REFINITIV

DELTA REPORT

10-Q

PCVX - VAXCYTE, INC.

10-Q - JUNE 30, 2024 COMPARED TO 10-Q - MARCH 31, 2024

The following comparison report has been automatically generated

TOTAL DELTAS	879
CHANGES	203
DELETIONS	207
ADDITIONS	469

REFINITIV

Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024 June 30, 2024

OR

o **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 x No o

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 x No o

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

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

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. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

As of May 6, 2024 August 2, 2024, the registrant had 108,795,188 111,609,671 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

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. and its wholly owned consolidated subsidiary.

"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.

Table of Contents

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 and prior clinical study results potentially being predictive of future clinical study results;
- the timing of the initiation, progress and potential results of our preclinical studies, clinical trials and our research and development programs;
- our ability to advance vaccine candidates into, and successfully complete, preclinical studies and clinical trials;
- the commercialization of our vaccine candidates, if approved;
- estimates of our future expenses, capital requirements and our needs for additional financing;
- our ability to compete effectively with existing competitors and new market entrants;

- our ability to establish and maintain intellectual property protection for our products or avoid claims of infringement;
- our and our third-party manufacturers' manufacturing capabilities and the scalable nature of our manufacturing process;
- potential effects of extensive government regulation;
- the pricing, coverage and reimbursement of our vaccine candidates, if approved;
- our ability and the ability of our third-party contract manufacturers to operate and continue operations;
- our ability to hire and retain key personnel;
- our ability to obtain additional financing; and
- the volatility of the trading price of our common stock.

Actual events or results may differ from those expressed in forward-looking statements. You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this 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

Table of Contents

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.

Table of Contents

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 stages of vaccine development and have a limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant net losses since inception and anticipate that we will continue to incur substantial net losses for the foreseeable future. We currently have no source of product revenue and may never achieve profitability. Our stock is a highly speculative investment.
- We will require substantial additional funding to finance our operations, which may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.

- Our approach to the discovery and development of our vaccine candidates is based on novel technologies that are unproven, which may expose us to unforeseen risks, require us to modify processes, and make it difficult to predict the time and cost of vaccine candidate development and the timing to apply for and obtain regulatory approvals.
- Our vaccine candidates are in clinical or preclinical stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we are unable to complete development of or commercialize our vaccine candidates or experience significant delays in doing so, our business would be materially harmed.
- The U.S. Food and Drug Administration 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 and VAX-31, both of which are in clinical 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 and commercialize our vaccine candidates, or may result in others discovering, developing or commercializing products before or more successfully than us.
- We may not be successful in our efforts to use our cell-free protein synthesis platform to expand our pipeline of vaccine candidates and develop marketable products.
- We currently rely on third-party manufacturing and supply partners, including Lonza Ltd. and Sutro Biopharma, Inc., to supply raw materials and components for, and the manufacture of, our preclinical and clinical supplies as well as our vaccine candidates. Our inability to procure necessary raw materials or to have sufficient quantities of preclinical and clinical supplies or the inability to have our vaccine candidates manufactured, including delays or interruptions at our third-party manufacturers, or our failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.
- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our vaccine candidates.
- 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.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

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

	March 31, 2024	December 31, 2023
	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Current assets:		
Current assets:		
Cash and cash equivalents		
Cash and cash equivalents		
Cash and cash equivalents		
Short-term investments		
Prepaid expenses and other current assets		
Total current assets		
Property and equipment, net		

Operating lease right-of-use assets		
Long-term investments		
Restricted cash		
Other assets		
Total noncurrent assets		
Total assets		
Liabilities and Stockholders' Equity		
Liabilities and Stockholders' Equity		
Liabilities and Stockholders' Equity		
Current liabilities:		
Current liabilities:		
Current liabilities:		
Accounts payable		
Accounts payable		
Accounts payable		
Accrued compensation		
Accrued manufacturing expenses		
Accrued expenses		
Operating lease liabilities — current		
Total current liabilities		
Operating lease liabilities — long-term		
Total liabilities		
Total liabilities		
Total liabilities		
Commitments and contingencies (Note 7)		
Commitments and contingencies (Note 7)		
Commitments and contingencies (Note 7)		
Stockholders' Equity		
Preferred stock, $0.001 par value — 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding at March 31, 2024 and December 31, 2023		
Preferred stock, $0.001 par value — 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding at March 31, 2024 and December 31, 2023		
Preferred stock, $0.001 par value — 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding at March 31, 2024 and December 31, 2023		
Common stock, $0.001 par value — 500,000,000 shares authorized at March 31, 2024 and December 31, 2023; 108,755,731 and 95,364,831 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively		
Preferred stock, $0.001 par value — 10,000,000 shares authorized at June 30, 2024 and December 31, 2023; no shares issued and outstanding at June 30, 2024 and December 31, 2023		
Preferred stock, $0.001 par value — 10,000,000 shares authorized at June 30, 2024 and December 31, 2023; no shares issued and outstanding at June 30, 2024 and December 31, 2023		
Preferred stock, $0.001 par value — 10,000,000 shares authorized at June 30, 2024 and December 31, 2023; no shares issued and outstanding at June 30, 2024 and December 31, 2023		
Common stock, $0.001 par value — 500,000,000 shares authorized at June 30, 2024 and December 31, 2023; 110,575,993 and 95,364,831 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively		
Additional paid-in capital		
Accumulated other comprehensive gain		
Accumulated deficit		
Total stockholders' equity		
Total liabilities and stockholders' equity		

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

Table of Contents

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

	Three Months Ended March 31,	Three Months Ended March 31,	Three Months Ended March 31,	Three Months Ended June 30,	Three Months Ended June 30,	Three Months Ended June 30,
	2024	2024	2024			
Operating expenses:						
Operating expenses:						
Operating expenses:						
Research and development						
Research and development						
Research and development						
General and administrative						
General and administrative						
General and administrative						
Total operating expenses						
Total operating expenses						
Total operating expenses						
Loss from operations						
Loss from operations						
Loss from operations						
Other income (expense), net:						
Other income (expense), net:						
Other income (expense), net:						
Other income, net:						
Other income, net:						
Other income, net:						
Interest income						
Interest income						
Interest income						
Grant income						
Grant income						
Grant income						
Realized gains on marketable securities						
Realized gains on marketable securities						
Realized gains on marketable securities						
Foreign currency transaction losses						
Foreign currency transaction losses						
Foreign currency transaction losses						
Foreign currency transaction gains (losses)						

Foreign currency transaction gains (losses)	
Foreign currency transaction gains (losses)	
Total other income, net	
Total other income, net	
Total other income, net	
Net loss	
Net loss	
Net loss	
Net loss per share, basic and diluted	
Net loss per share, basic and diluted	
Net loss per share, basic and diluted	
Weighted-average shares outstanding, basic and diluted	
Weighted-average shares outstanding, basic and diluted	
Weighted-average shares outstanding, basic and diluted	

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

Table of Contents

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

	Three Months Ended March 31,	**Three Months Ended June 30,**
	2024	**2024**
Net Loss		
Net Loss		
Net Loss		
Other comprehensive loss:		
Other comprehensive loss:		
Other comprehensive loss:		
Unrealized (losses) gains on investments		
Unrealized (losses) gains on investments		
Unrealized (losses) gains on investments		
Unrealized losses on investments, net		
Unrealized losses on investments, net		
Unrealized losses on investments, net		
Foreign currency translation adjustments, net		
Foreign currency translation adjustments, net		
Foreign currency translation adjustments, net		

Comprehensive loss	
Comprehensive loss	
Comprehensive loss	

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

Table of Contents

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

	Common Stock Shares	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain	Total Stockholders' Equity
Balance — December 31, 2023											
Balance — December 31, 2023											
Balance — December 31, 2023											
Exercise of stock options											
Issuance of common stock and pre-funded warrants in connection with follow-on public offering, net of commissions and offering expenses of $45,997											
Issuance of common stock and pre-funded warrants in connection with follow-on public offering, net of issuance costs of $45,997											
Release of restricted stock units											
Stock-based compensation expense											
Stock-based compensation expense											
Stock-based compensation expense											
Unrealized losses on investments											
Unrealized losses on investments, net											
Foreign currency translation adjustments, net											
Net loss											
Balance — March 31, 2024											
Exercise of stock options											
Follow-on public offering costs											
Issuance of common stock in connection with at-the-market offering, net of issuance costs of $2,551											
Release of restricted stock units											
Issuance of common stock under Employee Stock Purchase Plan											
Issuance of common stock under Employee Stock Purchase Plan											
Issuance of common stock under Employee Stock Purchase Plan											
Stock-based compensation expense											
Unrealized losses on investments, net											
Foreign currency translation adjustments, net											
Net loss											
Balance — June 30, 2024											

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

Table of Contents

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

	Common Stock Shares	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity
Balance — December 31, 2022											
Balance — December 31, 2022											
Balance — December 31, 2022											
Exercise of stock options											
Vesting of early exercised stock options											
Issuance of common stock in connection with at-the-market offering, net of issuance costs of $1,237											
Release of restricted stock units											
Release of restricted stock units											
Release of restricted stock units											
Vesting of early exercised stock options											
Stock-based compensation expense											
Unrealized gains on investments											
Unrealized gains on investments, net											
Net loss											
Balance — March 31, 2023											
Exercise of stock options											
Issuance of common stock and pre-funded warrants in connection with follow-on offering, net of issuance costs of $29,952											
Issuance of common stock under Employee Stock Purchase Plan											
Release of restricted stock units											
Vesting of early exercised stock options											
Stock-based compensation expense											
Unrealized losses on investments, net											
Net loss											
Balance — June 30, 2023											

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

Table of Contents

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

	Three Months Ended March 31,			Six Months Ended June 30,	
	2024	2024	2023	2024	2023
Cash flows from operating activities:					
Net loss					
Net loss					
Net loss					
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization					
Depreciation and amortization					
Depreciation and amortization					
Stock-based compensation expense					
Amortization of operating lease right-of-use assets					
Net accretion of discounts on investments					
Changes in operating assets and liabilities:					
Changes in operating assets and liabilities:					

Changes in operating assets and liabilities:	
Prepaid expenses and other current assets	
Prepaid expenses and other current assets	
Prepaid expenses and other current assets	
Other assets	
Operating lease liabilities	
Accounts payable	
Accrued compensation	
Accrued manufacturing expenses	
Accrued expenses	
Net cash used in operating activities	
Cash flows from investing activities:	
Purchases of property and equipment	
Purchases of property and equipment	
Purchases of property and equipment	
Purchases of investments	
Manufacturing facility and equipment construction-in-progress	
Purchases related to manufacturing facility and equipment construction-in-progress	
Maturities of investments	
Sale of investments	
Sales of investments	
Net cash used in investing activities	
Cash flows from financing activities:	
Proceeds from exercise of common stock options	
Proceeds from exercise of common stock options	
Proceeds from exercise of common stock options	
Proceeds from issuance of common stock related to at-the-market offering, net of issuance costs	
Proceeds from issuance of common stock from follow-on offering, net of issuance costs	
Proceeds from issuance of common stock related to at-the-market offerings, net of issuance costs	
Proceeds from issuance of common stock from follow-on offerings, net of issuance costs	
Release of restricted stock units	
Net cash provided by financing activities	
Net cash provided by financing activities	
Proceeds from issuance of common stock under Employee Stock Purchase Plan	
Net cash provided by financing activities	
Effect of exchange rate changes on cash and cash equivalents	
Net increase (decrease) in cash, cash equivalents and restricted cash	
Cash, cash equivalents and restricted cash, beginning of period	
Cash, cash equivalents and restricted cash, end of period	
Supplemental disclosure of non-cash investing activities:	
Supplemental disclosure of non-cash investing activities:	
Supplemental disclosure of non-cash investing activities:	
Purchases of property and equipment recorded in accounts payable and accrued expenses	
Purchases of property and equipment recorded in accounts payable and accrued expenses	
Purchases of property and equipment recorded in accounts payable and accrued expenses	
Proceeds from issuance of common stock from at-the-market offering, not yet received	

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

Table of Contents

VAXCYTE, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

1. Company Organization and Nature of Business

Vaxcyte, Inc. and its wholly owned consolidated subsidiary, collectively referred to as any of "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. On October 25, 2023, we formed Vaxcyte Switzerland GmbH ("Vaxcyte GmbH"), a wholly owned Swiss subsidiary. 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 consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding interim financial reporting. Certain information and footnote disclosures normally included in the condensed consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted in accordance with such rules and regulations.

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

Unaudited Interim Condensed Consolidated Financial Statements

The condensed consolidated balance sheet as of March 31, 2024 June 30, 2024, the condensed consolidated statements of operations, comprehensive loss and stockholders' equity for the three and six months ended March 31, 2024 June 30, 2024 and 2023 and the condensed consolidated statements of cash flows for the three six months ended March 31, 2024 June 30, 2024 and 2023 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited annual consolidated 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 consolidated financial statements related to the three and six months ended March 31, 2024 June 30, 2024 and 2023 are also unaudited. The results of operations for the three and six months ended March 31, 2024 June 30, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024 or for any other future annual or interim period. These interim condensed consolidated financial statements should be read in conjunction with our audited consolidated financial statements and related notes thereto for the year ended December 31, 2023 included in our Annual Report on Form 10-K filed with the SEC on February 27, 2024.

Use of Estimates

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

Table of Contents

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 standby letters of credit, which were issued to serve as collateral for the lease agreements related to our current corporate headquarters. Cash, cash equivalents and restricted cash as reported within the condensed consolidated balance sheets that total to the same amounts shown in the condensed consolidated statements of cash flows are as follows:

	March 31, 2024	December 31, 2023
	June 30, 2024	December 31, 2023
	(in thousands)	
	(in thousands)	

	(in thousands)
Cash and cash equivalents	
Restricted cash	
Cash, cash equivalents and restricted cash	

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 consolidated balance sheets at fair value. Unrealized gains and losses on these securities are included as a separate component of accumulated other comprehensive gain (loss). The cost of investment securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in other income (expense), net. Realized gains and losses are also included in other income (expense), net. When the fair value of a debt security declines below its amortized cost basis, any portion of that decline attributable to credit losses, to the extent expected to be nonrecoverable before the sale of the security, is recognized in our condensed consolidated statements of operations. When the fair value of a debt security declines below its amortized cost basis due to changes in interest rates, such amounts are recorded in other comprehensive loss, and are recognized in our condensed consolidated 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 anti-dilutive 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, 2024 June 30, 2024, our lease population consisted of office operating leases. As of March 31, 2024 June 30, 2024, 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 consolidated 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

Table of Contents

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. Operating lease ROU assets and lease liabilities may include options to extend or terminate leases if it is reasonably certain that we will exercise such options. Lease payments which are fixed and determinable are amortized as rent expense on a straight-line basis over the expected lease term. Variable lease costs, which are dependent on usage, a rate or index, including common area maintenance charges, are expensed as incurred. Lease agreements that include lease and non-lease components are accounted for as a single lease component. Lease agreements with non-cancelable terms of less than 12 months are not recorded on our condensed consolidated 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 consolidated 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 have not experienced any losses on these deposits or investments as a result of this market event. Management believes that we are not exposed to significant credit risk as our deposits are held at First Citizens Bank & Trust Company, which had agreed to purchase and assume all deposits and loans of Silicon Valley Bridge 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. 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 or for future potential commercialization; our ability to obtain additional capital to finance our operations; our ability to obtain, maintain and protect our intellectual property rights; developments relating to our competitors and our industry, including competing vaccine candidates; 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.

Recently Issued Accounting Pronouncements — Not Yet Adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by us as of the specified effective date. We believe that the impact of recently

Table of Contents

issued standards that are not yet effective will not have a material impact on our consolidated financial statements and disclosures.

In March 2024, the FASB issued Accounting Standards Update ("ASU") No. 2024-02, *Codification Improvements—Amendments to Remove References to the Concepts Statements* ("ASU 2024-02"). The amendments in ASU 2024-02 clarify and simplify references to certain concept statements within U.S. GAAP. The new standard is effective for us for the annual period beginning after December 15, 2024. We are currently evaluating the impact of the new guidance and do not expect adoption of ASU 2024-02 will have a material impact on our consolidated financial statements.

In March 2024, the FASB issued ASU No. 2024-01*, Compensation—Stock Compensation (Topic 718): Scope Application of Profits Interest and Similar Awards* ("ASU 2024-01"). The amendments in ASU 2024-01 improve consistent application of and simplify U.S. GAAP of Topic 718 by clarifying and amending existing guidance. The guidance is effective for us for the annual period beginning after December 15, 2024. We are currently evaluating the impact of the new guidance and do not expect adoption of ASU 2024-01 will have a material impact on our consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"). The ASU improves the transparency of income tax disclosures by requiring (i) consistent categories and greater disaggregation of information in the rate reconciliation and (ii) income taxes paid disaggregated by jurisdiction. The guidance is effective for us for the annual period beginning after December 15, 2024. We are currently evaluating the impact of the new guidance and do not expect adoption of ASU 2023-09 will have a material impact on our consolidated financial statements.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). The ASU requires entities to report incremental information about significant segment expenses included in a segment's profit or loss measure as well as the name and title of the chief operating decision maker. The guidance also requires interim disclosures related to reportable segment profit or loss and assets that had previously only been disclosed annually. The guidance is effective for us for the annual period beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Entities must adopt the changes to the segment reporting guidance on a retrospective basis, and early adoption is permitted. We are currently evaluating the impact of the new guidance and do not expect adoption of ASU 2023-07 will have a material impact this standard on our consolidated financial statements. disclosures and will adopt the ASU for our 2024 annual 10-K.

