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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39323

VAXCYTE, INC.
(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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

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

As of November 2, 2026, the registrant had 158,299,981 shares of common stock, $0.001 par value per share, outstanding.

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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.

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 or changes in government regulation;
- the pricing, coverage and reimbursement of our vaccine candidates, if approved;
- our ability and the ability of our third-party contract manufacturers to operate and continue operations;
- our ability to hire and retain key personnel;
- our ability to obtain additional financing; and
- the volatility of the trading price of our common stock.

Actual events or results may differ from those expressed in forward-looking statements. You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report on Form 10-Q primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Quarterly Report on Form 10-Q. While we

believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

The forward-looking statements made in this Quarterly Report on Form 10-Q relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report on Form 10-Q to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments.

Summary of Risks Affecting Our Business

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

- We are in the clinical or preclinical stages of vaccine development and have a limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant net losses since inception and anticipate that we will continue to incur substantial net losses for the foreseeable future. We currently have no source of product revenue and may never achieve profitability. Our stock is a highly speculative investment.
- We will require substantial additional funding to finance our operations, which may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.
- Our approach to the discovery and development of our vaccine candidates is based on novel technologies that are unproven, which may expose us to unforeseen risks, require us to modify processes, and make it difficult to predict the time and cost of vaccine candidate development and the timing to apply for and obtain regulatory approvals.
- Our vaccine candidates are in clinical or preclinical stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we are unable to complete development of or commercialize our vaccine candidates or experience significant delays in doing so, our business would be materially harmed.
- The U.S. Food and Drug Administration ("FDA") may disagree with our regulatory plan, and we may fail to obtain regulatory approval of our vaccine candidates.
- Our business is highly dependent on the success of our pneumococcal conjugate vaccine ("PCV") candidates. If we are unable to successfully develop, obtain approval for and effectively commercialize our PCV candidates, our business would be significantly harmed.
- Our primary competitors have significantly greater resources and experience than we do, which may make it difficult for us to successfully develop and commercialize our vaccine candidates, or may result in others discovering, developing or commercializing products before or more successfully than us.
- We may not be successful in our efforts to use our cell-free protein synthesis platform to expand our pipeline of vaccine candidates and develop marketable products.
- We currently rely on third-party manufacturing and supply partners to supply raw materials and components for, and the manufacture of, our preclinical and clinical supplies as well as our vaccine candidates. Our inability to procure necessary raw materials or to have sufficient quantities of preclinical and clinical supplies or the inability to have our vaccine candidates manufactured, including delays or interruptions at our third-party manufacturers, or our failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.
- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our vaccine candidates.
- The development, review and approval of our product candidates are subject to the operational capacity, processes and resource levels of regulatory authorities, which may fluctuate over time and could delay or adversely affect our business.
- If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

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

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 125,470	$ 173,959
Short-term investments	1,166,759	1,387,000
Prepaid expenses and other current assets	57,326	66,402
Total current assets	1,349,555	1,627,361
Property and equipment, net	253,359	257,370
Operating lease right-of-use assets	107,856	116,009
Finance lease right-of-use assets	301,711	—
Long-term investments	972,156	881,664
Restricted cash	1,251	1,466
Other assets	3,248	118,847
Total noncurrent assets	1,639,581	1,375,356
Total assets	$ 2,989,136	$ 3,002,717
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 67,612	$ 70,904
Accrued compensation	20,664	23,000
Accrued contract manufacturing expenses	159,188	74,654
Accrued expenses	30,619	31,068
Operating lease liabilities — current	6,692	6,124
Finance lease liabilities — current	10,922	—
Total current liabilities	295,697	205,750
Operating lease liabilities — non-current	107,365	111,457
Finance lease liabilities — non-current	96,856	—
Total liabilities	499,918	317,207
Commitments and contingencies (Note 7)		
Stockholders' Equity		
Preferred stock, $0.001 par value — 10,000,000 shares authorized at September 30, 2026 and December 31, 2025; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock, $0.001 par value — 500,000,000 shares authorized at September 30, 2026 and December 31, 2025; 149,299,027 and 131,058,858 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	152	134
Additional paid-in capital	5,560,981	4,838,736
Accumulated other comprehensive (loss) gain	(14,982)	1,587
Accumulated deficit	(3,056,933)	(2,154,947)
Total stockholders' equity	2,489,218	2,685,510
Total liabilities and stockholders' equity	$ 2,989,136	$ 3,002,717

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 270,326	$ 209,933	$ 850,956	$ 552,246
General and administrative	37,948	32,447	105,943	97,146
Total operating expenses	308,274	242,380	956,899	649,392
Loss from operations	(308,274)	(242,380)	(956,899)	(649,392)
Other income, net:				
Interest income	23,189	29,259	75,554	93,267
Other (expense) income	(11,977)	291	(20,641)	36,004
Total other income, net	11,212	29,550	54,913	129,271
Net loss	$ (297,062)	$ (212,830)	$ (901,986)	$ (520,121)
Net loss per share, basic and diluted	$ (1.99)	$ (1.56)	$ (6.25)	$ (3.83)
Weighted-average shares outstanding, basic and diluted	148,908,274	136,196,512	144,337,459	135,975,586

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Net loss	$ (297,062)	$ (212,830)	$ (901,986)	$ (520,121)
Other comprehensive loss:				
Unrealized (losses) gains on investments, net	(10,796)	3,031	(23,647)	8,617
Foreign currency translation adjustments, net	3,360	(288)	7,078	(3,888)
Comprehensive loss	$ (304,498)	$ (210,087)	$ (918,555)	$ (515,392)

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance — December 31, 2025	131,058,858	$ 134	$ 4,838,736	$ (2,154,947)	$ 1,587	$ 2,685,510
Issuance of common stock in connection with employee incentive plans	606,123	—	9,032	—	—	9,032
Issuance of common stock in connection with follow-on public offering, net of commissions and offering expenses of $30,654	12,650,000	13	601,833	—	—	601,846
Taxes paid related to the net share settlement of equity awards	—	—	(9,295)	—	—	(9,295)
Stock-based compensation expense	—	—	37,964	—	—	37,964
Other comprehensive loss	—	—	—	—	(8,421)	(8,421)
Net loss	—	—	—	(320,622)	—	(320,622)
Balance — March 31, 2026	144,314,981	$ 147	$ 5,478,270	$ (2,475,569)	$ (6,834)	$ 2,996,014
Issuance of common stock in connection with employee incentive plans	470,953	1	7,760	—	—	7,761
Taxes paid related to the net share settlement of equity awards	—	—	(2,060)	—	—	(2,060)
Stock-based compensation expense	—	—	41,241	—	—	41,241
Other comprehensive loss	—	—	—	—	(712)	(712)
Net loss	—	—	—	(284,302)	—	(284,302)
Balance — June 30, 2026	144,785,934	$ 148	$ 5,525,211	$ (2,759,871)	$ (7,546)	$ 2,757,942
Issuance of common stock in connection with employee incentive plans	567,073	—	7,317	—	—	7,317
Issuance of common stock from underlying pre-funded warrants in connection with follow-on public offerings	3,946,020	4	(4)	—	—	—
Taxes paid related to the net share settlement of equity awards	—	—	(12,643)	—	—	(12,643)
Stock-based compensation expense	—	—	41,100	—	—	41,100
Other comprehensive loss	—	—	—	—	(7,436)	(7,436)
Net loss	—	—	—	(297,062)	—	(297,062)
Balance — September 30, 2026	149,299,027	$ 152	$ 5,560,981	$ (3,056,933)	$ (14,982)	$ 2,489,218

