8 Price and Payment

8.1 Pricing for the Services provided by Lonza are set out in, and based on the assumptions and information set out in, the applicable Project Plan. In the event of changes to the Services based on Customer's request, Customer shall bear all additional costs.

8.2 Unless otherwise indicated in writing by Lonza, [***] all such charges applicable to the Services (other than taxes on Lonza's income) shall be paid by Customer.

8.3 Payment Terms. Unless otherwise agreed upon between the Parties (in a Project Plan or Statement of Work), the following payment terms shall apply:

8.3.1 For Stages of Work of less than [***] (or equivalent in the applicable currency): Unless otherwise agreed in writing Lonza shall issue invoices to Customer for [***] of the Price upon completion of that Stage of Work.

8.3.2 For Stages of Work of [***] or more (or equivalent in the applicable currency): Unless otherwise agreed in writing Lonza shall issue all invoices to Customer for [***] of the Price for Batches or Services upon the Commencement Date thereof and [***] upon Release of applicable Batches or completion of applicable Services, unless otherwise stated in the Project Plan.

8.3.3 Unless otherwise agreed to in writing by Parties, all undisputed invoices shall be paid within [***] from the date of receipt of the invoice. In the event of a disputed invoice, Customer shall timely pay the undisputed portion of the invoice.

8.3.4 Unless otherwise agreed in writing charges for Raw Materials (including media and feeds) and the applicable Raw Materials Fee for each Batch shall be

invoiced [***] upon the Commencement Date of the Batch [***].

8.4 If in default of payment of any undisputed invoice [***] after the due date, interest shall accrue on any amount overdue at the lesser of (i) rate of [***] or (ii) the maximum rate allowable by applicable law, interest to accrue on a day to day basis until full payment; and Lonza shall, at its sole discretion, and without prejudice to any other of its accrued rights, be entitled to suspend the provision of the Services and or delivery of Product until all overdue amounts have been paid in full including interest for late payments.

8.5 Price adjustments.

8.5.1 Not more than once per calendar year effective on or around January 1st, upon prior written notice and with first price increase effective on January 1, 2024, [***]. The new Price reflecting such Batch Price adjustment shall be effective for any Batch for which the Commencement Date is past June 30 of the respective calendar year.

8.5.2 In the event there is (i) a change in the cost of energy, utilities or labor of more than [***] that substantially increases Lonza's operating costs with respect to Services, the Parties shall meet and discuss in good faith potential adjustments to the Price of Services.

8.6 Financial Audit. Each Party shall maintain its books and records related to the Services, including (to the extent applicable) with respect to price adjustments, cancellation fees, FTE hours and raw material and component handling fees in accordance with its usual business practices for a period of at least [***]. Either Party may conduct a financial audit of the other Party to confirm such Party's compliance with financial terms of this Agreement upon [***] written notice and not more often than [***]. The audit will be conducted by an independent third party selected by the Party initiating the audit and at such Party's expense. In the event the audit reveals any net variance between amounts charged and amounts that should have been charged pursuant to the terms of this Agreement, such net overcharges/undercharges plus interest rate charges calculated in pursuant to Section 8.4 shall be paid by wire transfer to the relevant Party within [***] of final determination. If such audit reveals more than a [***] net overcharges or a net overcharged in excess of [***] to the detriment of the auditing Party, then expenses for said auditor shall be reimbursed by the audited Party to the auditing Party up to a cap of [***].

9 Capital Equipment

9.1 Any Capital Equipment required for the performance of the Services shall be acquired on terms to be agreed by the Parties prior to commencement of the relevant Services. Notwithstanding the foregoing, Lonza shall be responsible for procurement, installation and maintenance of any Capital Equipment generally required to maintain operations of the Facility.

10 Intellectual Property

10.1 Neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Background Intellectual Property of the other Party or any of its Affiliates.

10.2 Subject to Clause 10.3, Customer shall own all right, title, and interest in and to any and all Intellectual Property that Lonza and/or its Affiliates, the External Laboratories

or other contractors or agents of Lonza develops, conceives, invents, first reduces to practice or makes solely or jointly with Customer or others, to the extent that it is both:

10.2.1 solely a direct derivative of or improvement to Product, Customer Supplied Raw Materials, Customer Product Components, Customer Information and/or Customer Background Intellectual Property; and

10.2.2 is not an improvement of, or direct derivative of, any Lonza Background Intellectual Property or Lonza Information;

(the "New Customer Intellectual Property"). [***].