3. Fair Value Measurements and Fair Value of Financial Instruments

Assets and liabilities recorded at fair value on a recurring basis in the condensed consolidated balance sheets, as well as assets and liabilities measured at fair value on a non-recurring basis or disclosed at fair value, are categorized based upon the level of judgment associated with inputs used to measure their fair values. The accounting guidance for fair value provides a framework for measuring fair value and requires certain disclosures about how fair value is determined. Fair value is defined as the price that would be received upon the sale of an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance also establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity. The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3—Unobservable inputs 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

Table of Contents

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, 2024 June 30, 2024 or December 31, 2023.

There were no transfers within the hierarchies during the three and six months ended March 31, 2024 June 30, 2024 or the year ended December 31, 2023.

Table of Contents

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, 2024 June 30, 2024 and December 31, 2023:

	March 31, 2024						June 30, 2024				
	Fair Value Hierarchy Level	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Assets											
Assets											
Assets			(in thousands)					(in thousands)			
Cash and cash equivalents:											
Cash											
Cash											
Cash											
Money market funds											
U.S. Treasury securities											
Commercial paper											
Corporate debt											
U.S. government agency securities											
U.S. government agency securities											
U.S. government agency securities											
Total cash and cash equivalents											
Investments:											
U.S. Treasury securities											
U.S. Treasury securities											
U.S. Treasury securities											
Commercial paper											
Corporate debt											

Asset-backed securities											
U.S. government agency securities											
Total investments											
Total assets measured at fair value											
Total assets measured at fair value											
Total assets measured at fair value											

			December 31, 2023								
			December 31, 2023								
			December 31, 2023								
	Fair Value Hierarchy Level	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Assets											
Assets											
Assets			(in thousands)					(in thousands)			
Cash and cash equivalents:											
Cash											
Cash											
Cash											
Money market funds											
Commercial paper											
Total cash and cash equivalents											
Total cash and cash equivalents											
Total cash and cash equivalents											
Investments:											
U.S. Treasury securities											
U.S. Treasury securities											
U.S. Treasury securities											
Commercial paper											
Corporate debt											
Asset-backed securities											
U.S. government agency securities											
Total investments											
Total assets measured at fair value											
Total assets measured at fair value											
Total assets measured at fair value											

Table of Contents

The following table presents the contractual maturities of our investments as of March 31, 2024 June 30, 2024 (in thousands):

	March 31, June 30, 2024
	Fair Value
Due in less than one year	$ 875,006 934,027
Due in one to five years	413,247 399,243
Total	$ 1,288,253 1,333,270

4. Commercial Manufacturing and Supply Agreement

On October 13, 2023, Vaxcyte GmbH, a Swiss limited liability company and wholly owned subsidiary of ours, entered into a pre-commercial services and commercial manufacturing supply agreement with Lonza (the “Commercial Manufacturing and Supply Agreement”).

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

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

Unless earlier terminated, the Commercial Manufacturing and Supply Agreement will remain in effect until December 31, 2038, subject to automatic renewal for up to three additional renewal periods of five years each, unless Vaxcyte GmbH elects not to renew (with 24 months advanced notice to Lonza). Vaxcyte GmbH is permitted to terminate the Commercial Manufacturing and Supply Agreement for convenience or for Lonza’s uncured material breach, in each case subject to certain notice obligations. Lonza is permitted to terminate the Commercial Manufacturing and Supply Agreement in the event that Vaxcyte GmbH commits certain specified material breaches, including uncured failure to pay material, undisputed amounts of money due to Lonza, subject to certain notice obligations. Either party may terminate the Commercial Manufacturing and Supply Agreement in certain circumstances in the event of the other party’s bankruptcy. In the event that Vaxcyte GmbH terminates the agreement for convenience, or Lonza terminates the agreement in the event that Vaxcyte GmbH commits certain specified material breaches, then certain termination consequences may be triggered, including that (i) Vaxcyte GmbH would forfeit any outstanding entitlement to credit from Lonza of the Repurposing Fee (as defined below), and (ii) Vaxcyte GmbH would be obligated to pay Lonza a termination penalty equal to the greater of (a) Swiss Francs (“CHF”) 70 million 70.0 million, or (b) a prespecified number of months’ FTE fees for the actual FTEs assigned to Vaxcyte GmbH as of the date of termination. Within 30 days of the Effective Date, Vaxcyte GmbH paid Lonza a repurposing fee (the “Repurposing Fee”) of CHF 27 million 27.0 million that will be credited back to Vaxcyte GmbH over a 10-year period starting upon commencement of commercial production. In the event of a termination under certain circumstances, Lonza shall be obligated to provide certain wind-down and transition services to Vaxcyte GmbH for up to 12 and 24 months, respectively.

Table of Contents

As of March 31, 2024 June 30, 2024, we have incurred an accumulated (i) $58.2 $89.4 million of capital expenditures related to the Vaxcyte owned facility buildout and equipment and (ii) $43.6 $50.6 million of facility buildout expenditures that are owned and controlled by Lonza, including the Repurposing Fee, which have been accounted for as prepaid lease payments and will be recorded as a ROU asset under Accounting Standards Codification (“ASC”) 842 lease accounting when control over the Suite is transferred to us, which we expect to occur when the buildout of the Suite is complete and manufacturing activities commence (see Note 5, “Balance Sheet Details”).

5. Balance Sheet Details

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of March 31, 2024 June 30, 2024 and December 31, 2023 consisted of the following:

	March 31, 2024	December 31, 2023
	June 30, 2024	December 31, 2023
	(in thousands)	
	(in thousands)	
	(in thousands)	
At-the-market (“ATM”) receivable		
At-the-market (“ATM”) receivable		
At-the-market (“ATM”) receivable		
Prepaid expenses		
Interest receivable		
Prepaid expenses		
VAT on purchases		
Grant receivable		
Purchased equipment deposits		
Grant receivable		

Other current assets	
Total	

Property and Equipment, Net

Property and equipment, net as of March 31, 2024 June 30, 2024 and December 31, 2023 consisted of the following:

	March 31, 2024 June 30, 2024	December 31, 2023
	(in thousands)	(in thousands)
Furniture and equipment		
Computers and computer software		
Lab equipment		
Leasehold improvements		
Manufacturing equipment and auxiliary		
Manufacturing equipment		
Manufacturing facility and equipment construction-in-progress (1)		
Total property and equipment		
Less: accumulated depreciation and amortization		
Property and equipment, net		

(1) See Note 4, “Commercial Manufacturing and Supply Agreement,” for further details.

Depreciation and amortization expense was $1.0 million $1.4 million and $0.7 million $0.8 million for the three months ended March 31, 2024 June 30, 2024 and 2023, respectively, and $2.4 million and $1.5 million for the six months ended June 30, 2024 and 2023, respectively.

Table of Contents

Other Assets

Other assets as of March 31, 2024 June 30, 2024 and December 31, 2023 consisted of the following:

	March 31, 2024 June 30, 2024	December 31, 2023
	(in thousands)	(in thousands)
Manufacturing facility construction buildout (1)		
Other long-term assets		
Long-term prepaid assets		
Other long-term assets		
Total		

(1) See Note 4, “Commercial Manufacturing and Supply Agreement,” for further details.

Accrued Expenses

Accrued expenses as of March 31, 2024 June 30, 2024 and December 31, 2023 consisted of the following:

	March 31, 2024	December 31, 2023

	June 30, 2024	December 31, 2023
	(in thousands)	
	(in thousands)	
	(in thousands)	
Other research and development		
Other accrued expenses		
Other accrued expenses		
Other accrued expenses		
Clinical studies		
Other research and development		
Acquired manufacturing rights (1)		
Other accrued expenses		
Total		

_____

(1) See Note 7, “Commitments and Contingencies, Sutro Option Agreement,” for further details.

6. Leases

Operating Lease Obligations

In October 2023, we entered into the Commercial Manufacturing and Supply Agreement with Lonza. We have concluded that this agreement contains an embedded lease and will be accounted for in accordance with ASC 842 *Leases* upon the commencement date. As of March 31, 2024 June 30, 2024, the lease had not commenced and, as such, no lease liability or ROU asset was recorded on the consolidated balance sheets and no operating lease expense was recorded on the consolidated statements of operations. See Note 4, “Commercial Manufacturing and Supply Agreement,” for further details.

In September 2023, we entered into an assignment and assumption of lease agreement (the “Assignment Agreement”) for a new operating lease in the same building as our current corporate headquarters (the “Assumed Lease Premises”). headquarters. The assumed lease has an original contractual term of 10 years, expiring on November 30, 2031, unless earlier terminated. Pursuant to the Assignment Agreement, the base rent was abated for three full calendar months following the October 1, 2023 effective date of the Assignment Agreement. Thereafter, we are obligated to pay an aggregate of approximately $1.9 million in rent payments for the remaining nine months of the first year, with a 3% rent adjustment (not inclusive of rent abatement) every year thereafter. Upon commencement of the lease in October 2023, we recorded a ROU asset and lease liability of $16.7 million and $16.8 million, respectively.

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

Table of Contents

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.

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

	Three Months Ended	Three Months Ended	Three Months Ended	Six Months Ended	
				March 31, 2024	March 31, 2023

					June 30, 2024	June 30, 2023	June 30, 2024	June 30, 2023
Cash paid for operating lease liabilities	Cash paid for operating lease liabilities	$ 2,390	$ $ 1,671	Cash paid for operating lease liabilities	$ 2,390	$ $ 1,671	$ $ 4,779	$ $ 3,342
Weighted-average remaining lease term (in years)								
Weighted-average remaining lease term (in years)								
Weighted-average remaining lease term (in years)		5.61	2.54		5.61	2.29		
Weighted-average discount rate	Weighted-average discount rate	8.5 %	7.6 %	Weighted-average discount rate	8.5 %	7.6 %		

Maturities of lease liabilities as of March 31, 2024 June 30, 2024 were as follows:

Years ending December 31,	**Years ending December 31,**	**(in thousands)**	**Years ending December 31,**	**(in thousands)**
Remainder of 2024				
2025				
2026				
2027				
2028				
Thereafter				
Total future undiscounted lease payments				
Less: Imputed interest				
Total lease liabilities				

Rent expense recognized under the leases was $2.7 million and $1.9 million for the three months ended March 31, 2024 June 30, 2024 and 2023, respectively, and $5.4 million and $3.9 million for the six months ended June 30, 2024 and 2023, respectively.

7. Commitments and Contingencies

Legal Contingencies

From time to time, we may become involved in legal proceedings arising from the ordinary course of business. We record a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment by us is required to determine both probability and the estimated amount. We do not believe that there is any litigation or asserted or unasserted claim pending that could, individually or in the aggregate, have a material adverse effect on our results of operations or financial condition.

Guarantees and Indemnifications

In the normal course of business, we enter into agreements that contain a variety of representations and provide for general indemnification. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. As of March 31, 2024 June 30, 2024, 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

Table of Contents

any future amounts paid. We have not incurred any material costs as a result of such indemnification and are not currently aware of any indemnification claims.

Development and Manufacturing Services Agreements with Lonza

In April 2022, we entered into a non-exclusive development and manufacturing services agreement with Lonza effective as of March 22, 2022, which was subsequently amended on May 12, 2022, November 21, 2022 and October 31, 2023 (as amended, the "2022 Lonza DMSA"). Pursuant to the 2022 Lonza DMSA, Lonza is obligated to perform services, including manufacturing process development and clinical manufacture and supply of our proprietary PCV candidates. Subject to the terms and conditions set forth in the 2022 Lonza DMSA, Lonza has granted to us a non-exclusive, worldwide, fully paid-up, irrevocable, transferable license, including the right to grant sublicenses, under the New General

Application Intellectual Property, to research, develop, make, have made, use, sell and import the Product. Unless earlier terminated, the 2022 Lonza DMSA shall remain in place for a period of five years. Either party may terminate the 2022 Lonza DMSA for any reason on prior written notice to the other party, provided that Lonza may not exercise such right until a specified future date. In addition, either party may terminate the 2022 Lonza DMSA (i) within a given time period upon any material breach that is left uncured by the other party, or (ii) immediately if the other party becomes insolvent. We may also terminate the 2022 Lonza DMSA upon an extended force majeure event. Upon expiration and/or termination of the 2022 Lonza DMSA and/or any purchase order, we will pay Lonza for all service rendered, all costs incurred, all unreimbursed capital equipment and any cancellation fees (each term as defined in the 2022 Lonza DMSA).

In February 2023, we entered into another non-exclusive development and manufacturing services agreement with Lonza effective as of March 1, 2023 (the "2023 Lonza DMSA"). Pursuant to the 2023 Lonza DMSA, Lonza will perform manufacturing process development and the manufacture of components for 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 2022 Lonza DMSA and 2023 Lonza DMSA (collectively, the "Lonza Agreements"), we pay Lonza agreed-upon fees for their performance of development and manufacturing services and pass-through expenses incurred by Lonza for raw materials, as well as customary procurement and handling fees. Under each Lonza Agreement, we own all rights, title and interest in and to any and all New Customer Intellectual Property (as defined in each Lonza Agreement), and Lonza owns all rights, title and interest in New General Application Intellectual Property (as defined in each Lonza Agreement).

Commercial Manufacturing and Supply Agreement with Lonza

For details of the Commercial Manufacturing and Supply Agreement with Lonza, see Note 4, "Commercial Manufacturing and Supply Agreement."

Sutro Option Agreement

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

Table of Contents

and make improvements to extract (including the right to make improvements to the extract manufacturing process as well as cell lines) for use in connection with the exploitation of certain vaccine compositions (the "Option"). We and Sutro Biopharma agreed to negotiate the terms and conditions of a form definitive agreement to be entered into in the event we exercised the Option, which would include the terms and conditions set forth in an executed term sheet between us (the "Term Sheet") and such terms that were necessary to give effect to each of the terms and conditions set forth in the Term Sheet (the "Form Definitive Agreement"). The Option period was 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 paid Sutro Biopharma upfront consideration of $22.5 million, consisting of (i) $10.0 million in cash and $7.5 million worth of shares of our common stock (the number of shares calculated based on the arithmetic average of the daily volume weighted average price of our common stock as traded on Nasdaq in the three consecutive trading days immediately prior to the issuance thereof), and (ii) $5.0 million that was payable within five business days after we and Sutro Biopharma mutually agree agreed 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 elected to exercise the Option, we agreed to 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.

On September 28, 2023, we and Sutro Biopharma mutually agreed in writing upon the Form Definitive Agreement to become effective in the event that we exercise the Option and, on October 2, 2023, we paid the $5.0 million accrued commitment.

On November 21, 2023 (the "Option Exercise Date"), we exercised the Option by submitting written notice thereof to Sutro Biopharma and concurrently paid Sutro Biopharma $50.0 million in cash as the first of two installment payments for the Option exercise price. Under On May 13, 2024, we paid the Option Agreement, we are obligated to pay Sutro Biopharma an additional second and final installment of $25.0 million in cash within six months of the Option Exercise Date as the second of two installment payments for the Option exercise, which amount has been accrued on our consolidated balance sheets as of March 31, 2024 and December 31, 2023. Upon the occurrence of certain regulatory milestones, we would be obligated to pay Sutro Biopharma certain additional milestone payments totaling up to $60.0 million in cash. exercise. In the event that we undergo a change of control, certain rights and payments may be accelerated. As of March 31, 2024 June 30, 2024 and December 31, 2023, we determined there is no current alternative future use of the acquired manufacturing rights from the Option Agreement. As a result, the amounts paid and accrued for were expensed as incurred.

Manufacturing Rights Agreement with Sutro Biopharma

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

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

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

Unless earlier terminated, the Manufacturing Rights Agreement will remain in effect in perpetuity. Sutro Biopharma may only terminate the Manufacturing Rights Agreement in the event of our (i) uncured, intentional, material breach of certain confidentiality provisions resulting in actual, material harm to Sutro Biopharma's business, (ii) uncured, intentional material breach of certain provisions relating to the use of certain of Sutro Biopharma's know-how outside of the Vaccine Field, (iii) unintentional, material breach of certain provisions relating to the use of certain of Sutro Biopharma's know-how outside of the Vaccine Field that we do not use reasonable best efforts to cease and (to the extent reasonably curable)

Table of Contents

cure in a timely fashion, or (iv) uncured failure to pay the Option exercise price or any undisputed milestone payment under the Option Agreement when due. We may terminate the Manufacturing Rights Agreement at our discretion upon 60 days' written notice, and both parties may terminate the Manufacturing Rights Agreement upon mutual written consent.

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, 2024 June 30, 2024, we had the following amounts of non-cancelable purchase commitments related to manufacturing services and raw materials purchased due to our key manufacturing partners. These amounts represent our minimum contractual obligations, including termination fees. If we terminate certain firm orders with key manufacturing partners, we will be required to pay for the manufacturing services scheduled or raw materials purchased under our arrangements. The actual amounts we pay in the future to our vendors under such agreements may differ from the purchase order amounts.

Years ending December 31,	Years ending December 31, (in thousands)	Years ending December 31, (in thousands)
Remainder of 2024		
2025		
2026		
2027		
Total non-cancelable purchase commitments due to our key manufacturing partners		

8. Stockholders' Equity

Preferred Stock

Our certificate of incorporation authorizes us to issue up to 10,000,000 shares of preferred stock with $0.001 par value per share. There were no shares of preferred stock issued or outstanding as of March 31, 2024 June 30, 2024 and December 31, 2023. Our board of directors ("Board") are authorized to provide for the issuance of all or any of the shares of preferred stock in one or more series, and to fix, determine or alter the voting powers, designation, preferences and rights of the preferred shares, and the qualifications, limitations or restrictions of any wholly unissued shares, to establish from time to time the number of shares constituting any such series, and to increase or decrease the number of shares, if any. Holders of outstanding shares of preferred stock shall be entitled to receive dividends, when, and as declared by the Board in preference and priority to any declaration or payment of any distribution on common stock. The right to receive dividends on preferred shares of preferred stock shall not be cumulative and no right to dividends shall accrue to holders of preferred stock. No dividends have been paid or declared as of March 31, 2024 June 30, 2024 and December 31, 2023.