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance — December 31, 2024	124,893,034	$ 128	$ 4,697,883	$ (1,388,319)	$ (3,873)	$ 3,305,819
Issuance of common stock in connection with employee incentive plans	546,419	1	6,048	—	—	6,049
Issuance of common stock from underlying pre-funded warrants in connection with follow-on public offerings	3,499,959	3	(3)	—	—	—
Taxes paid related to the net share settlement of equity awards	—	—	(5,290)	—	—	(5,290)
Stock-based compensation expense	—	—	30,615	—	—	30,615
Other comprehensive gain	—	—	—	—	3,551	3,551
Net loss	—	—	—	(140,718)	—	(140,718)
Balance — March 31, 2025	128,939,412	$ 132	$ 4,729,253	$ (1,529,037)	$ (322)	$ 3,200,026
Issuance of common stock in connection with employee incentive plans	236,375	—	3,235	—	—	3,235
Issuance of common stock from underlying pre-funded warrants in connection with follow-on public offering	640,685	1	—	—	—	1
Taxes paid related to the net share settlement of equity awards	—	—	(717)	—	—	(717)
Stock-based compensation expense	—	—	36,927	—	—	36,927
Other comprehensive loss	—	—	—	—	(1,565)	(1,565)
Net loss	—	—	—	(166,573)	—	(166,573)
Balance — June 30, 2025	129,816,472	$ 133	$ 4,768,698	$ (1,695,610)	$ (1,887)	$ 3,071,334
Issuance of common stock in connection with employee incentive plans	212,639	—	306	—	—	306
Taxes paid related to the net share settlement of equity awards	—	—	(3,977)	—	—	(3,977)
Stock-based compensation expense	—	—	35,306	—	—	35,306
Other comprehensive gain	—	—	—	—	2,743	2,743
Net loss	—	—	—	(212,830)	—	(212,830)
Balance — September 30, 2025	130,029,111	$ 133	$ 4,800,333	$ (1,908,440)	$ 856	$ 2,892,882

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

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

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (901,986)	$ (520,121)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	11,727	8,899
Stock-based compensation expense	120,305	102,848
Amortization of operating lease right-of-use assets	8,153	6,161
Amortization of finance lease right-of-use assets	4,105	—
Net accretion of discounts on investments	(5,517)	(11,670)
Unrealized foreign exchange loss (gain)	18,955	(33,113)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	10,935	(7,251)
Operating lease right-of-use assets	—	(17,575)
Other assets	(87,023)	(28,347)
Operating lease liabilities	(3,524)	13,234
Accounts payable	(1,571)	(1,761)
Accrued compensation	(2,238)	(3,924)
Accrued contract manufacturing expenses	92,591	63,204
Accrued expenses	(2,089)	(1,329)
Net cash used in operating activities	(737,177)	(430,745)
Cash flows from investing activities:		
Purchases of property and equipment	(9,761)	(11,059)
Purchases of manufacturing facility build-out and equipment construction-in-progress	(14,568)	(37,493)
Purchases of investments	(1,089,123)	(918,850)
Maturities of investments	1,131,796	1,183,164
Sales of investments	66,736	106,467
Net cash provided by investing activities	85,080	322,229
Cash flows from financing activities:		
Proceeds from issuance of shares through employee equity incentive plans	24,110	9,590
Proceeds from issuance of common stock from follow-on offering, net of issuance costs	601,846	—
Taxes paid related to the net share settlement of equity awards	(23,998)	(9,984)
Net cash provided by (used in) financing activities	601,958	(394)
Effect of exchange rate changes on cash and cash equivalents	1,435	2,263
Net decrease in cash, cash equivalents and restricted cash	(48,704)	(106,647)
Cash, cash equivalents and restricted cash, beginning of period	175,425	389,195
Cash, cash equivalents and restricted cash, end of period	$ 126,721	$ 282,548
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 125,470	$ 281,080
Restricted cash	1,251	1,468
Cash, cash equivalents and restricted cash	$ 126,721	$ 282,548
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment recorded in accounts payable and accrued expenses	$ 2,065	$ 5,568
Right-of-use assets obtained in exchange for finance lease liabilities	$ 112,955	$ —

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

VAXCYTE, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

1. Company Organization and Nature of Business

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

Our primary activities since incorporation have been to perform research and development, undertake preclinical and clinical studies and conduct manufacturing activities in support of our product development and commercial readiness efforts; organize and staff our Company; establish our intellectual property portfolio; and raise capital to support and expand such activities.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

These 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 sheets as of September 30, 2026, the condensed consolidated statements of operations, comprehensive loss and stockholders' equity for the three and nine months ended September 30, 2026 and 2025 and the condensed consolidated statements of cash flows for the nine months ended September 30, 2026 and 2025 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 nine months ended September 30, 2026 and 2025 are also unaudited. The results of operations for the three and nine months ended September 30, 2026 are not necessarily indicative of the results to be expected for the year ending December 31, 2026 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, 2025 included in our Annual Report on Form 10-K filed with the SEC on February 24, 2026.

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 amounts reported in the condensed consolidated financial statements. On an ongoing basis, we evaluate our estimates and assumptions, including those related to stock-based compensation expense, accruals for certain research and development costs, the valuation of deferred tax assets and income taxes. Management bases our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from those estimates.

Summary of Significant Accounting Policies

There have been no material changes to our significant accounting policies as of and for the nine months ended September 30, 2026 from our Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

Property and Equipment, Net

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally three to 12 years. Leasehold improvements are amortized over the shorter of the expected life or lease term. Repairs and maintenance expenditures, which are not considered improvements and do not extend the useful life of property and equipment, are expensed as incurred. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the consolidated balance sheets and the resulting gain or loss is reflected in the consolidated statements of operations in the period realized.

Leases

We evaluate an arrangement at inception to determine whether an arrangement is a lease or contains an embedded lease in accordance with Accounting Standards Codification ("ASC") 842. An arrangement contains an embedded lease if it conveys the right to control the use of an identified asset for a period of time in exchange for consideration. 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. Lease agreements that include lease and non-lease components are accounted for as a single lease component. The lease term is the non-cancelable period of the lease and includes options to extend or terminate the lease when it is reasonably certain that an option will be exercised. Lease agreements with non-cancelable terms of less than 12 months are not recorded on our consolidated balance sheets.

Operating leases are included in Operating lease right-of-use ("ROU") assets, Operating lease liabilities — current and Operating lease liabilities — non-current in our consolidated balance sheets. Finance leases are included in Finance lease ROU assets, Finance lease liabilities — current and Finance lease liabilities — non-current in our consolidated balance sheets. ROU assets represent our right to use the underlying assets for the lease term, and lease liabilities represent our obligation to make lease payments arising from the leases. Lease ROU assets and liabilities for both operating leases and finance leases are recognized at the lease commencement date based on the present value of lease payments that are fixed or in substance fixed under ASC 842 over the lease term. In determining the present value of lease payments, if the rate implicit in the lease is not readily determinable, we use our incremental borrowing rate based on the information available at the lease commencement date. We determine the incremental borrowing rate based on an analysis of corporate bond yields with a credit rating similar to ours. The determination of our incremental borrowing rate requires management judgment, including development of a synthetic credit rating and cost of debt. We believe that the estimates used in determining the incremental borrowing rate are reasonable based upon current facts and circumstances. ROU assets also include adjustments for prepayments and accrued lease payments and exclude lease incentives. ROU assets and lease liabilities may include options to extend or terminate leases if it is reasonably certain that we will exercise such options. Variable lease costs, which are dependent on usage, a rate or index, including common area maintenance charges, are expensed as incurred. For operating leases, ROU assets are amortized as rent expense on a straight-line basis over the lease term. For finance leases, ROU assets are amortized on a straight-line basis over the shorter of the estimated useful life of the underlying asset or the lease term, and interest expense on the finance lease liability is recognized using the effective interest method over the lease term.