10.3 Notwithstanding Clause 10.1, and subject to the license granted in Clause 10.5, Lonza shall own all right, title and interest in Intellectual Property that Lonza and/or its Affiliates, the External Laboratories or other contractors or agents of Lonza, solely or jointly with Customer or others, develops, conceives, invents, or first reduces to practice or makes in the course of performance of the Services that:

10.3.1 is generally applicable to the development or manufacture of chemical or biological products or products components; or

10.3.2 is an improvement of, or direct derivative of, any Lonza Background Intellectual Property or Lonza Information;

(the "New General Application Intellectual Property"). [***].

10.4 [***].

10.5 Subject to the terms and conditions set forth herein (including the payment of the Price as required above and Section 10.9), Lonza hereby grants to Customer a non-exclusive, world-wide, 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 this Agreement (but no other products).

10.6 [***].

10.7 Provided that (i) Customer is not in breach of this Agreement; and/or (ii) Lonza has not terminated this Agreement [***], Customer will have the right to transfer the Manufacturing Process to itself and/or any Third Party [***].

10.8 Prosecution of Patents.

10.8.1 Subject to the following subsection, Customer will have the sole right and discretion to file (or not file), prosecute and maintain patent applications and patents claiming [***]. Lonza will cooperate with Customer, at Customer's expense, to file, prosecute, maintain, defend, and enforce patent applications and patents claiming any [***].

10.8.2 Unless the Parties agree otherwise, at least [***] prior to filing any application disclosing or claiming any [***].

10.8.3 Lonza will have the sole right and discretion to file (or not file), prosecute and maintain patent applications and patents [***].

10.9 Notwithstanding anything to the contrary in this Agreement, the Parties have agreed on the terms and conditions pertain to certain Intellectual Property generated prior to the Effective Date as set forth in a "Letter Agreement Regarding New Intellectual Property Ownership Rights" by and between Lonza and Customer, dated September 15, 2021 (the "Letter Agreement"), referred to as "Lonza New Inventions" and "Vaxcyte New Inventions" in such Letter Agreement, and that to the extent the terms and conditions of this Agreement are inconsistent with those in the Letter Agreement as they pertain to such Lonza New Invention and/or Vaxcyte New Invention, then terms and conditions in the Letter Agreement shall control.

11 Warranties

11.1 Lonza warrants that:

11.1.1 the Services shall be performed in accordance with all Applicable Laws;

11.1.2 [***];

11.1.3 [***];

11.1.4 [***];

11.1.5 it or its Affiliate holds all necessary permits, approvals, consents and licenses to enable it to perform the Services at the Facility;

11.1.6 it has the necessary corporate authorizations to enter into and perform this Agreement;

11.1.7 Lonza or its personnel have not been and are not debarred under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335(a) or (b)) (the "Act").

11.1.8 subject to payment of undisputed invoices, title to all Product and all New Customer Intellectual Property provided to Customer under this Agreement shall pass free and clear of any security interest, lien or other encumbrance in favor of Lonza; and

11.2 Customer warrants that:

11.2.1 [***];

11.2.2 Customer will promptly notify Lonza in writing if it receives or is notified of a formal written claim from a Third Party that Customer Information and/or Customer Intellectual Property or that the use by Lonza thereof for the provision of the Services infringes any Intellectual Property or other rights of any Third Party; and

11.2.3 Customer has the necessary corporate authorizations to enter into this Agreement.

11.2.4 Customer or its personnel have not been and are not debarred under the Act.

11.3 DISCLAIMER: THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, AND ALL OTHER WARRANTIES, BOTH EXPRESS AND IMPLIED, ARE EXPRESSLY

DISCLAIMED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

11.4 Debarment.

11.4.1 In the event a party receives a notice from the other party ("Defaulting Party") or otherwise becomes aware that a debarment, suspension, exclusion, sanction, or declaration of ineligibility action has been brought against the Defaulting Party, which would prevent such Party from performing its obligations and/or on this Agreement; then the party receiving such notice shall have the right to terminate this Agreement immediately; provided that if such event shall occur, the party receiving such notice shall not have such right of termination if the Defaulting Party is disputing and defending such action and the Defaulting Party is otherwise able to perform its obligations and/or Services in the manner required under this Agreement.