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 108,755,731 110,575,993 and 95,364,831 shares were issued and outstanding as of March 31, 2024 June 30, 2024 and December 31, 2023, respectively. The holders of our common stock are also entitled to

receive dividends whenever funds are legally available, when and if declared by our Board. As of March 31, 2024 June 30, 2024 and December 31, 2023, 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 had the right to issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $150.0 million through Jefferies acting as our sales agent or principal. As of February 27, 2023, we had sold 4,995,709 shares of our common stock under the Original ATM Sales Agreement at an a weighted average price of $27.57 per share for aggregate gross proceeds of $137.8 million. On February 27, 2023, we and Jefferies entered into an amendment to the Original ATM Sales Agreement (as amended, the "Amended ATM Sales Agreement") pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $400.0 million, which

is in addition to the $150.0 million aggregate offering price under the Original ATM Sales Agreement. million. The material terms and conditions of the Original ATM Sales Agreement otherwise remain unchanged. We will pay Jefferies a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Jefferies under the Amended ATM Sales Agreement; however, we are not obligated to make any sales of common stock. As of March 31, 2024 June 30, 2024, we have sold 1,588,807 3,091,842 shares of our common stock under the Amended ATM Sales Agreement at an a weighted average price of $44.06 $57.91 per share for aggregate gross proceeds of $70.0 million $179.1 million ($68.6 174.7 million net of commissions and offering expenses).

Table of Contents

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

In February 2024, we completed an underwritten public offering of 12,695,312 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 1,757,812 shares, at a price of $64.00 per share and pre-funded warrants to purchase 781,250 shares of our common stock at a price of $63.999 per underlying share. In aggregate, we received $816.5 million in net proceeds after deducting underwriting discounts and commissions and other 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 29,638 shares issued outside of the 2014 Plan and 2020 Plan:

		March 31, 2024	December 31, 2023		June 30, 2024	December 31, 2023
Options issued and outstanding	Options issued and outstanding	10,097,695	9,314,836	Options issued and outstanding	9,862,396	9,314,836
Restricted stock units outstanding	Restricted stock units outstanding	1,204,939	753,462	Restricted stock units outstanding	1,268,321	753,462
Shares available for future stock option grants		7,733,651	6,065,150			
Shares available for future stock option and restricted stock unit grants		7,641,966	6,065,150			
Total	Total	19,036,285	16,133,448	Total	18,772,683	16,133,448

9. Pre-Funded Warrants

In connection with our underwritten public offering in April 2023, we issued pre-funded warrants to purchase 1,000,000 shares of our common stock at a price of $40.999 per underlying share. Each pre-funded warrant has an exercise price of $0.001 per share.

In connection with our underwritten public offering in February 2024, we issued pre-funded warrants to purchase 781,250 shares of our common stock at a price of $63.999 per underlying share. Each pre-funded warrant has an exercise price of $0.001 per share.

The public offering prices for the pre-funded warrants were equal to the public offering prices 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, 2024 June 30, 2024, in aggregate, we have issued pre-funded warrants to purchase 8,031,250 shares of our common stock and no shares underlying the pre-funded warrants had been exercised.

Table of Contents

10. Equity Incentive Plans

2020 and 2014 Equity Incentive Plans

In June 2020, our Board 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. Effective January 1, 2024, the number of shares of common stock available under the 2020 Plan increased by 4,768,241 shares pursuant to the evergreen provision. As of March 31, 2024 June 30, 2024, an aggregate of 7,733,695 7,641,966 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, 2024 June 30, 2024, 1,775,740 1,641,048 shares and 9,526,850 9,489,669 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 consolidated balance sheet and is reclassified to common stock and additional paid-in capital as such shares vest.

Table of Contents

Stock Options and Restricted Stock Units Activity

Stock options and RSUs activity under our 2020 Plan and 2014 Plan, which excludes options to purchase 29,638 shares granted outside of the 2020 Plan and 2014 Plan, was as follows:

			Options Outstanding								
Stock Options and Restricted Stock Units Activity	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	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, 2023												
Additional shares authorized												
Plan shares expired												
Plan shares expired												
Plan shares expired												
Options granted												

Options granted

Options granted

Options exercised

Options exercised

Options exercised

Options forfeited

Options forfeited

Options forfeited

Restricted stock units granted

Restricted stock units granted

Restricted stock units granted

Restricted stock units withheld

Restricted stock units withheld

Restricted stock units withheld

Restricted stock units forfeited

Restricted stock units forfeited

Restricted stock units forfeited

Balances — March 31, 2024

Balances — March 31, 2024

Balances — March 31, 2024

Vested and expected to vest — March 31, 2024

Exercisable at March 31, 2024

Balances — June 30, 2024

Balances — June 30, 2024

Balances — June 30, 2024

Vested and expected to vest — June 30, 2024

Exercisable at June 30, 2024

(1) Shares returned due to net exercises.

During the three months ended March 31, 2024 June 30, 2024 and 2023, options to purchase 631,287 245,434 and 100,964 69,951 shares, respectively, were exercised for cash at a weighted-average price per share of $72.85 $13.79 and $5.40, $12.63, respectively. The weighted-average grant date fair value of options granted for the three months ended March 31, 2024 June 30, 2024 and 2023 was $47.28 $43.38 and $27.18, $30.99, respectively. The intrinsic value of the stock options exercised was $38.1 million $14.1 million and $3.8 million $2.4 million for the three months ended March 31, 2024 June 30, 2024 and 2023, respectively.

During the six months ended June 30, 2024 and 2023, options to purchase 876,113 and 170,915 shares, respectively, were exercised for cash at a weighted-average price per share of $10.16 and $8.34, respectively. The weighted-average grant date fair value of options granted for the six months ended June 30, 2024 and 2023 was $45.86 and $27.28, respectively. The intrinsic value of the stock options exercised was $52.2 million and $6.3 million for the six months ended June 30, 2024 and 2023, respectively.

In March 2022, our Board authorized the issuance of RSUs under our 2020 Plan and adopted a form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement (the “RSU Agreement”), which is intended to serve as a

Table of Contents

standard form agreement for RSU grants issued to employees. RSU activity for the three six months ended March 31, 2024 June 30, 2024 was as follows:

	Shares	Weighted-Average Grant-Date Fair Value
Unvested at December 31, 2023	753,462	$ 38.93
Granted	565,682	73.42
Vested and released	(110,580)	36.41

Cancelled	(3,625)	52.26
Unvested at March 31, 2024	1,204,939	$ 55.31

	Shares	Weighted-Average Grant-Date Fair Value
Unvested at December 31, 2023	753,462	$ 38.93
Granted	700,547	$ 72.97
Vested and released	(145,528)	$ 38.71
Cancelled	(40,160)	$ 58.85
Unvested at June 30, 2024	1,268,321	$ 57.13

The weighted-average grant date fair value of RSUs granted during the three months ended March 31, 2024 June 30, 2024 and 2023 was $73.42 $71.09 and $41.59, $51.70, respectively. The weighted-average grant date fair value of RSUs granted during the six months ended June 30, 2024 and 2023 was $72.97 and $43.21, respectively. The aggregate fair value of unvested RSUs is calculated using the closing price of our common stock on the grant date. As of March 31, 2024 June 30, 2024 and 2023, the unrecognized stock-based compensation cost of unvested RSUs was $62.6 million $63.2 million and $24.4 million $24.9 million, respectively, which is expected to be recognized over a weighted-average period of 2.97 2.86 years and 3.10 3.00 years, respectively.

2020 Employee Stock Purchase Plan

In June 2020, our Board adopted, and our stockholders approved, the 2020 Employee Stock Purchase Plan (the "2020 ESPP"), which became effective on June 11, 2020. The 2020 ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. Employees enrolled in the 2020 ESPP purchase shares of common stock at a price per share equal to 85% of the lower of the fair market value at the start or end of the six-month purchase periods within a 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. As of March 31, 2024 June 30, 2024, there were 2,257,745 2,204,120 shares available under the 2020 ESPP, which reflects increases of 794,706 and nil shares (as determined by our Board), and 794,706 shares on January 1, 2023 January 1, 2024 and 2024, 2023, respectively, and purchases of 53,625 shares and 43,060 shares during the six months ended June 30, 2024 and 2023, respectively.

Stock-based Compensation

We estimated the fair value of employee stock options using the Black-Scholes option-pricing model for the three and six months ended March 31, 2024 June 30, 2024 and 2023 using the following weighted-average assumptions:

	Three Months Ended March 31, Three Months Ended March 31, Three Months Ended March 31, Three Months Ended June 30, Three Months Ended June 30, Three Months Ended June 30,
	2024
Fair Value Assumptions **Fair Value Assumptions** **Fair Value Assumptions**	
Expected volatility	
Expected volatility	
Expected volatility	
Expected dividend yield	
Expected dividend yield	
Expected dividend yield	
Expected term (in years)	
Expected term (in years)	
Expected term (in years)	

Risk-free interest rate	
Risk-free interest rate	
Risk-free interest rate	

Table of Contents

We estimated the fair value of shares under the 2020 ESPP using the Black-Scholes option-pricing model for the three and six months ended March 31, 2024 June 30, 2024 and 2023 using the following weighted-average assumptions:

	Three Months Ended March 31,	
	Three Months Ended March 31,	
	Three Months Ended March 31,	
	Three Months Ended June 30,	
	Three Months Ended June 30,	
	Three Months Ended June 30,	
	2024	
	2024	
	2024	
Fair Value Assumptions		
Fair Value Assumptions		
Fair Value Assumptions		
Expected volatility		
Expected volatility		
Expected volatility		
Expected dividend yield		
Expected dividend yield		
Expected dividend yield		
Expected term (in years)		
Expected term (in years)		
Expected term (in years)		
Risk-free interest rate		
Risk-free interest rate		
Risk-free interest rate		

We recorded total stock-based compensation expense for the three and six months ended March 31, 2024 June 30, 2024 and 2023 related to the 2014 Plan, the 2020 Plan and the 2020 ESPP in the condensed consolidated statements of operations and allocated the amounts as follows:

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Research and development	$ 8,818	$ 4,527
General and administrative	8,811	5,121
Total	$ 17,629	$ 9,648

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(in thousands)		(in thousands)	
Research and development	$ 10,855	$ 5,911	$ 19,673	$ 10,438
General and administrative	10,703	6,633	$ 19,514	$ 11,754
Total	$ 21,558	$ 12,544	$ 39,187	$ 22,192

11. Retirement Plan

We sponsor a qualified 401(k) Plan (the "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 Code. The 401(k) Plan is a safe-harbor plan whereby we make mandatory employer-matching contributions to plan participants' accounts through payroll. For the three months ended March 31, 2024 June 30, 2024 and 2023, we contributed $0.7 million $0.5 million and $0.4 million $0.3 million, respectively, to the 401(k) Plan. For the six months ended June 30, 2024 and 2023, we contributed $1.3 million and $0.7 million, respectively, to the 401(k) Plan.

12. Funding Arrangement

Our vaccine development program for VAX-A1, a novel conjugate vaccine candidate designed to prevent disease caused by Group A Streptococcus, currently is funded in part by a grant obtained from Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator ("CARB-X"), a global non-profit partnership dedicated to accelerating antibacterial innovation to tackle the rising global threat of drug-resistant bacteria. The CARB-X grant provides for total potential provided funding of up to $14.6 million (including $11.7 million awarded to date since the grant's inception in 2019) upon the achievement of VAX-A1 development milestones through June 2024. As of the second quarter of 2024, all of these milestones had been successfully achieved, and no further amounts will be funded under this CARB-X grant.

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

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 nil $0.4 million and $0.7 million $2.5 million of grant income and recorded the amounts in Other income (expense), net in the condensed consolidated statement statements of operations during the three months ended March 31, 2024 June 30, 2024 and 2023, respectively, and $0.5 million and $3.1 million during the six months ended June 30, 2024 and 2023, respectively. A grant receivable of $0.1 million $0.4 million and nil representing unreimbursed, eligible costs incurred under the agreements were was recorded and included in Prepaid expenses and other current assets in the condensed consolidated balance sheets as of March 31, 2024 June 30, 2024 and December 31, 2023, respectively.

Table of Contents

13. Net Loss Per Share

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

	Three Months Ended March 31, Three Months Ended March 31, Three Months Ended March 31, Three Months Ended June 30, Three Months Ended June 30, Three Months Ended June 30,
	2024 2024 2024
Net loss (in thousands) Net loss (in thousands) Net loss (in thousands)	
Weighted-average shares outstanding used in computing net loss per share, basic and diluted(1)	
Weighted-average shares outstanding used in computing net loss per share, basic and diluted(1)	
Weighted-average shares outstanding used in computing net loss per share, basic and diluted(1)	
Net loss per share, basic and diluted Net loss per share, basic and diluted Net loss per share, basic and diluted	

(1) Includes shares of common stock into which pre-funded warrants may be exercised as of March 31, 2024 June 30, 2024. See Note 9, "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 and six months ended March 31, 2024 June 30, 2024 and 2023 because including them would have been anti-dilutive:

	March 31,				June 30,		
	2024		2024		2023	2024	2023
Stock options	Stock options	11,302,590	9,183,744	Stock options	9,892,034	9,342,630	
Restricted stock units	Restricted stock units	1,204,939	773,660	Restricted stock units	1,268,321	797,264	
Employee stock purchase plan shares		104,775	117,203				
Employee Stock Purchase Plan shares		105,829	106,756				
Total	Total	12,612,304	10,074,607	Total	11,266,184	10,246,650	

14. 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 and six months ended March 31, 2024 June 30, 2024, 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 and six months ended March 31, 2024 June 30, 2024, we reported zero tax provision. We do not have any tax audits or other issues pending.

15. Subsequent Events

Subsequent to June 30, 2024, through August 5, 2024, we sold a total of 881,307 shares of our common stock under the Amended ATM Sales Agreement at a weighted average price of $82.36 per share, generating aggregate gross proceeds of $72.6 million ($71.1 million net of commissions and offering expenses).

Table of Contents

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 consolidated financial statements and related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and notes thereto for the year ended December 31, 2023 filed with the Securities and Exchange Commission ("SEC") on February 27, 2024. 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 designed 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 pipeline includes:

- Pneumococcal conjugate vaccine ("PCV") candidates that we believe are among the most broad-spectrum PCV candidates currently in development, targeting the approximately $8 billion global pneumococcal vaccine market. Pneumococcal disease is an infection caused by *Streptococcus pneumoniae* ("pneumococcus") bacteria. It can result in invasive pneumococcal disease ("IPD"), including meningitis and bacteremia, and non-IPD, including pneumonia, otitis media and sinusitis. Our broad-spectrum, carrier-sparing PCV candidates, VAX-24 and VAX-31, are designed to improve upon the standard-of-care PCVs for both children and adults by covering the serotypes that are responsible for a significant portion of IPD in circulation and are associated with high case-fatality rates, antibiotic resistance and meningitis, while maintaining coverage of previously circulating strains that are currently contained through continued vaccination practice.
    - Our lead vaccine candidate, VAX-24, is a 24-valent, broad-spectrum, carrier-sparing investigational PCV being developed for the prevention of IPD.
        - VAX-24 Adult Indication:
            - In October 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 835 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 Prevnar 20® ("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. In this study, VAX-24 met the primary safety and tolerability objectives, demonstrating a safety profile similar to PCV20, for all doses studied. In the study, VAX-24 met or exceeded the established regulatory immunogenicity standards for all 24 serotypes at the conventional 2.2mcg dose, which is the dose selected for a potential Phase 3 program. At this dose, VAX-24 met the standard opsonophagocytic activity ("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 14-26 percent of strains causing IPD in adults over the current standard-of-care PCVs.

Table of Contents

- In April 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 across all 24 serotypes at all doses studied, confirming the prior Phase 2 adult study results. The VAX-24 2.2mcg dose, which is the dose selected for a potential Phase 3 program, 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. Additionally, the prespecified pooled immunogenicity analyses of data from both adult Phase 2 studies showed the VAX-24 2.2mcg dose met the OPA non-inferiority criteria for all 20 serotypes common with PCV20 and the superiority criteria for the four additional serotypes unique to VAX-24.
- The U.S. Food and Drug Administration ("FDA") has granted Fast Track designation and Breakthrough Therapy designation for VAX-24 in adults.
- In October 2023, we completed a successful End-of-Phase 2 meeting with the FDA. The meeting focused on the VAX-24 adult Phase 3 clinical program, including the design of the pivotal, non-inferiority study and other Phase 3 studies needed to support a Biologics License Application ("BLA") submission. Based on the End-of-Phase 2 meeting, we believe there is agreement with the FDA on the clinical design of a potential adult Phase 3 program, including the approximate overall number of subjects, the primary and secondary endpoints for the pivotal, non-inferiority study as well as confirmation that the planned immunogenicity analyses are sufficient to support licensure and a separate efficacy study is therefore not required.
- In January 2024, we announced that we received encouraging input from ongoing discussions with the FDA about the VAX-24 adult program to further inform our chemistry, manufacturing and controls ("CMC") licensure requirements and that we expect to seek additional CMC-focused input from the FDA as we prepare for and potentially conduct our VAX-24 adult Phase 3 program. Following the topline data from the VAX-31 adult Phase 1/2 study, which is expected in the third quarter of September 2024, we expect to determine whether to advance VAX-24 or VAX-31 to an adult Phase 3 program. If we move forward with the VAX-24 adult program, following the initiation of the VAX-24 Phase 3 program, we expect to initiate the pivotal, pivotal, non-inferiority study in adults aged 50 and older, in the second half of 2024 and we expect to announce topline safety, tolerability and immunogenicity data from this study in the second half of 2025. We would expect to initiate the remaining Phase 3 studies, which are shorter in duration than the non-inferiority study, for VAX-24 in the adult population in 2025 and 2026. If we move forward with the VAX-31 adult Phase 3 program, we expect to initiate the full complement of potential Phase 3 studies in 2025 and 2026. Subject to the results of the adult Phase 3 studies, we would expect to submit a BLA for VAX-24 or VAX-31 shortly following the completion of the last Phase 3 study.