Recently Issued Accounting Standards Not Yet Adopted

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

evaluating the impact of this guidance on our financial statement disclosures, which we expect to be expanded beginning with our Annual Report on Form 10-K for the year ending December 31, 2027.

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

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

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

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

3. Fair Value Measurements and Fair Value of Financial Instruments

The following tables set forth our financial instruments measured at fair value on a recurring basis by level within the fair value hierarchy at September 30, 2026 and December 31, 2025:

		September 30, 2026			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Assets		(in thousands)			
Cash and cash equivalents:					
Cash	Level 1	$ 83,846	$ —	$ —	$ 83,846
Money market funds	Level 1	941	—	—	941
U.S. Treasury securities	Level 1	4,500	—	—	4,500
Commercial paper	Level 2	36,189	—	(6)	36,183
Total cash and cash equivalents		125,476	—	(6)	125,470
Investments:					
U.S. Treasury securities	Level 1	648,161	2	(3,166)	644,997
Commercial paper	Level 2	63,130	—	(38)	63,092
Corporate debt	Level 2	1,084,542	26	(10,651)	1,073,917
Asset-backed securities	Level 2	139,431	1	(1,898)	137,534
U.S. government agency securities	Level 2	182,050	—	(2,675)	179,375
Certificates of Deposit	Level 2	40,000	—	—	40,000
Total investments		2,157,314	29	(18,428)	2,138,915
Total assets measured at fair value		$ 2,282,790	$ 29	$ (18,434)	$ 2,264,385

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

We had no Level 3 securities either as of September 30, 2026 or December 31, 2025.

There were no transfers within the hierarchies during the nine months ended September 30, 2026.

As of September 30, 2026 and December 31, 2025, we had investments with a total fair market value of $2.1 billion and $0.3 billion, respectively, in an unrealized loss position, of which $304.2 million and $120.2 million, respectively, were in a continuous unrealized loss position for more than 12 months. As of September 30, 2026, the gross unrealized losses of securities that have been in a continuous unrealized loss position were $18.4 million, of which $17.6 million related to securities that have been in a continuous unrealized loss position for less than 12 months. As of December 31, 2025, the gross unrealized losses of securities that have been in a continuous unrealized loss position were not material.

Unrealized losses related to our investments are primarily due to interest rate fluctuations as opposed to credit quality. We do not intend to sell any of the securities in an unrealized loss position and it is not likely that we would be required to sell these securities before recovery of their amortized cost basis, which may be at maturity. We did not recognize any credit losses related to our investments during the three and nine months ended September 30, 2026 or 2025.

The following table presents the contractual maturities of our investments as of September 30, 2026 (in thousands):

		Fair Value
Due in less than one year	$	1,166,759
Due in one to five years		972,156
Total	$	2,138,915

4. Commercial Manufacturing and Supply Agreements

Lonza Ltd. ("Lonza")

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

Pursuant to the Lonza Commercial Manufacturing and Supply Agreement, Lonza constructed and built 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 we may choose (collectively, the "Products"). Lonza is a preferred, non-exclusive, supplier of the Products to us, and we retain the right to procure the Products from one or more alternate and/or backup manufacturers of the Products (including at our own facilities).

Under the Lonza Commercial Manufacturing and Supply Agreement, prior to completion of construction and certification of the Suite for commercial operation, we contributed to the capital expenditure costs to construct the Suite (and own certain equipment in the Suite that was purchased or otherwise acquired by us), and paid Lonza a fixed-rate monthly service fee for Lonza's pre-commercial services prior to commencement of commercial operations. Following completion of construction and certification of the Suite for commercial operation, the Suite was transferred to the Lonza operations team in August 2026, at which time the lease was deemed to have commenced. Lonza now maintains and operates the Suite, utilizing their employees, to manufacture the Products on our behalf, including conducting related quality control and quality assurance activities. We are now obligated to pay Lonza (i) Suite fees based on allocations of certain of Lonza's costs to maintain the facility in which the Suite is located and to provide shared services to us and Lonza's other customers in such facility, (ii) service fees based upon Lonza's actual full-time equivalent employee ("FTE") costs to operate the Suite to manufacture the Products, and (iii) equipment expenditures and certain other pass-through costs, including for raw materials. In addition, we may be obligated to pay or reimburse Lonza for certain other fees and expenses under the Lonza Commercial Manufacturing and Supply Agreement. Lonza is eligible for certain financial bonuses, and subject to certain financial penalties, as incentives for the timely completion of certain scale-up activities, receipt of certain regulatory approvals for the Suite and manufacture of the Products in accordance with our commercial requirements.

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

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

As of December 31, 2025, we had incurred $217.1 million of capital expenditures related to the Vaxcyte-owned facility buildout and equipment. In addition, as of December 31, 2025, we had incurred $118.3 million of facility buildout expenditures that are owned and controlled by Lonza, including the Repurposing Fee, and costs associated with certification of the Suite for commercial operation, which were accounted for as prepaid lease payments under ASC 842 Lease accounting.

See Note 5, "Balance Sheet Details," for further details related to Vaxcyte-owned facility buildout and equipment, and Note 6, "Leases," for further details related to facility buildout expenditures owned and controlled by Lonza, each as of September 30, 2026.

Thermo Fisher Scientific

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

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

5. Balance Sheet Details

Property and Equipment, Net

In August 2026, we placed into service $138.5 million of company-owned equipment and $63.1 million of leasehold improvements pertaining to the Suite pursuant to the Lonza Commercial Manufacturing and Supply Agreement.

Depreciation of the equipment is recognized on a straight-line method over the shorter of the estimated useful life or the term of the agreement.

Property and equipment, net as of September 30, 2026 and December 31, 2025 consisted of the following:

	September 30, 2026	December 31, 2025
	(in thousands)	
Lab and manufacturing equipment	$ 209,340	$ 62,546
Leasehold improvements	73,330	7,239
Manufacturing facility build-out and equipment construction-in-progress	10,672	217,077
Furniture and equipment	1,608	1,608
Computers, computer software and office equipment	2,600	1,670
Total property and equipment	297,550	290,140
Less: accumulated depreciation and amortization	(44,191)	(32,770)
Property and equipment, net	$ 253,359	$ 257,370

Depreciation and amortization expense was $5.8 million and $3.1 million for the three months ended September 30, 2026 and 2025, respectively, and $11.7 million and $8.9 million for the nine months ended September 30, 2026 and 2025, respectively.