11.4.2 Each party shall ensure that it will not knowingly use in any capacity the services of any individual, corporation, partnership or association which has been debarred under 21 U.S.C. Sec. 335a(a) or (b), or listed in the DHHS/OIG List of Excluded Individuals/Entities or the General Services Administration's Listing of Parties Excluded from Federal Procurement and Non-Procurement Programs.

12 Indemnification and Liability

12.1 Indemnification by Lonza. Lonza shall indemnify the Customer, its Affiliates, and their respective officers, employees and agents ("Customer Indemnitees") for any loss, damage, costs and expenses (including reasonable attorney fees) that Customer Indemnitees may suffer as a result of any Third Party claim arising directly out of [***]. Notwithstanding the foregoing, Lonza shall have no obligations under this clause 12.1 for any liabilities, expenses, or costs to the extent arising out of or relating to claims covered under clause 12.2.

12.2 Indemnification by Customer. Customer shall indemnify Lonza, its Affiliates, and their respective officers, employees and agents ("Lonza Indemnitees") from and against any loss, damage, costs and expenses (including reasonable attorney fees) that Lonza Indemnitees may suffer as a result of any Third Party claim arising directly out of [***]. Notwithstanding the foregoing, Customer shall have no obligations under this clause 12.2 for any liabilities, expenses, or costs to the extent arising out of or relating to claims covered under clause 12.1.

12.3 Indemnification Procedure. If the Party to be indemnified intends to claim indemnification under this Clause 12, [***].

12.4 DISCLAIMER OF CONSEQUENTIAL DAMAGES. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, LOST PROFITS OR LOST REVENUES ARISING FROM OR RELATED TO THIS AGREEMENT, EXCEPT TO THE EXTENT RESULTING FROM FRAUD, GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT AND/OR FOR EITHER PARTY'S BREACH OF ARTICLE 13 HEREOF.

12.5 LIMITATION OF LIABILITY. [***].

13 Confidentiality

13.1 A Party receiving Confidential Information (the “Receiving Party”) agrees to strictly keep secret any and all Confidential Information received during the Term from or on behalf of the other Party (the “Disclosing Party”) using at least the same level of measures as it uses to protect its own Confidential Information, but in any case at least commercially reasonable and customary efforts. Confidential Information shall include information disclosed in any form including but not limited to in writing, orally, graphically or in electronic or other form to the Receiving Party, observed by the Receiving Party or its employees, agents, consultants, or representatives, or otherwise learned by the Receiving Party under this Agreement, which the Receiving Party knows or reasonably should know is confidential or proprietary.

13.2 Notwithstanding the foregoing, Receiving Party may disclose to any courts and/or other authorities Confidential Information which is or will be required pursuant to applicable governmental or administrative or public law, rule, regulation or order. In such case the Party that received the Confidential Information will, to the extent legally permitted, inform the other Party promptly in writing and cooperate with the Disclosing Party in seeking to minimize the extent of Confidential Information which is required to be disclosed to the courts and/or authorities.

13.3 The obligation to maintain confidentiality under this Agreement does not apply to Confidential Information, which:

13.3.1 at the time of disclosure was publicly available; or

13.3.2 is or becomes publicly available other than as a result of a breach of this Agreement by the Receiving Party; or

13.3.3 as the Receiving Party can establish by competent proof, was rightfully in its possession at the time of disclosure by the Disclosing Party and had not been received from or on behalf of Disclosing Party; or

13.3.4 is supplied to a Party by a Third Party which was not in breach of an obligation of confidentiality to Disclosing Party or any other party; or

13.3.5 is developed by the Receiving Party independently from and without use of the Confidential Information, as evidenced by contemporaneous written records.

13.4 The Receiving Party will use Confidential Information only for the purposes of this Agreement and will not make any use of the Confidential Information for its own separate benefit or the benefit of any Third Party including, without limitation, with respect to research or product development or any reverse engineering or similar testing. The Receiving Party agrees to return or destroy promptly (and certify such destruction) on Disclosing Party’s request all written or tangible Confidential Information of the Disclosing Party, except that one copy of such Confidential Information may be kept by the Receiving Party in its confidential files for record keeping purposes only.