▪ VAX-24 Pediatric Indication:

- In March 2023, we announced that the first participants were dosed in the first stage of a Phase 2 study of VAX-24 in healthy infants. The Phase 2 infant study is being conducted in two stages and compares VAX-24 to the broadest-spectrum standard-of-care PCVs currently available. Stage 1 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 VAXNEUVANCE™ ("PCV15"), the broadest-spectrum standard-of-care PCV at that time, in 48 infants in a dose-escalation approach.

Table of Contents

- In July 2023, we announced that the ongoing Phase 2 study of VAX-24 in healthy infants had advanced to the second and final stage of the study in which we continue to enroll participants. The independent Data Safety Monitoring Board approved advancing to the second stage of the study following the review of the safety and tolerability results from the first stage. Additionally, in agreement with the FDA, we amended the study protocol for Stage 2 of the study, changing the study comparator to PCV20, which became the broadest-spectrum PCV recommended by the Advisory Committee on Immunization Practices ("ACIP") in June 2023. This Phase 2 study is evaluating the safety, tolerability and immunogenicity of VAX-24 in healthy infants at the same three dose levels, 1.1mcg, 2.2mcg and 2.2mcg/4.4mcg, that were evaluated in Stage 1.

- In March 2024, we announced the completion of enrollment in the Phase 2 clinical study evaluating VAX-24 for the prevention of IPD in healthy infants. We expect to announce topline safety, tolerability and immunogenicity data from the Phase 2 primary three-dose immunization series by the end of the first quarter of 2025, followed by topline data from the booster dose by the end of 2025.

◦ Our second PCV candidate, VAX-31, is the broadest-spectrum PCV to enter the clinic. VAX-31 builds on what has been established with VAX-24 and is designed to expand the breadth of coverage to 31 strains, inclusive of the 24 strains in VAX-24, without compromising immunogenicity due to carrier suppression, and to cover approximately more than 95% of IPD circulating in the U.S. adult population.

- In October 2023, we announced the FDA clearance of the investigational new drug ("IND") application for VAX-31 for the prevention of IPD in adults. In November 2023, we announced that the first participants were dosed in a Phase 1/2 clinical study for VAX-31 in adults. The VAX-31 Phase 1/2 clinical study is a randomized, observer-blind, active-controlled, dose-finding clinical study designed to evaluate the safety, tolerability and immunogenicity of VAX-31 at three dose levels (low, middle and high) and compared to PCV20 in 1,015 healthy adults aged 50 and older. The Phase 1 portion of the study evaluated the safety and tolerability of a single injection of VAX-31 at three dose levels and compared to PCV20, in 64 healthy adults 50 to 64 years of age. An independent Data Monitoring Committee conducted an assessment of the Phase 1 safety and tolerability results and recommended that the study proceed as planned to Phase 2. Phase 1 participants will also be evaluated for immunogenicity, and the Phase 1 safety, tolerability and immunogenicity data will be pooled with the participants in the Phase 2 portion of the study. The Phase 2 portion of the study will evaluate the safety, tolerability and immunogenicity of a single injection of VAX-31 at the same three dose levels and compared to PCV20, in 951 healthy adults 50 years of age and older. Participants were randomized equally in four separate arms and, 30 days after dosing, serology samples will be collected to assess immunogenicity. The immunogenicity objectives of the study include an assessment of the induction of antibody responses, using OPA and immunoglobulin G ("IgG"), at each of the three VAX-31 doses and compared to PCV20, for the 20 serotypes in common, as well as for the additional 11 serotypes contained in VAX-31, but not in PCV20. Participants in the study are being evaluated for safety through six months after vaccination. The study is being conducted at approximately 25 sites in the United States.

- In January 2024, we announced the completion of enrollment in the Phase 1/2 clinical study evaluating VAX-31 in healthy adults aged 50 and older. We expect to announce topline safety, tolerability and immunogenicity data from the Phase 1/2 study in the third quarter of September 2024, following which we expect to determine whether to advance VAX-24 or VAX-31 to an adult Phase 3 program as discussed above.

- VAX-A1, a novel conjugate vaccine candidate designed to prevent disease caused by Group A Streptococcus ("Group A Strep"). Group A Strep is pervasive globally and causes an estimated 800 million cases of illness annually, including pharyngitis, or strep throat, and certain severe invasive infections and sequelae. There is currently no vaccine against Group A Strep, which is one of the leading infectious disease-related causes of death and disability worldwide and a significant contributor to the prescription of antibiotics in 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

Table of Contents

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.

- 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 2022 and are conducting large-animal confirmatory studies prior to advancing the program to potential IND-enabling activities. 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.

- VAX-GI, a novel preclinical vaccine candidate being developed as a preventative treatment for dysentery and shigellosis, which is caused by Shigella bacteria. Shigella, a bacterial illness that affects an is estimated 188 million people worldwide each year to cause 80 million to 165 million cases of disease and results in approximately 164,000 600,000 deaths annually, mostly among children under five years of age in low- and middle-income settings. children. The central antigen in VAX-GI is IpaB, a well-appreciated antigen that other developers have been unable to produce in an amount sufficient to enable a commercial product. With our cell-free technology, we believe we can produce this antigen at substantially improved yields, allowing for commercial-scale production. VAX-GI is being developed in collaboration with the University of Maryland, Baltimore as well as with partial funding from two research grants awarded by the National Institutes of Health ("NIH").

- 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, 2024 March 31, 2024, key developments affecting our business include the following:

PCV Franchise Adult Indication• ***VAX-24 Phase 2 Data in Adults Aged 65 and Older Published in Vaccine:*** In July 2024, the results from the VAX-24 Phase 2 study in adults aged 65 and older were published in the journal *Vaccine.*

- ***Completed Enrollment National Institute of Phase 1/2 Study Evaluating VAX-31 Allergy and Infectious Diseases (NIAID) Grant Awarded for the Prevention of IPD in Adults Aged 50 and Older: Preclinical Chlamydia Vaccine Development Program:*** In January July 2024, we announced the completion NIAID awarded a five-year,

$9.5 million grant to the University of enrollment in North Carolina at Chapel Hill, Vaxcyte and the Phase 1/2 clinical study evaluating VAX-31 in healthy adults aged 50 and older. This is University of Chicago to develop a randomized, observer-blind, active-controlled, dose-finding study designed to evaluate the safety, tolerability and immunogenicity of VAX-31 at three dose levels (low, middle and high) compared to PCV20 in 1,015 healthy adults aged 50 and older. VAX-31, the broadest-spectrum PCV in the clinic, has the potential to address a significant public health need by covering approximately 95% of IPD circulating in the U.S. adult population while maintaining coverage of previously circulating strains that are currently contained via ongoing vaccination.

PCV Franchise Infant Indication

- ***Completed Enrollment of Phase 2 Study Evaluating VAX-24 for the Prevention of IPD in Infants:*** In March 2024, we announced the completion of enrollment in the Phase 2 clinical study evaluating VAX-24 in healthy infants. The Phase 2 clinical study, which enrolled 802 healthy infants, is a randomized, observer-blind, dose-finding two-stage clinical study evaluating the safety, tolerability and immunogenicity of VAX-24 in healthy infants. The Stage 1 portion of the study evaluated the safety and tolerability of a single injection of VAX-24 at three dose levels (low dose/1.1mcg, middle dose/2.2mcg, mixed dose/2.2mcg or 4.4mcg) and compared to PCV15, which was the broadest-spectrum PCV at the time of study initiation, in 48 infants. The Stage 2 portion, which commenced in July 2023, is evaluating the safety, tolerability and immunogenicity of VAX-24 vaccine candidate for the prevention of IPD at Chlamydia. There is a significant need for a vaccine to protect against Chlamydia. It is the same three dose levels most common bacterial sexually transmitted infection worldwide, with nearly 130 million new cases per year. While it is treatable when detected early, it can cause permanent damage to the female reproductive system, potentially leading to complications such as infertility and compared to PCV20, currently the broadest-spectrum PCV recommended by the ACIP. Participants who received VAX-24 in Stage 1 will continue the standard dosing regimen as part of Stage 2 and will be included in the safety, tolerability and immunogenicity analysis of the study. ectopic pregnancy.

Equity Financings

- ***Completed Successful $862.5 Million Follow-On Financing:*** ***Appointed John Furey to Board of Directors:*** In February July 2024, we completed appointed John Furey to our Board of Directors. Mr. Furey is a seasoned biopharmaceutical executive with over 30 years of experience developing and implementing operational strategies and leading commercial and technical teams, including senior leadership roles in the U.S., Europe and Asia. He currently serves as Chief Executive Officer of Imvax, a clinical-stage biotechnology company developing novel immunotherapies for cancer. Mr. Furey earned an underwritten public offering executive Master of 12,695,312 shares Business Administration from Saint Joseph's University, a Bachelor of our common stock, which included the full exercise of the underwriters' option to purchase an additional 1,757,812 shares, at Science degree from Trinity College, Dublin, and a public offering price of $64.00 per share and pre-funded warrants to purchase 781,250 shares of our common stock at a public offering price of $63.999 per underlying share. The aggregate gross proceeds to us Diploma in Environmental Health from the offering were $862.5 million, before deducting underwriting

discounts Technological University, Dublin. Mr. Furey also serves on the Board of Directors of Adaptimmune and commissions and other estimated offering expenses payable by us, and excluding the exercise of any pre-funded warrants. Sensorion.

Since our inception in November 2013, we have devoted substantially all of our resources to performing research and development, undertaking preclinical studies, advancing our vaccine candidates through clinical trials, enabling manufacturing activities in support of our product development efforts, acquiring and developing our technology and vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from the sales of our common stock, pre-funded warrants to purchase our common stock and, prior to our initial public offering ("IPO") in June 2020, redeemable convertible preferred stock. We will continue to require additional capital to develop and commercialize our vaccine candidates and fund operations for the foreseeable future. Accordingly, until such time as we can generate significant revenue from sales of our vaccine candidates, if ever, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.

Table of Contents

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 $95.0 million $128.7 million and $223.7 million for the three and six months ended March 31, 2024. June 30, 2024, respectively. As of March 31, 2024 June 30, 2024, we had an accumulated deficit of $1,019.4 million $1,148.1 million and cash, cash equivalents and investments of $1,899.8 million $1,851.9 million, which we believe 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 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 and capital expenditures 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 adult Phase 3 program for VAX-24 or VAX-31, as well as the potential commercial launches of VAX-24 and/or VAX-31;

- incur additional costs that may be required for secondary supply sources;
- require the manufacture of supplies for our clinical trials;
- conduct clinical trials, in particular our clinical trials for our PCV candidates, VAX-24 and and/or 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 or VAX-31 in adults;
- hire additional personnel;
- expand our facilities to support our growing workforce and lab activities;
- acquire, discover, validate and develop additional vaccine candidates; and
- obtain, maintain, expand and protect our intellectual property portfolio.

We rely and will continue to rely on third parties to conduct our preclinical studies and clinical trials and for manufacturing and supply of our vaccine candidates. We have no internal manufacturing capabilities, and we will continue to rely on third parties, of which the main suppliers are single-source suppliers, for our preclinical and clinical trial materials. Given our stage of development, we do not yet have a marketing or sales organization 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

Development and Manufacturing Services Agreements

In April 2022, we entered into a non-exclusive development and manufacturing services agreement with Lonza effective as of March 22, 2022, which was subsequently amended on May 12, 2022, November 21, 2022 and October 31, 2023 (as amended, the "2022 Lonza DMSA"). Pursuant to the 2022 Lonza DMSA, Lonza is obligated to perform services, including manufacturing process development and clinical manufacture and supply of our proprietary PCV candidates. Subject to the terms and conditions set forth in the 2022 Lonza DMSA, Lonza has granted to us a non-exclusive, worldwide, fully paid-up, irrevocable, transferable license, including the right to grant sublicenses, under the New General Application Intellectual Property, to research, develop, make, have made, use, sell and import the Product. Unless earlier terminated, the 2022 Lonza DMSA shall remain in place for a period of five years. Either party may terminate the 2022 Lonza DMSA for any reason on prior written notice to the other party, provided that Lonza may not exercise such right until a specified future date. In addition, either party may terminate the 2022 Lonza DMSA (i) within a given time period upon any material

Table of Contents

breach that is left uncured by the other party, or (ii) immediately if the other party becomes insolvent. We may also terminate the 2022 Lonza DMSA upon an extended force majeure event. Upon expiration and/or termination of the 2022 Lonza DMSA and/or any purchase order, we will pay Lonza for all service rendered, all costs incurred, all unreimbursed capital equipment and any cancellation fees (each term as defined in the 2022 Lonza DMSA).

In February 2023, we entered into another non-exclusive development and manufacturing services agreement with Lonza effective as of March 1, 2023 (the "2023 Lonza DMSA"). Pursuant to the 2023 Lonza DMSA, Lonza will perform manufacturing process development and the manufacture of components for 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 2022 Lonza DMSA and 2023 Lonza DMSA (collectively, the "Lonza Agreements"), we pay Lonza agreed-upon fees for their performance of development and manufacturing services and pass-through expenses incurred by Lonza for raw materials, as well as customary procurement and handling fees. Under each Lonza Agreement, we

own all rights, title and interest in and to any and all New Customer Intellectual Property (as defined in each Lonza Agreement), and Lonza owns all rights, title and interest in New General Application Intellectual Property (as defined in each Lonza Agreement).

Commercial Manufacturing and Supply Agreement

On October 13, 2023, Vaxcyte Switzerland GmbH ("Vaxcyte GmbH"), a Swiss limited liability company and wholly owned subsidiary of ours, entered into a pre-commercial services and commercial manufacturing supply agreement with Lonza (the "Commercial Manufacturing and Supply Agreement").

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

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

Table of Contents

receipt of certain regulatory approvals for the Suite and manufacture of the Products in accordance with Vaxcyte GmbH's commercial requirements.

Unless earlier terminated, the Commercial Manufacturing and Supply Agreement will remain in effect until December 31, 2038, subject to automatic renewal for up to three additional renewal periods of five years each, unless Vaxcyte GmbH elects not to renew (with 24 months advanced notice to Lonza). Vaxcyte GmbH is permitted to terminate the Commercial Manufacturing and Supply Agreement for convenience or for Lonza's uncured material breach, in each case subject to certain notice obligations. Lonza is permitted to terminate the Commercial Manufacturing and Supply Agreement in the event that Vaxcyte GmbH commits certain specified material breaches, including uncured failure to pay material and undisputed amounts of money due to Lonza, subject to certain notice obligations. Either party may terminate the Commercial Manufacturing and Supply Agreement in certain circumstances in the event of the other party's bankruptcy. In the event that Vaxcyte GmbH terminates the agreement for convenience, or Lonza terminates the agreement in the event that Vaxcyte GmbH commits certain specified material breaches, then certain termination consequences may be triggered, including that (i) Vaxcyte GmbH would forfeit any outstanding entitlement to credit from Lonza of the Repurposing Fee (as defined below), and (ii) Vaxcyte GmbH would be obligated to pay Lonza a termination penalty equal to the greater of (a) CHF 70,000,000, 70.0 million, or (b) a prespecified number of months' FTE fees for the actual FTEs assigned to Vaxcyte GmbH as of the date of termination. Within 30 days of the Effective Date, Vaxcyte GmbH paid Lonza a repurposing fee (the "Repurposing Fee") of CHF 27,000,000 27.0 million that will be credited back to Vaxcyte GmbH over a 10-year period starting upon commencement of commercial production. In the event of a termination under certain circumstances, Lonza shall be obligated to provide certain wind-down and transition services to Vaxcyte GmbH for up to 12 and 24 months, respectively.

For additional details regarding our relationship with Lonza, see Note 4, "Commercial Manufacturing and Supply Agreement" and Note 7, "Commitments and Contingencies" to our condensed consolidated 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. In November 2023, we exercised this option and entered in a manufacturing rights agreement to obtain control over manufacturing and development of cell-free extract for our vaccine candidates.

Amended and Restated License Agreement with Sutro Biopharma

We are party to an amended and restated license agreement with Sutro Biopharma, dated October 12, 2015, which was subsequently amended on May 9, 2018, May 29, 2018, September 28, 2023 and November 21, 2023 (as amended, the "Sutro Biopharma License Agreement"). Under the Sutro Biopharma License Agreement, we received an exclusive, worldwide, royalty-bearing, sublicensable license under Sutro Biopharma's patents and know-how relating to cell-free expression of proteins to (i) research, develop, use, sell, offer for sale, export, import and otherwise exploit specified vaccine compositions, such rights being sublicensable, for the treatment or prophylaxis of infectious diseases, excluding cancer vaccines, and (ii) manufacture, or have manufactured by an approved contract manufacturing organization, such vaccine compositions from extracts supplied by Sutro Biopharma pursuant to the Sutro Biopharma Supply Agreement (as described below). We are obligated to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize the vaccine compositions. In consideration of the rights granted under the Sutro Biopharma License Agreement, we are obligated to pay Sutro Biopharma a 4% royalty on worldwide aggregate annual net sales of our vaccine products for human health and a 2% royalty on such net sales of vaccine products for animal

health. Such royalty rates are subject to specified reductions, including standard reductions for third-party payments and for expiration of relevant patent claims. We are also obligated to pay Sutro Biopharma any royalties due to Stanford University (the upstream licensor of Sutro Biopharma), to the extent the royalties payable by Sutro Biopharma to Stanford University are greater than the royalties payable by us to Sutro Biopharma. Royalties are payable on a vaccine composition-by-vaccine composition and country-by-country basis until the later of expiration of the last valid claim in the licensed patents covering such vaccine composition in such country and 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.