Other Assets

Other assets as of September 30, 2026 and December 31, 2025 consisted of the following:

	September 30, 2026	December 31, 2025
	(in thousands)	
Other long-term assets	$ 3,248	$ 508
Manufacturing facility construction buildout	—	118,339
Total	$ 3,248	$ 118,847

6. Leases

Operating Lease

Office Facility

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

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

In November 2024, we amended and restated the Original Lease (the "Amended and Restated Lease") as a single, unified lease for our Headquarters Facility which includes the existing space under the Original Lease and the Assumed Lease Premises (collectively, the "Existing Premises") and expanded space covering additional floors (the "Additional Premises"), which resulted in a lease modification in accordance with ASC 842. The Amended and Restated Lease has an initial contractual term of 10 years, contains rent-free periods, scheduled rent increases, lease incentives and the option of two consecutive rights to extend the term for 60 months each. The effective date of the Amended and Restated Lease was

November 15, 2024 which, for the purposes of lease accounting, is the commencement date of the lease of the Existing Premises. The commencement dates of the Additional Premises occur when certain leasehold improvements and specifications are substantially complete, the first, second and third of which occurred in February 2025, November 2025 and December 2025, respectively. Our Amended and Restated Lease expires on February 28, 2035.

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

Finance Lease

Manufacturing Facility

We have concluded that the Lonza Commercial Manufacturing and Supply Agreement contains an embedded lease, which was deemed to have commenced following completion of construction and certification of the Suite for commercial operation and the transfer to the Lonza operations team in August 2026. Upon lease commencement, we evaluated the embedded lease against the classification criteria in ASC 842 and determined that it met at least one of the criteria for finance lease classification. Accordingly, we classified the embedded lease as a finance lease. As of September 30, 2026, we recorded finance lease ROU assets of $301.7 million and corresponding lease liabilities of $107.8 million on our condensed consolidated balance sheet. The ROU assets include (i) the initial measurement of the lease liabilities and (ii) amounts previously accounted for as prepaid lease payments prior to the lease commencement date, specifically facility buildout expenditures that are owned and controlled by Lonza, the Repurposing Fee and costs associated with certification of the Suite for commercial operation. The finance lease liabilities were measured at the present value of the remaining lease payments, discounted using our incremental borrowing rate.

See Note 4, “Commercial Manufacturing and Supply Agreements,” for further details related to the agreement.

The following tables present additional information for our operating and finance leases:

	September 30, 2026	December 31, 2025
Weighted-average remaining lease term (in years):		
Operating lease	8.42	9.11
Finance lease	12.25	—
Weighted-average discount rate:		
Operating lease	7.3 %	7.2 %
Finance lease	3.9 %	—

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)			
Cash paid for operating lease liabilities	$ 3,780	$ 3,130	$ 10,742	$ 9,331
Cash paid for finance lease liabilities	—	—	—	—

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)			
Operating lease costs	$ 4,792	$ 3,889	$ 15,684	$ 11,393
Finance lease costs:				
Amortization of right-of-use assets	4,105	—	4,105	—
Interest on lease liabilities	748	—	748	—
Total lease costs	$ 9,645	$ 3,889	$ 20,537	$ 11,393

Maturities of lease liabilities as of September 30, 2026 were as follows:

Years ending December 31,	Operating Lease	Finance Lease
	(in thousands)	
Remainder of 2026	$ 2,516	$ 3,715
2027	15,788	14,861
2028	17,339	14,861
2029	17,859	11,622
2030	18,395	11,622
Thereafter	82,805	74,530
Total future undiscounted lease payments	154,702	131,211
Less: Imputed interest	(40,645)	(23,433)
Total lease liabilities	$ 114,057	$ 107,778

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 September 30, 2026, we did not have any material indemnification claims that were probable or reasonably possible and consequently have not recorded related liabilities.

To the extent permitted under Delaware law, we have agreed to indemnify our directors and officers for certain events or occurrences while the director or officer is, or was, serving at our request in such capacity. The indemnification period covers all pertinent events and occurrences during the director’s or officer’s service. The maximum potential amount of future payments we could be required to make under these indemnification agreements is not specified in the agreements; however, we have directors and officers insurance coverage that reduces our exposure and enables us to recover a portion of any future amounts paid. We have not incurred any material costs as a result of such indemnification and are not currently aware of any indemnification claims.

Development and Manufacturing Services Agreements with Lonza

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

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

Under each of the 2022 Lonza DMSA and 2023 Lonza DMSA (collectively, the "Lonza Agreements"), we pay Lonza agreed-upon fees for their performance of development and manufacturing services and pass-through expenses incurred by Lonza for raw materials, as well as customary procurement and handling fees.

In February 2026, we entered into another non-exclusive development and manufacturing services agreement with Lonza effective as of January 1, 2026 (the "2026 Lonza DMSA"). Pursuant to the 2026 Lonza DMSA, Lonza will perform manufacturing process development and commercial manufacture and supply of certain key components for our propriety PCV franchise.

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

For additional information about the Lonza Agreements, see "*Certain Significant Relationships—Lonza*—Development and Manufacturing Services Agreements" included in Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Quarterly Report on Form 10-Q.

Commercial Manufacturing and Supply Agreements

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

Sutro Option Agreement

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

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

In November 2023 (the "Option Exercise Date"), we exercised the Option by submitting written notice thereof to Sutro Biopharma and concurrently paid Sutro Biopharma $50.0 million in cash as the first of two installment payments for the Option exercise price, followed by the second and final installment of $25.0 million in cash in May 2024. We determined there was no current alternative future use of the acquired manufacturing rights from the Option Agreement and, as a result, the amounts paid were expensed as incurred. Upon the occurrence of certain regulatory milestones, we agreed to pay Sutro Biopharma certain additional milestone payments totaling up to $60.0 million in cash. In the event that we undergo a change of control, certain rights and payments may be accelerated. No milestone payments were made during the three months ended September 30, 2026.

Manufacturing Rights Agreement with Sutro Biopharma

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

For additional information about the Manufacturing Rights Agreement, see "*Certain Significant Relationships—Sutro Biopharma*—Manufacturing Rights Agreement with Sutro Biopharma" included in Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Quarterly Report on Form 10-Q.

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 September 30, 2026, we had the following amounts of non-cancelable purchase commitments related to manufacturing services and raw materials purchased due to our key manufacturing partners. These amounts represent our minimum contractual obligations, including termination fees. If we terminate certain firm orders with key manufacturing partners, we will be required to pay for the manufacturing services scheduled or raw materials purchased under our arrangements. The actual amounts we pay in the future to our vendors under such agreements may differ from the purchase order amounts.

Years ending December 31,	**(in thousands)**
Remainder of 2026	$ 203,435
2027	231,149
2028	79,301
2029	10,500
Thereafter	—
Total non-cancelable purchase commitments due to our key manufacturing partners	$ 524,385

8. Stockholders' Equity

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 149,299,027 and 131,058,858 shares were issued and outstanding as of September 30, 2026 and December 31, 2025, 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 September 30, 2026 and 2025, no dividends have been declared.

ATM Program

In July 2021, we entered into an Open Market Sales Agreement℠ (the "Original ATM Sales Agreement") with Jefferies LLC ("Jefferies") to issue and sell, from time to time at our discretion, shares of our common stock at an aggregate offering price up to $150.0 million through Jefferies acting as our sales agent or principal. As of February 27, 2023, we had sold 4,995,709 shares of our common stock under the Original ATM Sales Agreement at a weighted average price of $27.57 per share for aggregate gross proceeds of $137.8 million. On February 27, 2023, we and Jefferies entered into an amendment to the Original ATM Sales Agreement (as amended, the "Amended ATM Sales Agreement") to offer and sell additional shares of our common stock with an aggregate offering price up to another $400.0 million, which was in addition to the $150.0 million aggregate offering price under the Original ATM Sales Agreement. Effective as of February 24, 2026, we

terminated the Amended ATM Sales Agreement. Prior to termination, we sold 4,211,367 shares of our common stock under the Amended ATM Sales Agreement at a weighted average price of $64.19 per share for aggregate gross proceeds of $270.3 million, or $264.2 million net of commissions and offering expenses. The gross proceeds of the shares sold net of commission and related offering expenses are reflected as an addition to common stock and additional paid-in capital on our condensed consolidated balance sheets.