13.5 Each Party will restrict the disclosure of Confidential Information to such officers, employees, professional advisers, finance-providers, consultants and representatives of itself and its Affiliates who have been informed of the confidential nature of the Confidential Information and who have a need to know such Confidential Information for the purpose of this Agreement or an applicable financing or acquisition. Both Parties may disclose Confidential Information of the other Party and its Affiliates to potential and actual acquirers provided such disclosure is limited to the terms of this Agreement. Customer also may disclose to its potential (i.e., as

evidenced by a written term sheet or MOU) and actual: (i) acquirers and (ii) bona fide collaborators in the research, development and commercialization of the Products, the work product provided to Customer by Lonza as a consequence of the provision of the Services. Prior to disclosure to such persons, the Receiving Party shall inform the Disclosing Party and it shall bind its and its Affiliates' officers, employees, consultants and representatives to confidentiality and non-use obligations no less stringent than those set forth herein. The Receiving Party shall notify the Disclosing Party as promptly as practicable of any unauthorized use or disclosure of the Confidential Information.

13.6 The Receiving Party shall at any time be fully liable for any and all breaches of the confidentiality obligations in this Clause 13 by any of its Affiliates or the employees, consultants, potential and actual acquirers, and representatives of itself or its Affiliates.

13.7 Each Party hereto expressly agrees that any breach or threatened breach of the undertakings of confidentiality provided under this Clause 13 by a Party may cause irreparable harm to the other Party and that money damages may not provide a sufficient remedy to the non-breaching Party for any breach or threatened breach. In the event of any breach and/or threatened breach, then, in addition to all other remedies available at law or in equity, the non-breaching Party shall be entitled to seek injunctive relief and any other relief deemed appropriate by the non-breaching Party.

14 Term and Termination

14.1 Term. This Agreement shall commence on the Effective Date and shall end on the fifth (5^{th}) anniversary of the Effective Date and shall automatically renew for one additional two (2) year period unless either Party provide written notice of non-renewal at least two (2) years prior to the fifth anniversary of the Effective Date or the Agreement is terminated earlier as provided herein (the "Term"). Notwithstanding the foregoing, each Project Plan may have separate term and termination provisions so long as the term of any Project Plan does not extend beyond the Term.

14.2 Termination. This Agreement may be terminated as follows:

14.2.1 by either Party if the other Party breaches a material provision of this Agreement or a Project Plan and fails to cure such breach to the reasonable satisfaction of the non-breaching Party [***]; or

14.2.2 by either Party, 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; or

14.2.3 by either Party pursuant to Clause 15; or

14.2.4 by either Party if it becomes apparent to either Lonza or the Customer 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. [***]; or

14.2.5 by Customer with or without cause upon [***] written notice on a Project Plan-by-Project Plan basis.

14.3 Consequences of Termination.

14.3.1 In the event of termination by Lonza pursuant to Section 14.2.1 or by Customer pursuant to Section 14.2.4 or 14.2.2, Lonza shall be compensated for (i) Services rendered up to the date of termination, including in respect of any Product in-process; (ii) all costs incurred through the date of termination, including Raw Materials costs and Raw Materials Fees for Raw Materials used or purchased for use in connection with the Project Plan; (iii) all unreimbursed Capital Equipment and related decommissioning charges incurred pursuant to Clause 9; (iv) all amounts in accordance with Section 6, including any applicable Cancellation Fees for Services committed to be provided within the [***].

14.3.2 In the event of termination by Customer pursuant to Section 14.2.1 or by Lonza pursuant to Section 14.2.4, Lonza shall be compensated for (i) Services properly rendered up to the date of termination, including in respect of any Product in-process; and (ii) all costs incurred through the date of termination, including Raw Materials costs and Raw Materials Fees for Raw Materials used or purchased for use in connection with the Project Plan.

14.3.3 In the event of termination by either Party pursuant to Sections 14.2.3, neither party shall have any further liability to the other Party.

14.3.4 In addition to the above, solely with respect to terminations described in Sections 14.3.1 and 14.3.2, [***].

14.4 Survival. The rights and obligations of each Party which by their nature survive the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement, [***].

15 Force Majeure

15.1 If a Party is prevented or delayed in the performance of any of its obligations under the Agreement by Force Majeure and gives written notice thereof to the other Party within [***] of the Party becoming aware of a Force Majeure event and specifying the matters constituting Force Majeure together with such evidence as such Party reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue, the notifying Party and the other Party shall both be excused from the performance or the punctual performance of relevant obligations as the case may be from the date of such notice for so long as such cause of prevention or delay shall continue. Provided that, if such Force Majeure persists for a period of one hundred and [***] or more, Customer may terminate this Agreement by delivering written notice to Lonza.