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

Table of Contents

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 with Sutro Biopharma, which was subsequently amended on February 22, 2021 and November 21, 2023 (as amended, the "Sutro Biopharma Supply Agreement") pursuant to which we purchase from Sutro Biopharma extract and custom reagents for use in manufacturing non-clinical and certain clinical supply of vaccine compositions utilizing the technology licensed under the Sutro Biopharma License at prices not to exceed a specified percentage above Sutro Biopharma's fully burdened manufacturing cost. If any extracts or custom reagents do not meet the specifications and warranties provided, then we will not have an obligation to pay for the non-conforming product, and Sutro Biopharma will be obligated to replace the non-conforming product within the shortest possible time with conforming product at our cost. The term of the Sutro Biopharma Supply Agreement is from execution until the later of (i) July 31, 2022, or (ii) the date that we and Sutro Biopharma enter into the Phase 3/Commercial Supply Agreement and Sutro Biopharma is supplying to us each Product under the Phase 3/Commercial Supply Agreement (each term as defined in the Sutro Biopharma Supply Agreement). The Sutro Biopharma Supply Agreement may be terminated by either party for the other party's material breach uncured within 60 days' notice, by us at will with 60 days' notice, or by mutual agreement of the parties. In December 2019, we exercised our right to require Sutro Biopharma to establish a second supplier for extract and custom reagents to support our anticipated clinical and commercial needs.

Option Agreement with Sutro Biopharma

In December 2022, we entered into an option grant agreement with Sutro Biopharma (the "Option Agreement"). Pursuant to the Option Agreement, we acquired from Sutro Biopharma (i) authorization to enter into an agreement with an independent alternate contract manufacturing organization ("CMO") to directly source Sutro Biopharma's cell-free extract, allowing us to have direct oversight over financial and operational aspects of the relationship with the CMO; and (ii) a right, but not an obligation, to obtain certain exclusive rights to internally manufacture and/or source extract from certain CMOs and the right to independently develop and make improvements to extract (including the right to make improvements to the extract manufacturing process as well as cell lines) for use in connection with the exploitation of certain vaccine compositions (the "Option"). We and Sutro Biopharma agreed to negotiate the terms and conditions of a form definitive agreement to be entered into in the event we exercise the Option, which would include the terms and conditions set forth in an executed term sheet between us (the "Term Sheet") and such terms that were necessary to give effect to each of the terms and conditions set forth in the Term Sheet (the "Form Definitive Agreement"). The Option period was 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 paid Sutro Biopharma upfront consideration of $22.5 million, consisting of (i) $10.0 million in cash and $7.5 million worth of shares of our common stock (the number of shares calculated based on the arithmetic average of the daily volume weighted average price of our common stock as traded on Nasdaq in the three consecutive trading days immediately prior to the issuance thereof), 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 elected to exercise the Option, we agreed to 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.

On September 28, 2023, we and Sutro Biopharma mutually agreed in writing upon the Form Definitive Agreement to become effective in the event that we exercise the Option, and on October 2, 2023, we paid the $5.0 million accrued commitment.

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

Manufacturing Rights Agreement with Sutro Biopharma

Concurrent with the payment of the first installment of the Option exercise price pursuant to the Option Agreement, on November 21, 2023, the manufacturing rights agreement (in the form of the Form Definitive Agreement) between us and

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

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

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

Unless earlier terminated, the Manufacturing Rights Agreement will remain in effect in perpetuity. Sutro Biopharma may only terminate the Manufacturing Rights Agreement in the event of our (i) uncured, intentional, material breach of certain confidentiality provisions resulting in actual, material harm to Sutro Biopharma’s business, (ii) uncured, intentional material breach of certain provisions relating to the use of certain of Sutro Biopharma’s know-how outside of the Vaccine Field, (iii) unintentional, material breach of certain provisions relating to the use of certain of Sutro Biopharma’s know-

how know-how outside of the Vaccine Field that we do not use reasonable best efforts to cease and (to the extent reasonably curable) cure in a timely fashion, or (iv) uncured failure to pay the Option exercise price or any undisputed milestone payment under the Option Agreement when due. We may terminate the Manufacturing Rights Agreement at our discretion upon 60 days’ written notice, and both parties may terminate the Manufacturing Rights Agreement upon mutual written consent.

For additional details regarding our relationship with Sutro Biopharma, see Note 7, “Commitments and Contingencies,” to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Impact of Certain Trends

The recent trends towards rising inflation may materially adversely affect our business and corresponding financial position and cash flows. Inflationary factors, such as increases in the cost of our clinical trial materials and supplies, 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 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 (“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 all of our costs by vaccine candidates, as 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, manufacture drug product for our 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 or VAX-31 for adults, pursue regulatory approval of our vaccine candidates and expand our pipeline of vaccine candidates. The process of conducting the necessary preclinical and clinical research and completing the manufacturing requirements to obtain regulatory approval is costly and time-consuming. The actual probability of success for our vaccine candidates may be affected by a variety of factors, including the safety and efficacy or immunogenicity of our vaccine candidates, clinical data, investment in our clinical programs, competition, manufacturing capabilities and commercial viability. We may never succeed in achieving regulatory approval for any of our vaccine candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of our vaccine candidates.

We accrue for costs related to research and development activities based on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors, including CMOs and CROs, that conduct research, development and manufacturing activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors exceed the level of services provided and result in a prepayment of the research and development expense.

Advance payments for goods and services to be used in future research and development activities are expensed when the activity has been performed or when the goods have been received. We make significant judgments and estimates in determining accrued research and development liabilities as of each reporting period based on the estimated time period over which services will be performed and the level of effort to be expended. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period.

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

- the costs and timing of our CMC activities, including fulfilling good manufacturing practice (“GMP”) related standards and compliance, and identifying and qualifying second suppliers;
- the costs related to raw materials we purchase directly or through our third-party manufacturing and supply partners;
- the cost of clinical trials of our vaccine candidates;
- changes in the standard-of-care on which a clinical development plan was based, which may require new or additional trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- delays in adding a sufficient number of trial sites and recruiting suitable volunteers to participate in our clinical trials;
- the number of subjects that participate in the trials;

Table of Contents

- 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 or VAX-31 for adults;
- the costs that may be required for secondary supply sources; and

- the immunogenicity or efficacy and safety and tolerability profile of our vaccine candidates.

General and Administrative

General and administrative expenses consist primarily of costs and expenses related to personnel (including salaries, employee benefits and stock-based compensation) in our executive, legal, finance and accounting, human resources and other administrative functions; legal services relating to intellectual property and corporate matters; accounting, auditing, consulting and tax services; insurance; and facility and other allocated 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 human resources, finance and accounting, legal, 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 consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for more detail).

Interest Income

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

Grant Income

Our VAX-A1 vaccine development program currently for VAX-A1, a novel conjugate vaccine candidate designed to prevent disease caused by Group A Streptococcus, is funded in part by a grant obtained from Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (“CARB-X”), a global non-profit partnership dedicated to accelerating antibacterial innovation to tackle the rising global threat of drug-resistant bacteria. The CARB-X grant provides for total potential provided funding of up to $14.6 million (including $11.7 million awarded to date since the grant’s inception in 2019) $11.7 million upon the achievement of VAX-A1 development milestones through June 2024. As of the second quarter of 2024, all of these milestones had been successfully achieved, and no further amounts will be funded under this CARB-X grant.

Table of Contents

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

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 nil $0.4 million and $0.7 million $2.5 million of grant income and recorded the amounts in Other income (expense), net in the condensed consolidated statement statements of operations during the three months ended March 31, 2024 June 30, 2024 and 2023, respectively, and $0.5 million and $3.1 million during the six months ended June 30, 2024 and 2023, respectively. A grant receivable of $0.1 million $0.4 million and nil representing unreimbursed, eligible costs incurred under the agreements were was recorded and included in Prepaid expenses and other current assets in the condensed consolidated balance sheets as of March 31, 2024 June 30, 2024 and December 31, 2023, respectively.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 June 30, 2024 and 2023

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

	Three Months Ended March 31,		Change		Three Months Ended June 30,		Change	
	2024	2023	$	%	2024	2023	$	%
	(in thousands)				(in thousands)			
Operating expenses:								

Operating expenses:																			
Operating expenses:																			
Research and development																			
Research and development																			
Research and development		$ 94,587	$		$ 58,080	$		$ 36,507		62.9		62.9	%	$ 131,507		$		$	72,691
General and administrative	General and administrative	19,885	13,112		13,112	6,773		6,773		51.7		51.7	%	General and administrative	21,474		14,456		
Total operating expenses	Total operating expenses	114,472	71,192		71,192	43,280		43,280		60.8		60.8	%	Total operating expenses	152,981		87,147		
Loss from operations	Loss from operations	(114,472)	(71,192)		(71,192)	(43,280)		(43,280)		60.8		60.8	%	Loss from operations	(152,981)		(87,147)		
Other income (expense), net:																			
Other income, net:																			
Interest income																			
Interest income																			
Interest income		21,666	10,393		10,393	11,273		11,273		108.5		108.5	%	23,813		16,451			
Grant income	Grant income	126	654		654	(528)		(528)		(80.7)		(80.7)	%	Grant income	394		2,464		
Realized gains on marketable securities	Realized gains on marketable securities	22	—		—	22		22		100.0		100.0	%	Realized gains on marketable securities	27		—		
Foreign currency transaction losses		(2,362)			(317)			(2,045)					*						
Foreign currency transaction gains (losses)		44			(107)			151					*						
Total other income, net	Total other income, net	19,452	10,730		10,730	8,722		8,722		81.3		81.3	%	Total other income, net	24,278		18,808		
Net loss	Net loss	$(95,020)	$		$(60,462)	$		$(34,558)		57.2		57.2	%	Net loss	$ (128,703)		$		$(

* *not meaningful*

Table of Contents

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		Three Months Ended June 30,		Change			
	2024	2023	$	%	2024	2023	$	%	2024	2023
	(in thousands)				(in thousands)				(in thousands)	
Product and clinical development (1)										
Product and clinical development (1)										
Product and clinical development (1)	$52,167	$	$33,095	$	$19,072	57.6	57.6	%	$ 76,133	$

Personnel-related	Personnel-related	22,551	12,981	12,981	9,570		9,570	73.7		73.7	%	Personnel-related	26,708	15,206		15,206
Professional and consulting services	Professional and consulting services	1,272	1,592	1,592	(320)		(320)	(20.1)		(20.1)	%	Professional and consulting services	5,630	1,802		1,802
Research and development consumables	Research and development consumables	2,733	3,259	3,259	(526)		(526)	(16.1)		(16.1)	%	Research and development consumables	6,445	5,168		5,168
Facility related and other allocated	Facility related and other allocated	8,419	4,599	4,599	3,820		3,820	83.1		83.1	%	Facility related and other allocated	10,274	5,191		5,191
Laboratory supplies and equipment	Laboratory supplies and equipment	6,347	1,914	1,914	4,433		4,433	231.6		231.6	%	Laboratory supplies and equipment	5,045	2,929		2,929
Other (2)	Other (2)	1,098	640	640	458		458	71.6		71.6	%	Other (2)	1,272	892		892
Total research and development expenses	Total research and development expenses	$94,587	$	$58,080	$		$36,507	62.9		62.9	%	Total research and development expenses	$ 131,507	$		$72,691	$

(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 $36.5 million $58.8 million, or 62.9% 80.9%, during the three months ended March 31, 2024 June 30, 2024 compared to the corresponding period in 2023. The increases of $19.1 million $34.6 million in product and clinical development expenses and $4.4 million $2.1 million in laboratory supplies and equipment were primarily due to (i) the VAX-31 Phase 1/2 study in adults, (ii) Phase 3 readiness manufacturing activities for related to our adult PCV program, primarily related to manufacturing, (iii) manufacturing readiness activities programs, including in connection with the potential future commercial launches of our PCV programs and (iv) Phase 3 clinical trials, (ii) the VAX-31 Phase 1/2 study in adults, and (iii) the VAX-24 Phase 2 study in infants. The increase increases of $9.6 million $11.5 million in personnel-related expenses was and $5.1 million in facility related and other allocated costs were primarily due to the growth in the number of employees in our research and development functions and higher compensation costs, including salaries, benefits and stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses increased by $6.8 million, $7.0 million, or 51.7% 48.5%, during the three months ended March 31, 2024 June 30, 2024 compared to the corresponding period in 2023. The increase was primarily due to an increase increases of $6.5 million (i) $7.3 million in personnel-related expenses as a result of the growth in the number of employees in our general and administrative functions and higher compensation costs, including salaries, benefits and stock-based compensation expense. expense and (ii) $1.8 million in professional and consulting services, adjusted for $2.1 million in higher facility, personnel and other costs allocated to research and development expenses.

Other Income (Expense), Net

Other income (expense), net increased by $8.7 million $5.5 million, or 29.1%, during the three months ended March 31, 2024 June 30, 2024 compared to the corresponding period in 2023. The increase was primarily attributable to greater interest income of $11.3 million $7.4 million as a result of higher cash and investment balances resulting from our follow-on offerings equity and ATM financings combined with an increase in the interest rates earned by such cash and investments, offset by a decrease in grant income of $2.1 million.

Table of Contents

Comparison of the Six Months Ended June 30, 2024 and 2023

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

	Six Months Ended June 30,		Change	
	2024	2023	$	%
	(in thousands)			
Operating expenses:				
Research and development	$ 226,094	$ 130,771	$ 95,323	72.9 %
General and administrative	41,359	27,567	13,792	50.0 %

Total operating expenses	267,453	158,338	109,115	68.9 %
Loss from operations	(267,453)	(158,338)	(109,115)	68.9 %
Other income (expense), net:				
Interest income	45,479	26,844	18,635	69.4 %
Grant income	520	3,119	(2,599)	(83.3)%
Realized gains on marketable securities	49	—	49	100.0 %
Foreign currency transaction losses	(2,318)	(426)	(1,892)	*
Total other income, net	43,730	29,537	14,193	48.1 %
Net loss	$ (223,723)	$ (128,801)	$ (94,922)	73.7 %

Operating Expenses

Research and Development Expenses

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

	Six Months Ended June 30,		Change	
	2024	2023	$	%
	(in thousands)			
Product and clinical development (1)	$ 128,299	$ 74,598	$ 53,701	72.0 %
Personnel-related	49,259	28,187	21,072	74.8 %
Professional and consulting services	6,902	3,395	3,507	103.3 %
Research and development consumables	9,178	8,426	752	8.9 %
Facility related and other allocated	18,693	9,790	8,903	90.9 %
Laboratory supplies and equipment	11,392	4,843	6,549	135.2 %
Other (2)	2,371	1,532	839	54.8 %
Total research and development expenses	$ 226,094	$ 130,771	$ 95,323	72.9 %

(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 $95.3 million, or 72.9%, during the six months ended June 30, 2024 compared to the corresponding period in 2023. The increases of $53.7 million in product and clinical development expenses and $6.5 million in laboratory supplies and equipment were primarily due to (i) manufacturing activities related to our adult PCV programs, including in connection with the potential future commercial launches and Phase 3 clinical trials, (ii) the VAX-31 Phase 1/2 study in adults, and (iii) the VAX-24 Phase 2 study in infants. The increases of $21.1 million in personnel-related expenses and $8.9 million in facility related and other allocated costs were primarily due to the growth in the number of employees in our research and development functions and higher compensation costs, including salaries, benefits and stock-based compensation expense.

Table of Contents

General and Administrative Expenses

General and administrative expenses increased by $13.8 million, or 50.0%, during the six months ended June 30, 2024 compared to the corresponding period in 2023. The increase was primarily due to increases of (i) $13.8 million in personnel-related expenses as a result of the growth in the number of employees in our general and administrative functions and higher compensation costs, including salaries, benefits and stock-based compensation expense; (ii) $2.2 million in professional and consulting services and (iii) $1.6 million in other expenses, adjusted for $3.7 million in higher facility, personnel and other costs allocated to research and development expenses.

Other Income (Expense), Net

Other income (expense), net increased by $14.2 million, or 48.1%, during the six months ended June 30, 2024 compared to the corresponding period in 2023. The increase was primarily attributable to greater interest income of $18.6 million as a result of higher cash and investment balances resulting from our follow-on equity and ATM financings combined with an increase in the interest rates earned by such cash and investments, offset by a decrease in grant income of $2.6 million and an increase in foreign currency transaction losses of $2.0 million $1.9 million.

Liquidity and Capital Resources

From inception through March 31, 2024 June 30, 2024, 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 $3.02 billion $3.13 billion in aggregate gross proceeds and $2.87 billion $2.97 billion net of underwriting discounts, commissions and offering expenses. As of March 31, 2024 June 30, 2024, we had $612.6 million $518.7 million in cash and cash equivalents, $1,899.8 million $1,333.3 million in investments and an accumulated deficit of $1,019.4 million $1,148.1 million.

On July 2, 2021, we filed a shelf registration statement on Form S-3ASR (the "Shelf "2021 Shelf Registration Statement") under which we could, from time to time, sell securities in one or more offerings of our common stock, preferred stock, debt securities or warrants. The 2021 Shelf Registration Statement became automatically effective upon the filing of the Form S-3ASR on July 2, 2021, and was scheduled to expire on July 2, 2024. In anticipation of such expiration, we filed a new shelf registration statement on Form S-3ASR on May 24, 2024 solely to replace the 2021 Shelf Registration Statement (such replacement registration statement, the "2024 Shelf Registration Statement"). Pursuant to the 2024 Shelf Registration Statement, we may, from time to time, sell securities in one or more offerings of our common stock, preferred stock, debt securities or warrants. The 2024 Shelf Registration Statement became automatically effective upon the filing of the Form S-3ASR on July 2, 2021 May 24, 2024.