On February 24, 2026, we entered into a Sales Agreement (the "2026 ATM Sales Agreement") with Leerink Partners LLC ("Leerink Partners"), to issue and sell, from time to time at our discretion, shares of our common stock at an aggregate offering price up to $500.0 million through Leerink Partners as our sales agent. As of September 30, 2026, we have not sold any shares of our common stock under the 2026 ATM Sales Agreement.

Underwritten Follow-on Public Offerings

From January 2022 through September 2024, we successfully completed a number of underwritten public offerings, which included pre-funded warrants to purchase a total of 10,458,434 shares of our common stock. 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. Each pre-funded warrant has an exercise price of $0.001 per share. 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.

During the three and nine months ended September 30, 2026, 3,946,094 shares underlying the pre-funded warrants were exercised to receive 3,946,020 shares of common stock, net of exercise costs. During the three months ended September 30, 2025, no shares underlying the pre-funded warrants were exercised. During the nine months ended September 30, 2025, 4,140,705 shares underlying the pre-funded warrants were exercised to receive 4,140,644 shares of common stock, net of exercise costs. As of September 30, 2026 and December 31, 2025, a total of 1,517,699 and 5,463,793 shares underlying pre-funded warrants were outstanding, respectively.

In February 2026, we completed an underwritten public offering of 12,650,000 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 1,650,000 shares, at a price of $50.00 per share. In aggregate, we received $601.8 million in net proceeds after deducting underwriting discounts, commissions and other offering expenses payable by us. We did not have any public offerings during the three and nine months ended September 30, 2025.

9. Equity Incentive Plans

Equity Incentive Plans

We currently grant stock options and restricted stock units (“RSUs”) under the 2020 Equity Incentive Plan (“2020 Plan”), which became effective in June 2020 and replaced our 2014 Equity Incentive Plan (“2014 Plan”).

Effective January 1, 2026, the number of shares of common stock available under the 2020 Plan increased by 6,552,942 shares pursuant to the evergreen provision of the 2020 Plan. As of September 30, 2026, an aggregate of 12,544,936 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 September 30, 2026, 725,859 shares and 14,700,405 shares of common stock were subject to outstanding options and RSUs under the 2014 Plan and 2020 Plan, respectively.

Stock Option Activity

Stock option activity under our 2020 Plan, including performance contingent stock options ("PCSOs"), and 2014 Plan, was as follows:

	Options Outstanding				PCSOs Outstanding			
	(in thousands, except share and per share data)							
	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balances — December 31, 2025	10,960,801	$ 43.64	7.16	$ 130,351	621,860	$ 102.70	8.85	$ —
Options granted	1,756,482	58.47			—			
Options exercised	(859,521)	24.68			—			
Options forfeited	(158,872)	69.96			(8,250)	$ 102.70		
Balances — September 30, 2026	11,698,890	$ 46.90	6.96	$ 183,887	613,610	$ 102.70	8.10	$ —
Vested and expected to vest — September 30, 2026	11,698,890	$ 46.90	6.96	$ 183,887	613,610	$ 102.70	8.10	$ —
Exercisable at September 30, 2026	7,572,260	$ 40.19	6.05	$ 159,624	—			$ —

During the three months ended September 30, 2026 and 2025, options to purchase 262,535 and 18,895 shares, respectively, were exercised for cash at a weighted-average price per share of $27.98 and $17.31, respectively. The intrinsic value of the stock options exercised was $8.1 million and $0.3 million for the three months ended September 30, 2026 and 2025, respectively. The weighted-average grant date fair value of options granted for the three months ended September 30, 2026 and 2025 was $35.80 and $18.17, respectively.

During the nine months ended September 30, 2026 and 2025, options to purchase 859,521 and 568,497 shares, respectively, were exercised for cash at a weighted-average price per share of $24.68 and $13.15, respectively. The intrinsic value of the stock options exercised was $26.9 million and $33.7 million for the nine months ended September 30, 2026 and 2025, respectively. The weighted-average grant date fair value of options granted for the nine months ended September 30, 2026 and 2025 was $34.94 and $32.60, respectively.

Stock Unit Award Activity

Stock unit award activity, including performance based stock units ("PSUs"), for the nine months ended September 30, 2026 was as follows:

	Unvested RSUs				Unvested PSUs			
	(in thousands, except share and per share data)							
	Number of Shares	Weighted-Average Grant-Date Fair Value Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value	Number of Shares	Weighted-Average Grant-Date Fair Value Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Unvested at December 31, 2025	2,340,589	$ 54.55	1.42	$ 107,995	175,513	$ 151.48	2.85	$ 8,098
Granted	1,765,735	58.74			—	—		
Vested and released	(1,056,803)	54.40			—	—		
Cancelled	(111,270)	56.97			—	—		
Unvested at September 30, 2026	2,938,251	$ 57.03	1.55	$ 167,186	175,513	$ 151.48	2.10	$ 9,987

The weighted-average grant date fair value of RSUs granted during the three months ended September 30, 2026 and 2025 was $60.34 and $31.17, respectively. The weighted-average grant date fair value of RSUs granted during the nine months ended September 30, 2026 and 2025 was $58.74 and $49.12, respectively. The aggregate intrinsic value of unvested RSUs is calculated using the closing price of our common stock on the grant date.

Shares Available for Grant

Shares available for grant under our 2020 Plan for the nine months ended September 30, 2026 were as follows:

	Number of Shares
Balance — December 31, 2025	8,821,691
Shares authorized	6,552,942
Options and RSUs granted	(3,522,217)
Shares forfeited	278,392
Shares withheld for taxes	414,128
Balance — September 30, 2026	12,544,936

2020 Employee Stock Purchase Plan

Effective January 1, 2026, the number of shares of common stock available under the 2020 Employee Stock Purchase Plan (the "2020 ESPP") increased by 1,310,588 shares pursuant to the evergreen provision of the 2020 ESPP. During the nine months ended September 30, 2026 and 2025, 112,315 shares and 83,221 shares were purchased, respectively, under the 2020 ESPP. As of September 30, 2026, there were 3,217,631 shares available under the 2020 ESPP.

Stock-based Compensation

The following assumptions were used in the Black-Scholes options pricing model for stock options granted in the respective period of:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Expected volatility	62.4% - 64.1%	63.7% - 65.2%	62.4% - 66.6%	63.7% - 67.5%
Expected term (in years)	5.5	5.3 - 5.4	5.4 - 5.5	5.2 - 5.4
Risk-free interest rate	4.3% - 5.0%	3.6% - 3.9%	3.6% - 5.0%	3.6% - 4.5%

We recorded total stock-based compensation expense for the three and nine months ended September 30, 2026 and 2025 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
Research and development	$ 24,074	$ 18,383	$ 66,897	$ 54,499
General and administrative	17,026	16,923	53,408	48,349
Total stock-based compensation expense	$ 41,100	$ 35,306	$ 120,305	$ 102,848

As of September 30, 2026, there was $335.6 million of unrecognized stock-based compensation expense related to unvested employee and non-employee awards, which is expected to be recognized over a weighted-average period of 2.60 years.