15.2 “Force Majeure” shall be deemed to include any reason or cause beyond Party’s reasonable control after exercising customary care and planning affecting the performance by a Party of its obligations under the Agreement, including, but not limited to, any cause arising from or attributable to acts of God, strike, lockouts, labor troubles, restrictive governmental orders or decrees, riots, insurrection, war, terrorist acts, or the inability of Lonza to obtain any required raw material, energy source, equipment, labor or transportation. For clarity, prevalence of the Covid pandemic/endemic at the current levels (July 2022) shall not be deemed a Force Majeure event as long as there is no impact on laboratory and operational continuity to operate as usual. For clarity, Force Majeure does not apply to Customer’s obligation to make payments under this Agreement.

15.3 With regard to Lonza, any such event of Force Majeure affecting services or production at its Affiliates or suppliers shall be regarded as an event of Force Majeure.

16 Miscellaneous

16.1 Severability. If any provision hereof is or becomes at any time illegal, invalid or unenforceable in any respect, neither the legality, validity nor enforceability of the remaining provisions hereof shall in any way be affected or impaired thereby. The Parties hereto undertake to substitute any illegal, invalid or unenforceable provision by a provision which is as far as possible commercially equivalent considering the legal interests and the Purpose.

16.2 Amendments. Modifications and/or amendments of this Agreement must be in writing and signed by the Parties.

16.3 Assignment. Lonza shall be entitled to instruct one or more of its Affiliates to perform any of Lonza's obligations contained in this Agreement, but Lonza shall remain fully responsible in respect of those obligations. Neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, provided, however that either Party may assign this Agreement to (i) any Affiliate of such Party or (ii) any third party in connection with the sale or transfer (by whatever method) of all or substantially all of the assets of the business or Product of such Party to which this Agreement relates, whether by merger, consolidation, acquisition or other form of business combination. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment. Lonza shall be entitled to sell, assign and/or transfer its trade receivables resulting from this Agreement without the consent of the Customer.

16.4 Notice. All notices must be written and sent to the address of the Party first set forth above. All notices must be given (a) by personal delivery, with receipt acknowledged, (b) by facsimile followed by hard copy delivered by the methods under (c) or (d), (c) by prepaid certified or registered mail, return receipt requested, or (d) by prepaid recognized next business day delivery service. Notices will be effective upon receipt or at a later date stated in the notice.

16.5 Governing Law/Jurisdiction. This Agreement is governed in all respects by the laws of [***]. The Parties agree to submit to the jurisdiction of the courts of [***].

16.6 Entire Agreement. With exception to the subject matter in the certain agreement titled Letter Agreement Regarding New Intellectual Property Ownership Rights (the "Letter Agreement"), with an effective date of September 15, 2021, attached hereto as Appendix D, this Agreement contains the entire agreement between the Parties as to the subject matter hereof and supersedes all prior and contemporaneous agreements with respect to the subject matter hereof. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same document. Each Party acknowledges that an original signature or a copy thereof transmitted by facsimile or by .pdf shall constitute an original signature for purposes of this Agreement.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Development and Manufacturing Services Agreement to be executed by its duly authorized representative effective as of the date written above.

LONZA LTD

By: /s/ Bart van Aarnhem
Name Bart van Aarnhem

Title Associate General Counsel

Date 2/24/2023

By: /s/ Iwan Bertholjotti
Name Iwan Bertholjotti

Title Senior Director, Commercial Development

Date 2/24/2023

Vaxcyte, Inc.

By: /s/ Grant Pickering
Name Grant Pickering

Title CEO

Date 2/28/2023

APPENDIX A
Project Plan

[***]

APPENDIX B
Quality Agreement

[***]

APPENDIX C
Specifications

[***]

APPENDIX D
Letter Agreement

[***]
27

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Grant E. Pickering, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vaxcyte, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2023 By: /s/ Grant E. Pickering

Grant E. Pickering
Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Guggenhime, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vaxcyte, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2023 By: /s/ Andrew Guggenhime

Andrew Guggenhime
President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Grant E. Pickering, Chief Executive Officer of Vaxcyte, Inc. (the "Company"), and Andrew Guggenhime, President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1.The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2023, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2.The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 8, 2023

/s/ Grant E. Pickering
Grant E. Pickering
Chief Executive Officer

/s/ Andrew Guggenhime
Andrew Guggenhime
President and Chief Financial Officer

"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Vaxcyte, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."