ATM Program

In July 2021, we entered into an Open Market Sales Agreement℠ (the "Original ATM Sales Agreement") with Jefferies LLC ("Jefferies"), which provided that, upon the terms and subject to the conditions and limitations set forth in the Original ATM Sales Agreement, we may elect had the right to issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $150.0 million through Jefferies acting as our sales agent or principal. As of February 27, 2023, we had sold 4,995,709 shares of our common stock under the Original ATM Sales Agreement at an a weighted average price of $27.57 per share for aggregate gross proceeds of $137.8 million. On February 27, 2023, we and Jefferies entered into an amendment to the Original ATM Sales Agreement (as amended, the "Amended ATM Sales Agreement") pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $400.0 million, which is in addition to the $150.0 million aggregate offering price under the Original ATM Sales Agreement. million. The material terms and conditions of the Original ATM Sales Agreement otherwise remain unchanged. We will pay Jefferies a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Jefferies under the Amended ATM Sales Agreement; however, we are not obligated to make any sales of common stock. As of March 31, 2024 June 30, 2024, we have sold 1,588,807 3,091,842 shares of our common stock under the Amended ATM Sales Agreement at an a weighted average price of $44.06 $57.91 per share for aggregate gross proceeds of $70.0 million $179.1 million ($68.6 174.7 million net of commissions and offering expenses).

Underwritten Follow-on Public Offerings

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

Table of Contents

In February 2024, we completed an underwritten public offering of 12,695,312 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 1,757,812 shares, at a price of $64.00 per share and pre-funded warrants to purchase 781,250 shares of our common stock at a price of $63.999 per underlying share. In aggregate, we received $816.5 million in net proceeds after deducting underwriting discounts and commissions and other 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, development and manufacturing expenditures related to our programs and, to a lesser extent, capital expenditures for our commercial manufacturing facility build-out and general and administrative expenditures. We anticipate that we will continue to incur significant expenses and capital expenditures for the foreseeable future as we continue to advance our vaccine candidates, expand our corporate infrastructure, further our research and development initiatives for our vaccine candidates, build out and operate our commercial manufacturing facilities, and scale our laboratory and manufacturing operations. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We believe that our existing cash, cash equivalents and investments as of the date of this 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, manufacturing and commercialization of our drug candidates. Until we can generate sufficient revenue from the commercialization of our vaccine candidates or from collaboration agreements with third parties, if ever, we expect to finance our future cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. The sale of equity, pre-funded warrants or convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financings may subject us to covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions, including higher inflation rates and changes in interest rates, and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide. There can be no assurance that we will be successful in acquiring additional

funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms favorable or acceptable to us, we may be forced to delay, reduce the scope of or eliminate one or more of our research and development programs.

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

- the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical development and clinical trials;
- the costs of establishing additional manufacturing capacity to meet potential incremental supply requirements following the potential initial commercial launch of VAX-24 or VAX-31 for adults;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, which may require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the cost of building a sales force in anticipation of any product commercialization;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our vaccine candidates for which we receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- exchange rate fluctuations due to exposure of foreign operations and foreign currency fluctuations and translations;
- any product liability or other lawsuits related to our products;
- the revenue, if any, received from commercial sales, or sales to foreign governments, of our vaccine candidates for which we may receive marketing approval;

Table of Contents

- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing our patents or other intellectual property rights;
- expenses needed to attract, hire and retain skilled personnel; and

- the impact of macroeconomic factors, including 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,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(in thousands)			
Net cash used in operating activities				
Net cash used in investing activities				
Net cash provided by financing activities				
Effect of exchange rate changes on cash and cash equivalents				
Net increase (decrease) in cash, cash equivalents and restricted cash				

Cash Flows from Operating Activities

Net cash used in operating activities for the three six months ended March 31, 2024 June 30, 2024 was $159.1 million, $280.5 million, which primarily resulted from a net loss of $95.0 million $223.7 million and a net change in our operating assets and liabilities of $73.8 million $81.6 million, partially offset by non-cash charges of $9.7 million $24.8 million. Non-cash charges primarily consisted of $17.6 million in stock-based compensation expense, $2.1 million in amortization of right-of-use ("ROU") assets and $1.0 million in depreciation and amortization, partially offset by a decrease of $11.0 million in net amortization of premiums on investments. The net change in operating assets and liabilities of $73.8 million $81.6 million was primarily due to decreases in (i) accrued expenses of $35.0 million, (ii) accrued manufacturing expenses of $51.8 million $16.3 million, (ii) (iii) accounts payable of $5.0 million, (iv) accrued compensation of $7.9 million $4.6 million and (iii) (v) operating lease liabilities of $1.8 million $3.6 million and increases in (iv) (vi) other

assets of $8.6 million $15.1 million mainly attributable to the manufacturing facility buildout and (v) (vii) prepaid and other assets of $5.0 million, which were $2.0 million. Non-cash charges primarily consisted of $39.2 million in stock-based compensation expense, $4.2 million in amortization of right-of-use ("ROU") assets and $2.4 million in depreciation and amortization, partially offset by an increase $20.9 million in (vi) accounts payable and accrued expenses net accretion of $1.3 million. discounts on investments.

Net cash used in operating activities for the three six months ended March 31, 2023 June 30, 2023 was $47.7 million $110.4 million, which primarily resulted from a net loss of $60.5 million $128.8 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 $9.3 million and non-cash charges primarily consisted of $9.6 million in stock-based compensation expense, $1.6 million in amortization of 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. $9.1 million. The net change in operating assets and liabilities of $6.8 million $9.3 million was primarily due to increases in (i) in accrued manufacturing expenses of $6.7 million, $6.1 million resulting from increased outsourced manufacturing activities, (ii) in accounts payable and accrued expenses of $4.8 million $6.3 million resulting from the timing of payments and (iii) in accrued compensation of $0.7 million. $3.2 million related to higher headcount. These increases changes were partially offset by (i) an increase in prepaid and other assets of $4.1 million $3.6 million related to prepaid insurance and research costs and (ii) a decrease in operating lease liabilities of $1.4 million. $2.7 million related to our San Carlos office. Non-cash charges primarily consisted of $22.2 million in stock-based compensation expense, $3.2 million in amortization of ROU assets and $1.5 million in depreciation and amortization, partially offset by $17.8 million in net accretion of discounts on investments.

Cash Flows from Investing Activities

Cash used in investing activities for the three six months ended March 31, 2024 June 30, 2024 was $451.1 million, $531.5 million, which was attributable primarily to $687.7 million $1.04 billion in purchases of investments, $6.4 million $37.6 million in purchases related to our manufacturing facility and equipment construction-in-progress and $5.7 million $13.5 million in purchases of lab property and equipment, partially offset by $242.3 million $542.0 million in maturities of investments and $6.4 million $15.9 million in sales of investments.

Table of Contents

Cash used in investing activities for the three six months ended March 31, 2023 June 30, 2023 was $448.1 million $781.7 million, which was attributable primarily to $483.8 million $916.6 million in purchase purchases of investments and $5.6 million of $3.5 million in purchases of lab property and equipment, and leasehold improvements, partially offset by $40.2 million $136.0 million in maturities of investments and $1.1 million $2.4 million in sales of investments.

Cash Flows from Financing Activities

Cash provided by financing activities for the three six months ended March 31, 2024 June 30, 2024 was $818.2 million, $928.6 million, which primarily consisted of net proceeds from (i) our February 2024 follow-on public offering of $816.5 and proceeds from $816.5 million, (ii) our Amended ATM Sales Agreement of $106.5 million, (iii) the exercise of stock options of $5.0 million $7.8 million and (iv) stock issued under our Employee Stock Purchase Plan of $1.7 million, partially offset by releases of restricted stock units of $3.3 million $3.9 million.

Cash provided by financing activities for the three six months ended March 31, 2023 June 30, 2023 was $41.6 million $588.5 million, which primarily consisted of net proceeds from (i) our April 2023 follow-on public offering of $545.3 million and (ii) our Original and Amended ATM Sales Agreement Agreements of $41.8 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, 2024 June 30, 2024, we had total lease payment obligations of $34.7 million $32.3 million, of which $8.9 million is payable within one year.

Option Agreement

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

Purchase Commitments

We have certain payment obligations under various license agreements. Under these agreements, we are required to make milestone payments upon successful completion and achievement of certain intellectual property, clinical, regulatory and sales milestones. The payment obligations under the license agreements are contingent upon future events such as our achievement of specified development, clinical, regulatory and commercial milestones, and we will be required to make development milestone payments and royalty payments in connection with the sale of products developed under these agreements. As the achievement and timing of these future milestone payments are not probable or estimable, such amounts have not been included in our condensed consolidated balance sheets as of March 31, 2024 June 30, 2024 or December 31, 2023.

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, 2024 June 30, 2024, 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,	Years ending December 31, (in thousands)	Years ending December 31, (in thousands)
Remainder of 2024		
2025		
2026		
2027		
Total non-cancelable purchase commitments due to our key manufacturing partners		

Table of Contents

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

While our significant accounting policies are described in the notes to our condensed consolidated 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 condensed consolidated 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 10, "Equity Incentive Plans," to our condensed consolidated financial

Table of Contents

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 ("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, 2024 June 30, 2024, 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 lease 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 6, "Leases," to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Recently Adopted Accounting Pronouncements

See Note 2, "Basis of Presentation and Summary of Significant Accounting Policies," to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our cash and cash equivalents as of March 31, 2024 June 30, 2024 and December 31, 2023 consisted of readily available checking and money market funds. As of March 31, 2024 June 30, 2024 and December 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, 2024 June 30, 2024 and December 31, 2023, we had approximately $1,899.8 million $1,851.9 million and $1,242.9 million in cash, cash equivalents and investments. For the three and six months ended March 31, 2024 June 30, 2024, we had interest income of $21.7 million. $23.8 million and $45.5 million,

Table of Contents

respectively. The following table shows the impact of a hypothetical 10% increase or decrease in interest rates on our net assets as of March 31, 2024 June 30, 2024 and our net loss for the three six months ended March 31, 2024 June 30, 2024:

	Impact on Net Assets as of March 31, 2024 Impact on Net Assets as of June 30, 2024	Impact on Net Loss for the Three Months Ended March 31, 2024 Impact on Net Loss for the Six Months Ended June 30, 2024
Hypothetical Change in Interest Rates		
Hypothetical Change in Interest Rates		
Hypothetical Change in Interest Rates	**(in thousands)**	**(in thousands)**
10% increase		
10% decrease		

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 consolidated 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 have not experienced any losses on these deposits or investments as a result of this market event. Management believes that we are not exposed to significant credit risk as our deposits are held at First Citizens Bank & Trust Company, which had agreed to purchase and assume all deposits and loans of Silicon Valley Bridge 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. 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 contracts with Lonza, our CMO in Switzerland. We have also entered into a limited number of contracts with other parties with payments denominated in foreign currencies. Payments under these contracts are made in foreign currencies and are subject to fluctuations in foreign currency rates. We do not currently have a formal program in place to hedge foreign currency risks. However, from time to time, we buy Swiss Francs ("CHF"), which is the majority of our foreign currency exposure, at market and are holding hold CHF in our bank accounts. As of March 31, 2024 June 30, 2024 and December 31, 2023, we had approximately $20.1 million $6.5 million and $7.6 million of CHF cash and cash equivalents, respectively, held at one two financial institution. institutions. As of March 31, 2024 June 30, 2024 and December 31, 2023, we had foreign currency denominated accounts payable and accrued expenses of $12.6 million $38.5 million and $60.3 million, respectively. As of March 31, 2024 June 30, 2024 and December 31, 2023, we had foreign currency denominated property, plant and equipment of $58.2 million $89.4 million and $51.8 million, $51.8 million, respectively. As of March 31, 2024 June 30, 2024 and December 31, 2023, we had foreign currency denominated other assets of $43.6 million $50.6 million and $34.7 million, respectively. For the three and six months ended March 31, 2024 June 30, 2024, we had foreign currency transaction losses of $2.4 million. $0 million and $2.3 million, respectively. 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, 2024 June 30, 2024 and our net loss for the three six months ended March 31, 2024 June 30, 2024:

	Impact on Net Assets as of March 31, 2024 Impact on Net Assets as of June 30, 2024	Impact on Net Loss for the Three Months Ended March 31, 2024 Impact on Net Loss for the Six Months Ended June 30, 2024
Hypothetical Change in Currency Exchange Rates		
Hypothetical Change in Currency Exchange Rates		
Hypothetical Change in Currency Exchange Rates	**(in thousands)**	**(in thousands)**
10% increase		
10% decrease		

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

Table of Contents

Effects of Inflation

Recently, the 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 ("CEO") and our Chief Financial Officer ("CFO"), our principal executive officer and principal financial officer, respectively, have evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of March 31, 2024 June 30, 2024. Based on this evaluation, our CEO and CFO have concluded that our disclosure controls and procedures as of March 31, 2024 June 30, 2024 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, 2024 June 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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 consolidated 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 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 two clinical and three 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 $402.3 million and $223.5 million for the years ended December 31, 2023 and 2022, respectively, $128.7 million and $95.0 million and $60.5 million $68.3 million for the three months ended March 31, 2024 June 30, 2024 and 2023, respectively, and $223.7 million and $128.8 million for the six months ended June 30, 2024 and 2023, respectively. As of March 31, 2024 June 30, 2024, we had an accumulated deficit of $1,019.4 million $1,148.1 million.

Table of Contents

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, 2024 June 30, 2024, we had cash, cash equivalents and investments of $1,899.8 million $1,851.9 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. Furthermore, we will need to raise substantial additional capital to complete the development, manufacturing and commercialization of our drug candidates. We expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements or any combination of these approaches.

Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions, including higher inflation rates 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 civil and political unrest in certain countries and regions. Our future capital requirements will depend on many factors, including:

- the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical development and clinical trials;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our vaccine candidates for which we receive marketing approval;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory authorities, which may require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the costs of establishing additional manufacturing capacity to meet potential incremental supply requirements following the initial commercial launch of VAX-24 or VAX-31 if approved;
- our ability to set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors;
- the costs of building a sales force in anticipation of any product commercialization;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- market acceptance of our product candidates in the medical community and with third-party payors and consumers;
- any product liability or other lawsuits related to our products;
- the revenue, if any, received from commercial sales, or sales to foreign governments, of our vaccine candidates for which we may receive marketing approval;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing our patents or other intellectual property rights;
- expenses needed to attract, hire and retain skilled personnel; and
- macroeconomic factors that may exacerbate the magnitude of the factors discussed above.

Table of Contents

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, manufacturing and commercialization rights.

Risks Related to Our Business and Industry

Our approach to the discovery and development of our vaccine candidates is based on novel technologies that are unproven, which may expose us to unforeseen risks, require us to modify processes, and make it difficult to predict the time and cost of vaccine candidate development and the timing to apply for and obtain regulatory approvals.

We are developing a pipeline of vaccine candidates utilizing our cell-free protein synthesis platform, which is comprised of the XpressCF™ platform exclusively licensed from Sutro Biopharma, Inc. ("Sutro Biopharma") and our proprietary know-how for vaccine applications against infectious disease, 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 may experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be overcome. For example, although we have achieved proof-of-concept for our carrier-sparing approach with VAX-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 on any of our product candidates, we do not know the specific doses that may be effective in the clinic or, if approved, commercially. Finding a suitable dose may delay our anticipated clinical development timelines.

Furthermore, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our vaccine candidates and learn more about these critical factors. Conjugate vaccine development is highly complex, and development of broad-valency pneumococcal conjugate vaccines ("PCVs") is further complicated by the number of components, analytical assays and potential for adjustments, including but not limited to changes in raw materials, composition, formulation, manufacturing methods and dosing, which could result in drug substances and/or drug product that may vary between preclinical and clinical studies over time. Over the course of the development and manufacturing of VAX-24, we 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. ("Lonza"). The cumulative impact of the time required to make adjustments to our processes led to a delay of our drug substance manufacturing campaign due to scheduling conflicts and capacity constraints at Lonza. There can be no assurance that we or Lonza will be able to successfully manufacture drug substances in a timely manner in the future, or at all. Such process changes and manufacturing delays have caused a change in our Investigational New Drug ("IND")

Table of Contents

application timelines in the past and future changes or delays could impact future timelines for VAX-24, VAX-31 or for our other product candidates.

In addition, the preclinical and clinical trial requirements of the FDA, European Medicines Agency ("EMA") and other regulatory agencies and the criteria these regulators use to determine the safety and immunogenicity or efficacy of a vaccine candidate are determined according to the type, complexity, novelty and intended use and market of the potential products, taking into consideration the benefits and risks for the intended population who will receive the vaccine, as well as the disease(s) to be prevented. Regulatory agencies also evaluate a sponsor's data to determine whether the manufacturing and facility information assure product quality and consistency. Approvals by the FDA and EMA for existing pneumococcal vaccines, such as Pfizer Inc.'s ("Pfizer's") Prevnar 13® ("PCV13"), and Prevnar 20® ("PCV20"), and Merck & Co., Inc.'s ("Merck") VAXNEUVANCE™ ("PCV15"), Capvaxive™ ("PCV21") and Pneumovax® 23 ("PPSV23"), may not be indicative of what these regulators may require for approval of our vaccine candidates. For example, the FDA may challenge our VAX-24 Phase 3 Chemistry, Manufacturing and Controls ("CMC") strategy, which could cause significant delays or unanticipated costs. Additionally, novel aspects of our vaccine candidates and manufacturing processes may create further challenges in obtaining regulatory approval. The regulatory approval process for our novel vaccine candidates can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other vaccine candidates. More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new vaccine candidates. Moreover, our vaccine candidates may not perform successfully in clinical trials.

Our vaccine candidates are in clinical or preclinical stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we are unable to complete development of or commercialize our vaccine candidates or experience significant delays in doing so, our business would be materially harmed.

Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing our vaccine candidates, either alone or with third parties, and we cannot guarantee that we will ever obtain regulatory approval for any of our vaccine candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. None of our vaccine candidates have been the subject of late-stage or pivotal clinical trials, and we may never be able to obtain marketing approval for any of our product candidates. Before obtaining regulatory approval for the commercial distribution of our vaccine candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate the safety and immunogenicity or efficacy of our vaccine candidates.