10. Funding Arrangements

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

Our vaccine development program for VAX-GI, a novel preclinical vaccine candidate being developed as a preventative treatment for dysentery and shigellosis, which is caused by Shigella bacteria, is currently funded in part by two grants obtained from the National Institutes of Health ("NIH") administered by the University of Maryland, Baltimore. Our first grant from the NIH was awarded in April 2021 and provides for potential funding up to five years totaling approximately $0.5 million. In June 2023, we received another grant from the NIH that provides for potential funding up to five years totaling approximately $4.6 million. As of September 30, 2026, we have received and expect to continue to receive funding under each of these grants.

We are currently working on a discovery program with the University of North Carolina at Chapel Hill and the University of Chicago to develop a vaccine candidate for the prevention of Chlamydia, which is funded in part by a grant from the National Institute of Allergy and Infectious Diseases that provides potential funding up to five years totaling approximately $9.5 million. As of September 30, 2026, we have received and expect to continue to receive funding under this grant.

Income from grants is recognized in the period during which the related specified expenses are incurred, provided that the conditions under which the grants were provided have been met. The amount of grant income was not material during the three and nine months ended September 30, 2026 and September 30, 2025. The grant receivable related to unreimbursed, eligible costs incurred under the agreements recorded within prepaid expenses and other current assets in the condensed consolidated balance sheets was not material as of September 30, 2026 and December 31, 2025.

11. Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net loss (in thousands)	$ (297,062)	$ (212,830)	$ (901,986)	$ (520,121)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted [1]	148,908,274	136,196,512	144,337,459	135,975,586
Net loss per share, basic and diluted	$ (1.99)	$ (1.56)	$ (6.25)	$ (3.83)

[1] Includes shares of common stock into which pre-funded warrants may be exercised as of September 30, 2026. See Note 8, "Stockholders' Equity."

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

	As of September 30,	
	2026	2025
Stock options	12,312,500	11,669,523
Restricted stock units	3,113,764	2,543,233
Employee stock purchase plan shares	274,918	345,588
Total potentially dilutive securities outstanding	15,701,182	14,558,344

12. 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 changes in our valuation allowance against our deferred tax assets. During the three and nine months ended September 30, 2026 and 2025, we incurred net pre-tax losses in the jurisdictions we operate in and had no income tax provisions. During the three and nine months ended September 30, 2026, 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. We do not have any tax audits or other issues pending that would have a material impact on our condensed consolidated financial statements.

13. Segment Reporting

We operate and manage our business as one reportable and operating segment. Our chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance based on consolidated net loss, as is reported in our condensed consolidated statements of operations.

Our long-lived assets are based in the United States and Switzerland. Long-lived assets are comprised of property and equipment. As of September 30, 2026 and December 31, 2025, property and equipment based in the United States was $43.4 million and $39.7 million, respectively. As of September 30, 2026 and December 31, 2025, property and equipment based in Switzerland was $210.0 million and $217.7 million, respectively.

The following table presents segment operating results for the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)			
Operating expenses:				
Research and development – external costs [1]	$ 209,027	$ 161,270	$ 674,302	$ 409,805
Research and development – internal costs [2]	61,299	48,663	176,654	142,441
General and administrative	37,948	32,447	105,943	97,146
Total operating expenses	$ 308,274	$ 242,380	$ 956,899	$ 649,392
Total other income, net	11,212	29,550	54,913	129,271
Net loss	$ 297,062	$ 212,830	$ 901,986	$ 520,121

(1) Research and development – external costs consist primarily of product and clinical development, research, facility, depreciation, professional and consulting services expenses attributed to the research and development departments.
(2) Research and development – internal costs consist of internal employee costs including stock-based compensation expenses.

14. Subsequent Events

In October 2026, we completed concurrent underwritten public offerings of 8,584,375 shares of common stock at a public offering price of $64.00 per share, pre-funded warrants to purchase 400,000 shares of common stock at a public offering price of $63.999 per pre-funded warrant and $575 million aggregate principal amount of 1.50% convertible senior notes due 2032. These offerings included the exercise in full by the underwriters of their option to purchase up to 1,171,875 additional shares of common stock at the public offering price per share and their option to purchase up to an additional $75 million aggregate principal amount of notes at the public offering price, solely to cover over-allotments, in each case less underwriting discounts and commissions. The aggregate net proceeds to us from these offerings were approximately $1.1 billion, after deducting underwriting discounts, commissions and other offering expenses payable by us. We are currently assessing the accounting effects of these public offerings on our consolidated financial statements.

On November 1, 2026, the lease of the final floor space of the Additional Premises commenced. We are currently assessing the accounting effects of the lease commencement on our consolidated financial statements.

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, 2025 filed with the Securities and Exchange Commission ("SEC") on February 24, 2026. This discussion and analysis contain forward-looking statements based upon our current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. You should carefully read the "Risk Factors" section of this Quarterly Report on Form 10-Q to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

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

Our pipeline includes:

- Pneumococcal conjugate vaccine (*"*PCV") candidates that we believe are among the broadest-spectrum PCV candidates currently in development, targeting the approximately $8.5 billion global pneumococcal vaccine market. Pneumococcal disease (*"*PD") is an infection caused by *Streptococcus pneumoniae* bacteria. It can result in invasive pneumococcal disease ("IPD"), including meningitis and bacteremia, and non-invasive PD, including pneumonia, otitis media and sinusitis. Our broad-spectrum, carrier-sparing PCV candidates, VAX-31, VAX-24 and VAX-XL, are designed to improve upon standard-of-care PCVs for both adults and children by covering the serotypes that are responsible for increasing portions of IPD in circulation and are associated with high case-fatality rates, antibiotic resistance and meningitis, while maintaining coverage of previously circulating strains that are currently contained through continued vaccination.

    - PCV Franchise Adult Indication:

        - VAX-31 is a 31-valent, broad-spectrum, carrier-sparing investigational PCV being developed for the prevention of IPD and pneumonia. VAX-31 is the broadest-spectrum PCV in the clinic, and has the potential to provide protection against both currently circulating and historically prevalent serotypes. VAX-31 was designed to increase coverage, in a single vaccine, to approximately 95% of IPD and approximately 88% of pneumococcal pneumonia circulating in adults in the United States aged 50 and older, with the potential to provide an incremental 13-36% broader coverage for IPD and an incremental 19-31% broader coverage for pneumococcal pneumonia over current standard-of-care adult PCVs.

            - In October 2026, we announced positive topline results from the pivotal adult Phase 3 trial of VAX-31 (*"*OPUS-1"). OPUS-1 is a randomized, double-blind, active-controlled Phase 3 trial which evaluated the safety, tolerability and immunogenicity of VAX-31 in healthy, pneumococcal-naïve U.S. adults (defined as having no known prior history of IPD or pneumococcal pneumonia, or receipt of any licensed or investigational pneumococcal vaccine) aged 50 years and older (n=3,572) through direct, head-to-head comparisons with both Prevnar 20® (*"*PCV20") and/or Capvaxive® (*"*PCV21"), the current standard-of-care PCVs, with a separate cohort of adults aged 18-49 years

(n=475). In this trial, VAX-31 met all prespecified primary endpoints across age groups studied compared to PCV20 and PCV21.

- VAX-31 met all prespecified co-primary immunogenicity endpoints in adults 50 and older:
  - All 28 VAX-31 serotypes shared with PCV20 and/or PCV21 met the prespecified noninferiority criteria (lower bound of the 95% confidence interval ("LBCI") >0.667) with the prespecified Hochberg multiplicity adjustment.
    - For the 11 serotypes shared by VAX-31, PCV20 and PCV21, VAX-31 met all 11 primary noninferiority assessments based on opsonophagocytic activity ("OPA") geometric mean ratios ("GMRs"). For each serotype, the prespecified analysis required noninferiority against one or both comparators, using an OPA GMR noninferiority criterion of LBCI >0.667 with the prespecified Hochberg multiplicity adjustment.
    - For the nine serotypes only in VAX-31 and PCV20, all nine met the prespecified OPA GMR noninferiority criterion (LBCI >0.667).
    - For the eight serotypes only in VAX-31 and PCV21, all eight met the prespecified OPA GMR noninferiority criterion (LBCI >0.667).
  - The three serotypes unique to VAX-31 and cross-reactive serotype 20B met the OPA GMR superiority criterion (LBCI >2.0) with prespecified Hochberg multiplicity adjustment.
- For the prespecified primary immunobridging endpoint, VAX-31 met the noninferiority criterion (LBCI >0.667) for all 32 serotype (31 vaccine serotypes plus cross-reactive serotype 20B) OPA GMR comparisons in adults aged 18-49 compared to adults aged 50-64.
- In the prespecified individual comparator analyses, VAX-31 met the noninferiority criterion (LBCI >0.667) for 20 of 20 serotypes shared with PCV20 and 17 of 19 shared with PCV21. Compared to PCV21, serotypes 3 and 12F missed the LBCI >0.667 noninferiority criterion, but did meet the historical LBCI >0.5 threshold; compared to PCV20, VAX-31 met the LBCI>0.667 noninferiority criterion.
- In the study, VAX-31 was well tolerated and demonstrated a safety profile similar to PCV20 and PCV21 at all ages studied.

- In January 2026, we announced the initiation of a Phase 3 descriptive study evaluating the safety, tolerability and immunogenicity of VAX-31 when administered either concomitantly with or one month following administration of a licensed seasonal influenza vaccine in healthy, pneumococcal-naïve adults aged 50 years and older ("OPUS-2"). In February 2026, we announced the initiation of a separate Phase 3 descriptive study evaluating the safety, tolerability and immunogenicity of VAX-31 in healthy U.S. adults aged 50 years or older who have previously received pneumococcal vaccination ("OPUS-3"). In March 2026, we announced we completed enrollment of the OPUS-2 trial and in May 2026, we announced we completed enrollment of the OPUS-3 trial. We expect to report safety, tolerability and immunogenicity data from the OPUS-2 and OPUS-3 studies in the first half of 2027. We are also planning for a

manufacturing consistency study (e.g., a lot-to-lot study) as the final Phase 3 study to enable the submission of the Biologics License Application ("BLA").

- The U.S. Food and Drug Administration ("FDA") has granted breakthrough therapy designation for VAX-31 in adults for the prevention of IPD and pneumonia caused by *Streptococcus pneumoniae*.

- In September 2024, prior to the initiation of our VAX-31 adult Phase 3 program, we announced positive topline results from a Phase 1/2 study of VAX-31 in adults. The VAX-31 Phase 1/2 clinical study was a randomized, observer-blind, active-controlled, dose-finding clinical study designed to evaluate the safety, tolerability and immunogenicity of a single injection of VAX-31 at three dose levels (Low, Middle and High) and compared to PCV20 in 1,015 healthy adults aged 50 and older.

    - VAX-31 was observed to be well tolerated and demonstrated a safety profile at all doses studied through the full six-month evaluation period similar to PCV20. VAX-31 showed robust OPA immune responses for all 31 serotypes at all doses studied. At the VAX-31 High Dose, average OPA immune responses were greater for 18 of 20 serotypes compared to PCV20 (GMR greater than 1.0), with seven of these serotypes achieving statistically higher immune responses compared to PCV20. For all 11 incremental serotypes unique to VAX-31, and not in PCV20, all three doses met the superiority criteria.

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

- PCV Franchise Pediatric Indication:

    - VAX-31 is a 31-valent, broad-spectrum, carrier-sparing investigational PCV also being developed for the prevention of IPD in children. VAX-31 is the broadest-spectrum PCV in the clinic designed to cover approximately 91% of IPD in U.S. children under five years of age and approximately 96% of otitis media due to *Streptococcus pneumoniae* in U.S. children five years of age or under.

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

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

        - In September 2025, we announced advancement of the VAX-31 infant Phase 2 randomized, dose-finding study to the third and final stage following modifications to the protocol to add a new dose arm to evaluate a VAX-31 Optimized Dose (majority of serotypes dosed at 4.4mcg and the balance dosed at 3.3mcg) and discontinue further

enrollment in the Low Dose arm. The Middle and High Dose arms continued as planned.

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

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

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

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

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

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

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

    - Post-dose 3, all VAX-24 doses met target precedent Phase 2 non-inferiority criteria on relative seroconversion rates (lower limit of the 95% confidence interval for the difference between the proportion of participants achieving the pre-defined seroconversion rate (IgG concentration ≥0.35 mcg/mL) is > -15% for each serotype) for the highest circulating serotypes, as defined by the percentage of IPD caused in individuals <5 years of age in the U.S. in 2023 based on the U.S. Center for Disease Control (“CDC”) active bacterial core (“ABC”) surveillance data, contained in VAX-24. The Low and Mid doses met the seroconversion rate criteria for 20 of 24 serotypes overall and the Mixed Dose met such criteria for 19 of 24 serotypes. The Mid and Mixed Doses met the target Phase 2 IgG GMR point estimate of >0.6 for 21 of 24 serotypes.

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

the Mid dose met this target for 18 of 24 serotypes. Post-dose 4, VAX-24 elicited robust memory responses across all doses for all serotypes.

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

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

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

- VAX-A1, a novel conjugate vaccine candidate designed to prevent disease caused by Group A Streptococcus (*Streptococcus pyogenes*) ("Group A Strep"). Group A Strep is pervasive globally and causes an estimated 800 million cases of illness annually, including pharyngitis, or strep throat, and certain severe invasive infections and sequelae. There is currently no vaccine against Group A Strep, which is one of the leading infectious disease-related causes of death and disability worldwide and a significant contributor to the prescription of antibiotics in children. We believe we have demonstrated preclinical proof of concept for VAX-A1, the data for which were published in December 2020. In June 2026, we initiated a Phase 1 adult study for VAX-A1, with the primary objective of assessing safety and tolerability, along with a secondary objective of evaluating initial immunogenicity data, to support potential further advancement. The study is advancing to Stage 2 following the completion of an independent Data Safety Monitoring Board ("DSMB") review of Stage 1 safety and tolerability data. We are completing plans to initiate Stage 2 including an updated study design that incorporates the DSMB's recommendations for sequential enrollment, beginning with the Low and Mid Dose cohorts. Enrollment of the High Dose cohort will be part of a new Stage 3 and will follow completion of the prespecified safety assessments and further DSMB review and approval. The study design has also been updated to add a third vaccination at the Low and Mid Dose levels, while the High Dose regimen remains two vaccinations. We expect to report topline data from this study in the second half of 2027.