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

- negative or inconclusive results from our preclinical or clinical trials, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon a program;
- product-related adverse effects experienced by volunteers in our clinical trials;
- difficulty achieving successful development of our manufacturing processes, including process development and scale-up activities to supply products for preclinical studies, clinical trials and commercial sale, if approved;

- timely completion of our preclinical studies and clinical trials, including any field efficacy studies that may be required, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- inability of us or any third-party contract manufacturer to scale up manufacturing of our vaccine candidates to supply the needs of preclinical studies, clinical trials and commercial sales, and to manufacture such products in conformity with regulatory requirements;
- delays in submitting IND applications or comparable foreign applications or delays or failures in obtaining necessary authorizations from regulators to commence a clinical trial, or suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or similar foreign authorities regarding the scope or design of our clinical trials, including any requirements to perform field efficacy studies;
- challenges by the FDA to our clinical or regulatory strategies;
- 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;

Table of Contents

- inability to obtain alternative sources of supply for which we have a single source for vaccine candidate components;

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

In addition, changes to the standard-of-care or the approval standards for new vaccines 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 and VAX-31, both of which are in clinical 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 31-valent clinical PCV candidate. Although VAX-24 has produced positive topline results in clinical studies, it may not demonstrate the same results in future pivotal studies needed to obtain marketing approval from FDA or comparable foreign regulatory authorities. In addition, past and future VAX-24 results may not be indicative of future VAX-31 results. VAX-24 and VAX-31 will 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 ("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 and immunogenicity or 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 (“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 immunogenicity or efficacy of our vaccine candidates or any future vaccine candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our vaccine candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our vaccine candidates or any future vaccine candidates;
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims;
- our ability to set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors; and
- macroeconomic factors that may exacerbate the magnitude of the factors discussed above.

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

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

The vaccine market is intensely competitive and is dominated by a small number of multinational, globally established pharmaceutical corporations with significant resources; in recent history, Pfizer, Merck, GSK plc (“GSK”) and Sanofi have been responsible for developing and introducing most new vaccines to the world. We may also face competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions.

Vaccine candidates that we successfully develop and commercialize may compete with existing vaccines and new vaccines that may become available in the future. Many of our competitors have substantially greater financial, lobbying, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior vaccines, including the potential that our competitors may develop chemical processes or utilize novel technologies for developing vaccines that may be superior to those we employ. In addition, many of these competitors have significantly greater experience than we have in undertaking preclinical studies and clinical trials of new products and in obtaining regulatory approvals, including for many vaccine franchises. Accordingly, our competitors may succeed in obtaining FDA approval or a preferred recommendation from ACIP for their products. For example, PCV13 obtained FDA approval for the prevention of invasive pneumococcal disease (“IPD”) in infants based on non-inferior IgG antibody responses relative to Prevnar, using the surrogate immune endpoints established by the prior Prevnar field efficacy study. Pfizer implemented a similar approach to the development of its 20-valent PCV vaccine candidate, PCV20, which was approved by the FDA in June 2021 for use in adults and in April 2023 for use in infants and children. Pfizer announced in July 2024 that it is developing a new PCV that is currently in adult and pediatric Phase 2 clinical trials. 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 June 2024 that V116, Merck's investigational PCV21, its 21-valent PCV, for adults, received Breakthrough Therapy designation approval from the FDA. In July 2023, Merck announced positive topline results from two Phase 3 trials evaluating V116, FDA for use in vaccine-naïve and previously vaccinated individuals. In November 2023, Merck presented positive results from a Phase 3 study evaluating V116 in

pneumococcal vaccine-naïve adults. Merck reported that V116 elicited non-inferior immune responses compared to PCV20 for the common 10 serotypes and superior responses for 10 of the 11 unique serotypes and that safety and tolerability endpoints were met. In December 2023, Merck also announced that based on these Phase 3 results, the FDA accepted for priority review a new Biologics License Application ("BLA") for V116 and set a Prescription Drug User Fee Act ("PDUFA"), or target action date, of June 17, 2024. In addition, Sanofi and SK Chemicals have partnered to develop a 21-valent PCV and, in June 2023, announced positive results from their Phase 2 clinical trials in infants. GSK, which previously acquired Affinivax, is developing a 24-valent affinity-bound pneumococcal vaccine. vaccine, which is currently in a Phase 2 clinical trial in infants with data anticipated in 2026 or later. GSK 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, manufacturing and commercialization.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

While we are designing and developing a manufacturing process that we believe can scale to address clinical and commercial vaccine supply, we do not own or operate any manufacturing facilities. We rely on contract manufacturing organizations ("CMOs"), including our strategic partnership with our contract manufacturer, Lonza, to access resources to facilitate the development and, if approved, commercialization of VAX-24 or VAX-31 and our other vaccine candidates. Advancing our vaccine candidates may create significant challenges for our CMOs, including:

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

- 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

Table of Contents

("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. In January 2024, we announced that we received encouraging input from ongoing discussions with the FDA about the VAX-24 adult program to further inform our CMC licensure requirements and that we expect to seek additional CMC-focused input from the FDA as we prepare for and potentially conduct our VAX-24 adult Phase 3 program. Delays in establishing our manufacturing process and ensuring the facilities we utilize for manufacturing comply with cGMP or disruptions in our manufacturing processes, implementation of novel technologies or scale-up activities, may delay or disrupt our development efforts.

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

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

- receiving Centers for Disease Control and Prevention ("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, the ACIP forms working groups that gather, analyze and prepare scientific information. The ACIP also considers many of the factors above, as well as myriad additional factors such as the value of vaccination for the target population regarding the outcomes, health economic data and implementation issues. The ACIP recommendations are also made within categories, such as in an age group or a specified risk group. For example, the ACIP may determine that a preferred recommendation in a smaller child population may be more economical than recommending vaccinations for a larger adult population, which could adversely impact our market opportunity.
New pediatric vaccines that receive an ACIP preferred recommendation are almost universally adopted, and adult vaccines that receive a preferred recommendation are widely adopted. 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. The 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 PCV20, or PCV15 with PPSV23, for routine use in adults aged 65 years and older as well as for those between the ages of 19 and 64 years with certain underlying medical conditions or other risk factors. factors who had not previously received a PCV or whose previous vaccination history was unknown. In June 2022, the ACIP voted to recommend that PCV15 may be used as an

Table of Contents

option to the currently available then recommended PCV13 for children aged under 19 years according to currently then recommended PCV13 dosing and schedules. In June 2023, the ACIP voted to recommend the use of either PCV20 as an option to PCV15 or PCV20 for routine use in children under the age of two, and as a “catch up” vaccination for healthy children between the ages of 24 and 59 months with incomplete PCV vaccination status and children between the ages of 24 and 71 months with certain underlying conditions and an incomplete PCV vaccination. vaccination status. Further, the ACIP voted to recommend that children between the ages of two and 18 years with any risk condition who have received all recommended PCV doses before the age of six do not need additional doses if they have received at least one dose of PCV20. If children between the ages of two and 18 years with any risk condition received PCV13 or PCV15, but not PCV20, the ACIP recommend that they should receive a dose of PCV20 or PPSV23. The ACIP also voted to recommend that children between the ages of six and 18 years with any risk condition who have not received any dose of PCV13, PCV15 or PCV20 should receive a single dose of PCV15 or PCV20. When PCV15 is used in this instance, the ACIP recommended that it should be followed by a dose of PPSV23 at least eight weeks later if not previously given.In June 2023, the ACIP also recommended shared clinical decision-making regarding PCV20 use for adults aged 65 years and older who have completed the recommended vaccine series with both PCV13 and PPSV23. In June 2024, the ACIP voted to recommend PCV21 as an option to either PCV20, or PCV15 with PPSV23 for (i) adults aged 65 years and older who have not previously received a PCV or whose previous vaccination history is unknown, (ii) adults between the ages of 19 and 64 with certain underlying medical conditions or other risk factors who have not previously received a PCV or whose previous vaccination history is unknown and (iii) adults aged 19 years and older who have received PCV13 but not all recommended doses of PPSV23. Additionally, the ACIP recommended shared clinical decision-making regarding a supplemental dose of PCV21 for adults aged 65 and older who have completed their vaccine series with both PCV13 and PPSV23.

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 and, VAX-31 for IPD, including VAX-A1 for Group A Streptococcus (“Group A Strep”), VAX-PG for periodontitis and VAX-GI for dysentery and shigellosis. Our research programs may fail to identify potential vaccine candidates for clinical development for a number of reasons or we may focus our efforts and resources on potential programs or vaccine candidates that ultimately prove to be 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, we believe current PCVs do not address provide adequate coverage of the majority of circulating strains currently causing pneumococcal disease or those that previously caused pneumococcal disease. There has been a decrease in the incidence of

disease attributable to the strains covered by existing vaccines but an increase in incidence attributable to non-covered strains that now cause most residual disease. Such change is driven by the void created when strains are taken out of circulation after widespread vaccination, which is a phenomenon known as serotype replacement. As a result of such change, broader spectrum PCVs are required to maintain protection against historically pathogenic strains while expanding coverage to current circulating and emerging strains. There can be no assurance that we will be able to develop higher-valent vaccines to address serotype replacement.

In addition, because VAX-24 and VAX-31 are our most advanced vaccine candidates, and because our other vaccine candidates are also based on our cell-free protein synthesis platform, if VAX-24 or VAX-31 encounter safety or immunogenicity problems, manufacturing problems, developmental delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

We currently rely on third-party manufacturing and supply partners, including Lonza and Sutro Biopharma, to supply raw materials and components for, and the manufacture of, our preclinical and clinical supplies as well as our vaccine

Table of Contents

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 third-party manufacturers, or our failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

Efficient and scalable manufacturing and supply is a vital component of our business strategy. We do not own or operate any manufacturing facilities. We are designing and developing a manufacturing process that we believe can scale to address clinical and commercial vaccine supply. However, our assumptions as to our ability and our CMOs' ability to produce vaccines at the scale needed for clinical development, manufacturing and commercial demand, in particular for our PCVs, may prove to be wrong. If we encounter substantial problems in our manufacturing processes or in our ability to scale to address commercial vaccine supply, our business would be materially adversely affected. Examples of potential issues related to our manufacturing processes or our ability to scale include difficulties with production costs, yields and quality control, including stability of the drug substance or drug product.

We rely on third-party contract manufacturers to manufacture preclinical and clinical trial product materials and supplies for our needs. There can be no assurance that our preclinical and clinical development product supplies will not be limited or interrupted or be of satisfactory quality or continue to be available on acceptable terms. Over the course of the development and manufacturing of VAX-24, we 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, VAX-31 or for our other product candidates. Since we utilize 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. Certain aspects of our manufacturing process for our clinical trial product materials and supplies have also been adversely affected by macroeconomic factors, such as the COVID-19 pandemic, and could be adversely affected by earthquakes and other natural or man-made disasters, equipment failures, labor shortages, health epidemics, power failures and numerous other factors in the future.

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. For example, in October 2023, Vaxcyte Switzerland GmbH ("Vaxcyte GmbH"), a Swiss limited liability company and wholly owned subsidiary of ours, entered into a pre-commercial services and commercial manufacturing supply agreement (the "Commercial Manufacturing and Supply Agreement") with Lonza, pursuant to which Lonza will (i) construct and build out a dedicated suite ("Suite") at Lonza's facilities in Visp, Switzerland to manufacture certain key components (including drug substance) for our proprietary PCV franchise and any other products or intermediates Vaxcyte GmbH may choose (collectively, the "Products"), and (ii) maintain and operate the

Suite (utilizing Lonza's employees) to manufacture the Products as a service provided to Vaxcyte GmbH, including conducting related quality control and quality assurance operations. Pursuant to the Commercial Manufacturing and Supply

Agreement, Lonza will be a preferred, non-exclusive, supplier of the Products to Vaxcyte GmbH, and Vaxcyte GmbH retains the right to procure the Products from one or more alternate and/or backup manufacturers of the Products (including at our own facilities).

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 grant agreement with Sutro Biopharma (the "Option Agreement"). Pursuant to the Option Agreement, we acquired from Sutro Biopharma (i) authorization to enter into an agreement with an independent alternate CMO to directly source Sutro Biopharma's cell-free extract, allowing us to have direct oversight over financial and operational aspects of the relationship with the CMO; and (ii) a right, but not an obligation, to obtain certain exclusive rights to internally manufacture and/or source extract from certain CMOs and the right to independently develop and make improvements to extract (including the right to make improvements to the extract manufacturing process as well as cell lines) for use in connection with the exploitation of certain vaccine compositions (the "Option"). We and Sutro Biopharma agreed to negotiate the terms and conditions of a form definitive agreement to be entered into in the event we exercise the Option, which would include the terms and conditions set forth in an executed term sheet between us (the "Term Sheet") and such terms that were necessary to give effect to each of the terms and conditions set forth in the Term Sheet (the "Form Definitive Agreement"). On September 28, 2023, we and Sutro Biopharma mutually agreed in writing upon the Form Definitive Agreement to become effective in the event that we exercise the Option. In November 2023, we exercised the Option and entered into a manufacturing rights agreement (the "Manufacturing Rights Agreement") with Sutro Biopharma to obtain control over the development and manufacture of cell-free extract. Pursuant to the Manufacturing Rights Agreement, we obtained exclusive rights to independently, or through certain third parties, develop, improve and manufacture cell-free extract for use in connection with our vaccine candidates. If Sutro Biopharma, the independent alternate CMO or the designated third parties are unable to provide a sufficient supply of cell-free extract, our third-party manufacturers may be delayed in their production of intermediate components, which may lead to delays of our drug substance manufacturing campaigns.

If we are unable to obtain additional or maintain third-party manufacturing for vaccine candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our vaccine candidates successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMPs could adversely affect our business in a number of ways, including:

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

In addition, because VAX-24, VAX-31 and our other vaccine candidates are also based on our cell-free protein synthesis platform, if our vaccine candidates encounter safety and immunogenicity or efficacy problems, manufacturing problems, developmental delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

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

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

Adverse effects or other undesirable or unacceptable side effects caused by our vaccine candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In such an event,

our clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our vaccine candidates. Such side effects could also affect trial recruitment or the ability of enrolled subjects to complete the clinical trial or result in potential product liability claims. 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, but are not limited to:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in reaching a consensus with regulatory agencies on study design or clinical or regulatory strategies;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required institutional review board (“IRB”) approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related

Table of Contents

technology that raise FDA concerns about risk to patients of the technology broadly; or if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;

- delays in adding a sufficient number of trial sites and recruiting volunteers to participate in our clinical trials;
- failure by our CROs, other third parties or us, to adhere to clinical study requirements;
- failure to perform in accordance with the FDA’s good clinical practice (“GCP”) requirements or applicable regulatory guidelines in other jurisdictions;
- transfer of manufacturing processes to any new CMO or our own manufacturing facilities or any other development or commercialization partner for the manufacture of vaccine candidates;
- delays in having subjects complete participation in a study or return for post-injection follow-up;
- subjects dropping out of a study;
- occurrence of side effects associated with our vaccine candidates that are viewed to outweigh their potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard-of-care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our vaccine candidates being greater than we anticipate;
- clinical studies of our vaccine candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs;

- delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary raw materials; and
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our vaccine candidates for use in clinical studies or the inability to do any of the foregoing.

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 or stop the 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 but not limited to:

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

Table of Contents

Based on our End-of-Phase 2 meeting with the FDA in October 2023, we believe there is agreement with the FDA on the clinical design of the VAX-24 adult Phase 3 program, including the approximate overall number of subjects, the primary and secondary endpoints for the pivotal, non-inferiority study as well as confirmation that the planned immunogenicity analyses are sufficient to support licensure and an efficacy study is therefore not required. In the event that we are required to conduct any field efficacy studies for VAX-24 or any of our other product candidates, enrollment of a sufficient number of subjects may require additional time and resources given widespread vaccination rates in the United States, particularly in the pediatric population. As a result, we may be required to conduct any such trials outside the United States, which could cause additional complexity and delay. Delays in enrollment may result in increased costs or may affect the timing or outcome of any clinical trials we may conduct, which could prevent completion of these trials and adversely affect our ability to advance the development of our vaccine candidates.

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

From time to time, we may publish interim topline or preliminary data from our preclinical or clinical trials. Interim topline data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data when we publish such data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we may publish. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular vaccine candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular vaccine candidate or our business. If the topline data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, vaccine candidates may be harmed, which could significantly harm our business prospects.

We have in the past and may in the future seek Breakthrough Therapy designation or Fast Track designation by the FDA for one or more of our vaccine candidates, but we may not receive the designations we seek, and even if we do, such designation may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our vaccine candidates will receive marketing approval.

We have in the past and may in the future seek 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 when 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

Table of Contents

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 when one or more of our vaccine candidates qualify for either of these designations, the FDA may later decide that the vaccine candidate no longer meets the conditions for qualification and rescind the designations.

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

We currently have no sales, marketing or distribution capabilities and as an organization have no experience in marketing products. If we develop an in-house marketing organization and sales force, we will require significant 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 but not limited to:

- 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;

Table of Contents

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

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

As our discovery, development, manufacturing and commercialization plans and strategies develop, we have rapidly expanded our employee base and expect to continue to add managerial, operational, sales, research and development, marketing, financial and other personnel. Current and future growth imposes significant added responsibilities on members of management, including but not limited to:

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

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

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

Table of Contents

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

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

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

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

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

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

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

We intend to initially seek approval of our VAX-24 or VAX-31 vaccine candidates in adults. If approved, we believe it may have the potential to serve as a "catch up" or booster to those adults who have previously received PPSV23 or a lower-valent PCV. Previous vaccines with a "catch up" opportunity have seen a high initial capture rate, but sales may decline over time as the number of individuals who remain unvaccinated with the new vaccine, and eligible for "catch up" opportunities, declines. Such decline could adversely affect our revenue over time.

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

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

Table of Contents

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

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

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to software bugs; malicious code (such as viruses and worms); social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as a fake, and phishing attacks); employee error, theft or misuse; denial-of-service attacks (such as credential stuffing); malware (including as a result of advanced persistent threat intrusions); natural disasters; terrorism; war; telecommunication and electrical failures; supply-chain attacks; ransomware attacks; attacks enhanced or facilitated by artificial intelligence ("AI"); and other similar threats. In particular, severe ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of data and income, reputational harm and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. We may also be the subject of server malfunction, software or hardware failures, supply-chain cyberattacks, loss of data or other computer assets and other similar issues.

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

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

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

We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against cybersecurity incidents or other security breaches and to mitigate, detect and remediate actual or potential vulnerabilities. Certain data

Table of Contents

privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and Sensitive Information. If we (or a third party upon which we rely) experience a cybersecurity incident or are perceived to have experienced a cybersecurity incident, we may experience adverse consequences, including interruptions in our operations, which could result in a disruption of our development programs and our business operations. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development, manufacturing and commercialization of our vaccine candidates could be delayed. Furthermore, consequences from an actual or perceived security breach may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Cybersecurity incidents and attendant consequences may cause customers to stop using our platform/products/services, deter new customers from using our products, and negatively impact our ability to grow and operate our business.

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

We cannot be sure that our insurance coverage, if any, will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or other materially adverse impacts arising out of our processing activities, privacy and security practices, or security breaches we may experience. The successful assertion of one or more large claims against 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.

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

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

We have incorporated, and may continue to incorporate, certain AI solutions into our operations, and the use of AI involves various risks and challenges that could adversely affect our business. The development and deployment of AI systems involve inherent technical complexities and uncertainties, and our potential AI systems may encounter unexpected

technical difficulties, limitations or errors, including inaccuracies in data processing or flawed algorithms. In addition, our competitors or other third parties may incorporate AI into their operations and products more quickly or more successfully than us, which could impair our ability to compete effectively.

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

Governments have passed and are likely to pass additional laws regulating generative AI. The introduction of AI technologies into our operations may result in new or enhanced governmental or regulatory scrutiny, litigation, confidentiality or security risks or other complications that could adversely affect our business. The regulatory landscape governing AI technologies is evolving rapidly, and changes in laws, regulations or enforcement practices may impose new

Table of Contents

compliance requirements, restrict certain AI applications or increase our regulatory obligations, which could negatively impact our business.

Natural or man-made disasters or business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CMOs, CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The impact of climate change may increase these risks due to changes in weather patterns, such as increases in storm intensity, sea-level rise, melting of permafrost and temperature extremes on facilities or operations. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

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

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

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

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Assuming we obtain clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

Table of Contents

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 ("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 ("NOL") 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.

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 impactful to 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 IRA of 2022 specifically introduces the topic of corporate alternative minimum tax 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. We do not believe that this update to IRC 162(m) would have a material impact on our income tax provision currently and will continue to monitor this provision.

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

Table of Contents

Our ability to utilize our NOL carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. As of December 31, 2023, we had federal and state NOL carryforwards of $351.9 million and $693.6 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, 2023, we also had federal and state research credit carryforwards of $12.8 million and $4.6 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 2023, as such we have determined that no federal research credits will expire unutilized or are excluded from our research carryforwards as of December 31, 2023. 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.

Table of Contents

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 Manufacturing Rights Agreement, we obtained exclusive rights to independently, or through certain third parties, develop, improve and manufacture cell-free extract for use in connection with our vaccine candidates. We have engaged Lonza to perform manufacturing process development and clinical manufacture and supply of components for VAX-24 and VAX-31, including the manufacture of polysaccharide antigens, our proprietary eCRM protein carrier and conjugated drug substances.

In addition, Lonza is currently in the process of manufacturing certain components of our vaccine candidates on a clinical scale. In October 2023, Vaxcyte GmbH and Lonza entered into the Commercial Manufacturing and Supply Agreement pursuant to which Lonza will (i) construct and build out a Suite at Lonza's facilities in Visp, Switzerland to manufacture the Products, and (ii) maintain and operate the Suite (utilizing Lonza's employees) to manufacture the Products as a service provided to Vaxcyte GmbH. Pursuant to the Commercial Manufacturing and Supply Agreement, Lonza will be a preferred, non-exclusive, supplier of the Products to Vaxcyte GmbH, and Vaxcyte GmbH retains the right to procure the Products from one or more alternate and/or backup manufacturers of the Products (including at our own facilities). Our agreements with Lonza are denominated in Swiss Francs ("CHF"). Fluctuations in the exchange rate for CHF may increase our costs and affect our operating results.

We have not yet caused our vaccine candidates to be manufactured on a commercial scale and may not be able to achieve commercial scale manufacturing and may be unable to create an inventory of mass-produced product to satisfy demands for any of our vaccine candidates.

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

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

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any;

Table of Contents

- Our third-party suppliers and manufacturers might be unable to timely formulate and manufacture or supply raw materials for our vaccine candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any. For example, if Sutro Biopharma, the independent alternate CMO or the designated third parties under the Manufacturing Rights Agreement are unable to provide a sufficient supply of cell-free extract, our third-party manufacturers may be delayed in their production of intermediate components, which may lead to delays of our drug substance manufacturing campaigns. Additionally, if Lonza is unable to identify a timely or manageable solution for handling cell-free extract during our clinical studies, such studies may be delayed, and we will incur additional costs;
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately;
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products; and
- Our third-party suppliers and manufacturers could breach or terminate their agreement with us.

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

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

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

Risks Related to Government Regulation

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

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products, including biologics such as conjugate vaccines, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We expect that our vaccine candidates will be regulated by the FDA as biologics. We are not permitted to market any biological drug product in the United States until we receive approval of a BLA Biologics License Application ("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 and various comparability assessments. The FDA's review of our BLA may be significantly delayed if the FDA views that the CMC information included in our submission is not adequate or requests additional CMC information or data.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our vaccine candidates may not be

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

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

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

We could also 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 immunogenicity or efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a vaccine candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial or based on a recommendation by the 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 are still in the process of having discussions with the FDA regarding our Phase 3 regulatory plans, including discussions regarding our CMC strategy, the FDA may ultimately disagree with our regulatory strategy or we may be unable to successfully complete development to the FDA's satisfaction. We believe our previously reported topline results for VAX-24 support clinical non-inferiority to PCV20, but there can be no assurance that this approach in pivotal studies will be sufficient for regulatory approval.

We may seek Accelerated Approval from the FDA for our vaccine candidates and, if granted, the FDA may require us to perform post-marketing studies as a condition of approval to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoints. If the results from such post-marketing studies are not positive or otherwise fail to show the predicted effect, 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

Table of Contents

third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our vaccine candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of regulatory approvals;
- exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid;
- product seizure or detention, or refusal to permit the import or export of our vaccine candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our vaccine candidates. For example, on June 28, 2024, the U.S. Supreme Court, in *Loper Bright Enterprises v. Raimondo*, overturned long-standing precedent regarding the deference courts owe to agencies' interpretation of ambiguous statutes in their rulemaking. While the impact of the *Loper Bright* decision on our business and regulatory strategy is unknown, the decision generally may, among other things, increase the frequency of challenges to decisions and rulemaking of health regulators, including FDA determinations of drug approval and market exclusivity and the Centers for Medicare & Medicaid Services' ("CMS") rules regarding reimbursement, and also impact the speed at which such health regulators make decisions and issue regulations.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

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

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

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") established an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until twelve years after the reference product was approved under a BLA and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. 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.

In addition, there is a risk that any exclusivity period we receive for any of the vaccine candidates we develop that is approved in the United States as a biological product under a BLA could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject vaccine candidates to be reference products for competing products, potentially creating the opportunity for 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.

Table of Contents

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 ("HIPAA") which , among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, regardless of the payor (e.g., public or private), or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (the "HITECH") and its implementing regulations, which also impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, including health plans, healthcare clearinghouses and certain healthcare providers, and their business associates that perform certain services involving the use or disclosure of individually identifiable health information for or on their behalf, as well as their covered subcontractors. HITECH also created tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the Federal Food Drug 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 ("CMS") 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,

Table of Contents

which require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;

- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers; and

- laws governing the privacy and security of certain protected information, such as the EU GDPR, and the CCPA, which impose obligations and restrictions on the collection, use and disclosure of personal data (including health data) relating to individuals located in the European Economic Area ("EEA") and California, respectively.

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

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock options for consulting services provided, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, injunctions, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace. In addition, if the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

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

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

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

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and

Table of Contents

- 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 ("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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), was passed, which substantially changed the way healthcare is financed by both governmental and private payors in the United States. The ACA, among other things: (i) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended

Table of Contents

the rebate program to individuals enrolled in Medicaid managed care organizations; (ii) created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (iii) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in specific government healthcare programs; (iv) expanded the eligibility criteria for Medicaid programs; (v) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; (vi) created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (vii) and established a Center for Medicare & Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drugs.

There have been 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. 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 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 2015 and 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 (“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 (“APM”) and the Merit-based Incentive Payment System (“MIPS”). Under both APMs and MIPS, performance data collected each performance year will affect Medicare payments in later years, including potentially reducing payments. 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 For example, 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, IRA will, among other things, (i) directs the Department of Health and Human Services (“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) directs 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) imposes 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 certain 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 take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug negotiation program is currently 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.

Table of Contents

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. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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, in September 2020, the FDA issued a final rule that sets up a legal framework for allowing the importation of certain prescription drugs from Canada, and CMS issued guidance that addresses the treatment of certain imported drugs under the Medicaid Drug Rebate Program. On January 5, 2024, FDA authorized the state of Florida’s Section 804 Importation Program, which is the first major step in allowing the state to import certain prescription drugs from Canada. If the program is ultimately approved, it will be the first such program authorized in the United States. Further, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs, biological products and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

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

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 FDA 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.

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 increasingly subject to stringent and rapidly changing U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. The obligations and

Table of Contents

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

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

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

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

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

In addition, many jurisdictions have enacted data localization laws and cross-border personal data transfer laws. These laws may make it more difficult for companies to transfer personal data across jurisdictions, which could impede our business. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal

challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If we need but cannot implement a valid compliance mechanism for cross-border privacy and security

Table of Contents

transfers, or if the requirements for a legally-compliant transfer are too onerous, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or elsewhere. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to European and other data privacy and security laws; or requiring us to increase our personal data processing capabilities in Europe and/or elsewhere at significant expense.

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

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

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

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our vaccine development programs and vaccine candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to VAX-24, VAX-31 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, VAX-31 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, VAX-31 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.

Table of Contents

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, VAX-31 or any future vaccine candidate, it could dissuade companies from collaborating with us to develop vaccine candidates and threaten our ability to commercialize future vaccines. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent

protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

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

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

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

We have licensed certain intellectual property rights related to the XpressCF™ platform, components of our PCV candidates, and methods of making components of VAX-24 or VAX-31 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.

Table of Contents

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, VAX-31 or any future vaccine candidate, or the XpressCF™ platform, our competitors might be able to enter the market, which would have an adverse effect on our business.

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent the development, manufacturing and commercialization of VAX-24 or VAX-31 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,

Table of Contents

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

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

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

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares.

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

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of PTA for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in future and whether patent expiration dates may be impacted. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant

governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications 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 ("UPC"). As the

Table of Contents

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 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 patents validated in Russia, and Eurasian patent applications. Russian decrees may also significantly limit our ability to enforce Russian patents. We cannot predict when or how this situation will change.

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

Because we rely on third parties to manufacture VAX-24, VAX-31 and potentially future vaccine candidates, and we collaborate with third parties on the development of VAX-24, VAX-31 and potentially future vaccine candidates, we must, at times, share trade secrets with them. We also conduct joint research and development that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Further, disputes may arise under these agreements regarding inventorship or ownership of proprietary information generated during research and development.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our

Table of Contents

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 addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, these factors include, but are not limited to:

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

In addition, the stock market in general, and the Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. You may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

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

Table of Contents

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

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

There is an increasing focus from certain investors and other key stakeholders concerning corporate responsibility, specifically related to environmental, social and governance ("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 ("Board") is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board. Among other things, these provisions:

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

- require the approval of the holders of at least 66 ⅔% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law ("DGCL"), which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These

Table of Contents

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.

Table of Contents

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act of 1933 (as amended, the "Securities Act") creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these types of lawsuits. If a court were to find the exclusive-forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

General Risk Factors

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or vaccine candidates.

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

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

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

The cash and cash equivalents that we use to meet our working capital and operating expense needs and investments we hold are held and managed with financial institutions. If any of the financial institutions in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations. For example, on March 10, 2023, the California Department of Financial Protection and Innovation took control of Silicon Valley Bank ("SVB") and appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. While SVB was our primary bank at the

time, we have not experienced any losses on our deposits or investments with SVB as a result of this market event. We continue to maintain a banking relationship with SVB, which is almost

Table of Contents

entirely comprised of our funds held in custodial accounts of a third-party institution for which SVB Asset Management was the advisor ("SVB Custodial Accounts"). While we were able to recover all deposited amounts from SVB, and continue to have access to all investments held in the SVB Custodial Accounts, there can be no assurance that our current or future banks will not face similar risks as SVB or that we will be able to recover in full our deposits in the event of similar closures. If one or any of the financial institutions in which we hold our funds for working capital and operating expense needs were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner.

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm with our annual reports on Form 10-K. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the Sarbanes-Oxley Act, the requirements of being a reporting company under the Exchange Act and any complex accounting rules in the future, we may need to upgrade our information technology systems, implement additional financial and management controls, reporting systems and procedures, and hire additional accounting and finance staff. We are currently in the process of hiring additional accounting and finance staff as we grow our business. If we are unable to hire the additional accounting and finance staff necessary to comply with these requirements, we may need to retain additional outside consultants. If we or, if required, our auditors, are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

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

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

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

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

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

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

Table of Contents

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**

Not applicable.

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

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Trading Arrangements

The adoption, modification or termination of contracts, instructions or written plans for the purchase or sale of our securities by our Section 16 officers or directors for the three months ended March 31, 2024 June 30, 2024, each of which was entered into during an open trading window and is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act ("10b5-1 Plan"), were as follows:

Halley Gilbert, Grant Pickering, our Board Chief Executive Officer and Audit Committee a member of our Board, adopted a 10b5-1 Plan on March 1, 2024 April 12, 2024, with an effective date of October 1, 2024. Mr. Pickering's 10b5-1 Plan provides for the potential sale of up to 45,000 shares of our common stock held by Mr. Pickering and the potential exercise and sale of up to 195,000 shares of our common stock held by Mr. Pickering. Mr. Pickering's 10b5-1 Plan also provides for the potential sale of up to 35,490 shares of our common stock held by trusts in which the beneficiaries are children of Mr. Pickering. Mr. Pickering's 10b5-1 Plan expires on October 1, 2025, or upon the earlier completion of all authorized transactions thereunder.

Andrew Guggenhime, our President and Chief Financial Officer, adopted a 10b5-1 Plan on May 17, 2024, with an effective date of October 18, 2024. Mr. Guggenhime's 10b5-1 Plan provides for the potential exercise and sale of up to 146,000 shares of our common stock, and expires on October 17, 2025, or upon the earlier completion of all authorized transactions thereunder.

Mikhail Eydelman, our General Counsel, Chief Compliance Officer and Corporate Secretary, adopted a 10b5-1 Plan on June 11, 2024, with an effective date of October 1, 2024. Mr. Eydelman's 10b5-1 Plan provides for the potential exercise

Table of Contents

and sale of up to 65,500 shares of our common stock, and expires on September 30, 2025, or upon the earlier completion of all authorized transactions thereunder.

Teri Loxam, a member of our Board, adopted a 10b5-1 Plan on June 18, 2024, with an effective date of September 16, 2024. Ms. Loxam's 10b5-1 Plan provides for the potential exercise and sale of up to 12,500 shares of our common stock, and expires on September 15, 2025, or upon the earlier completion of all authorized transactions thereunder.

Halley Gilbert, a member of our Board, terminated her 10b5-1 Plan on June 16, 2024. Ms. Gilbert's 10b5-1 Plan provides was originally adopted on March 1, 2024 for the potential exercise and sale of up to 51,950 shares of our common stock and expires on until May 31, 2025, or upon the earlier completion of all authorized transactions thereunder.
Jim Wassil, our Chief Operating Officer, adopted a 10b5-1 Plan on March 1, 2024. Mr. Wassil's 10b5-1 Plan provides for the potential exercise and sale of up to 108,000 shares of our common stock, and expires on September 1, 2025, or upon the earlier completion of all authorized transactions thereunder.
During the three months ended March 31, 2024 June 30, 2024, none of the Company's other directors or Section 16 officers adopted, modified or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

Table of Contents

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., as amended.	10-Q	001-39323	3.2	November 6, 2023
4.1	Form of Common Stock Certificate of the Registrant.	S-1/A	333-238630	4.1	June 8, 2020
4.2	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
4.5	Form of Pre-Funded Warrant.	8-K	001-39323	4.1	January 31, 2024
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.

† 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.

Table of Contents

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, 2024August 6, 2024 By: /s/ Grant E. Pickering

Grant E. Pickering

Chief Executive Officer

Date: May 8, 2024August 6, 2024 By: /s/ Andrew Guggenhime

Andrew Guggenhime

President and Chief Financial Officer

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, 2024August 6, 2024 By: /s/ Grant E. Pickering

Grant E. Pickering
Chief Executive Officer

style="bottom:0;;width:100%">

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, 2024 August 6, 2024 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, 2024 June 30, 2024, 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, 2024 August 6, 2024

/s/ Grant E. Pickering	/s/Andrew Guggenhime
Grant E. Pickering	**Andrew Guggenhime**
Chief Executive Officer	**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.”

DISCLAIMER

THE INFORMATION CONTAINED IN THE REFINITIV CORPORATE DISCLOSURES DELTA REPORT™ IS A COMPARISON OF TWO FINANCIALS PERIODIC REPORTS. THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORT INCLUDING THE TEXT AND THE COMPARISON DATA AND TABLES. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED IN THIS REPORT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S ACTUAL SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

REFINITIV