- VAX-GI, a novel preclinical vaccine candidate being developed as a preventative treatment for dysentery and shigellosis, which is caused by Shigella bacteria. Shigella is a bacterial illness estimated to cause 80 million to 165 million cases of disease and 600,000 deaths annually, mostly among children. The central antigen in VAX-GI is IpaB, a well-appreciated antigen that other developers have been unable to produce in an amount sufficient to enable a commercial product. With our cell-free technology, we believe we can produce this antigen at substantially improved yields, allowing for commercial-scale production. VAX-GI is being developed in collaboration with the University of Maryland, Baltimore as well as with partial funding from two research grants awarded by the National Institutes of Health ("NIH"). As part of our continued focus on strategic capital deployment and in order to prioritize our resources towards our PCV franchise, we announced in August 2025 that we had paused the advancement, beyond preclinical development, of VAX-GI while remaining confident in its potential and preserving the option to advance the program in the future.

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

Since June 30, 2026, key developments affecting our business include the following:

- ***Reported Positive Topline Data from OPUS-1, the Pivotal Adult Phase 3 Trial of VAX-31:*** In October 2026, we announced positive results from the OPUS-1 trial. VAX-31 was well tolerated and demonstrated a safety profile similar to PCV20 and PCV21 across all ages studied. VAX-31 met all prespecified primary endpoints across age groups studied compared to PCV20 and/or PCV21. Importantly, VAX-31 met all prespecified co-primary immunogenicity endpoints in adults 50 and older:

    - All 28 serotypes shared with PCV20 and/or PCV21 met the prespecified noninferiority criteria of LBCI >0.667 with the prespecified Hochberg multiplicity adjustment.

        - For the 11 serotypes shared by VAX-31, PCV20 and PCV21, VAX-31 met all 11 primary noninferiority assessments based on OPA GMRs. For each serotype, the prespecified analysis required noninferiority against one or both comparators, using an OPA GMR noninferiority criterion of LBCI >0.667 with the prespecified Hochberg multiplicity adjustment.

- For the nine serotypes shared only with PCV20, all nine met the prespecified OPA GMR noninferiority criterion (LBCI >0.667).
- For the eight serotypes shared only with PCV21, all eight met the prespecified OPA GMR noninferiority criterion (LBCI >0.667).

- The three VAX-31 unique serotypes and cross-reactive serotype 20B met the OPA GMR superiority criterion (LBCI >2.0) with the prespecified Hochberg multiplicity adjustment.
- For the prespecified primary immunobridging endpoint, VAX-31 met the OPA GMR noninferiority criterion (LBCI >0.667) for all 32 serotype (31 vaccine serotypes plus cross-reactive serotype 20B) OPA GMR comparisons in adults aged 18-49 compared to adults aged 50-64.
- In the OPUS-1 prespecified individual comparator analyses, VAX-31 met the noninferiority criterion (LBCI >0.667) for 20 of 20 serotypes shared with PCV20 and 17 of 19 shared with PCV21. Compared to PCV21, serotypes 3 and 12F missed the LBCI >0.667 noninferiority criterion, but did meet the historical LBCI >0.5 threshold; compared to PCV20, VAX-31 met the LBCI>0.667 noninferiority criterion.

- ***Completed $1.15 Billion Public Offerings of Common Stock, Pre-Funded Warrants and Convertible Senior Notes, Including Full Exercise of Underwriters' Options to Purchase Additional Shares and Convertible Senior Notes:*** In October 2026, we completed concurrent underwritten public offerings that were initiated following the disclosure of the OPUS-1 trial results. The aggregate gross proceeds to us from these offerings were approximately $1.15 billion, before deducting underwriting discounts and commissions and other offering expenses payable by us.
- ***Appointed Chief Medical Officer and Chief Legal Officer:*** In September 2026, we announced the appointments of experienced industry leaders Luis Jodar, Ph.D. as Chief Medical Officer and David McAvoy, J.D. as Chief Legal Officer. Dr. Jodar has more than 30 years of experience in vaccine development and launch across industry, international health organizations and academia. He spent 17 years at Pfizer Inc., most recently as Senior Vice President and Chief Medical Officer for Vaccines and Infectious Diseases. Mr. McAvoy brings more than three decades of legal leadership in the biopharmaceutical industry, including serving as Executive Vice President and Chief Legal Officer of Teva Pharmaceutical Industries Ltd.

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, issuance of convertible senior notes and, prior to our initial public offering ("IPO") in June 2020, redeemable convertible preferred stock. We will continue to require additional capital to develop and commercialize our vaccine candidates and fund operations for the foreseeable future. Accordingly, until such time as we can generate significant revenue from sales of our vaccine candidates, if ever, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.

We have incurred net losses in each year since inception and expect to continue to incur net losses in the foreseeable future. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending in large part on the timing of our clinical trials and manufacturing activities, and our expenditures on other research and development activities. Our net loss was $297.1 million and $902.0 million for the three and nine months, respectively, ended September 30, 2026. As of September 30, 2026, we had an accumulated deficit of $3.1 billion and cash, cash equivalents and investments of $2.3 billion. We believe our cash, cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months from the filing date of this 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. We expect our expenses will continue to remain high in connection with our ongoing activities, as we:

- advance our vaccine candidates through preclinical studies and clinical trials;

- progress in the scale-up of our manufacturing capabilities, in particular to prepare for the potential commercial launches of VAX-31 in the adult population and VAX-31 or VAX-24 in the pediatric population;
- incur additional costs that may be required for secondary supply sources;
- require the manufacture of supplies for our clinical trials;
- conduct clinical trials, in particular VAX-31 and VAX-24;
- pursue regulatory approval of our vaccine candidates;
- establish additional manufacturing capacity to meet potential incremental supply requirements following the potential commercial launches of VAX-31 in the adult population and VAX-31 or VAX-24 in the pediatric population;
- hire additional personnel;
- scale medical affairs and commercial infrastructure to support anticipated product launches;
- expand our facilities to support our growing workforce and lab activities;
- acquire, discover, validate and develop additional vaccine candidates; and
- obtain, maintain, expand and protect our intellectual property portfolio.

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

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

Certain Significant Relationships

Lonza Ltd. ("Lonza")

Development and Manufacturing Services Agreements

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

In February 2023, we entered into another non-exclusive development and manufacturing services agreement with Lonza effective as of March 1, 2023 (the "2023 Lonza DMSA"). Pursuant to the 2023 Lonza DMSA, Lonza will perform manufacturing process development and the manufacture of components for our PCV candidates, including the polysaccharide antigens, our proprietary eCRM protein carrier and conjugated drug substances. Subject to the terms and conditions set forth in the 2023 Lonza DMSA, Lonza has granted to us a non-exclusive, worldwide, fully paid-up,

transferable license, including the right to grant sublicenses (subject to the prior written consent of Lonza), under the New General Application Intellectual Property, to use, sell and import the Product manufactured under the 2023 Lonza DMSA (but no other products). Unless earlier terminated, the 2023 Lonza DMSA shall remain in place for a period of five years and shall automatically renew for one additional two-year period unless either party provides written notice of non-renewal at least two years prior to the fifth anniversary of the effective date. We may terminate the 2023 Lonza DMSA for any reason on prior written notice to the other party on a Project Plan-by-Project Plan basis. Either party may terminate the 2023 Lonza DMSA (i) within a given time period upon any material breach that is left uncured by the other party, (ii) immediately if the other party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, or files or has filed against it, a petition in bankruptcy or has a receiver appointed for a substantial part of its assets, (iii) upon an extended force majeure event, or (iv) if it becomes apparent to either party at any stage in the provision of the Services that it will be impossible to complete the Services for scientific or technical reasons despite exercise of best commercial efforts by both parties. Pursuant to the reason for termination and the party initiating the termination, we will pay Lonza for some combination of services rendered, costs incurred, unreimbursed capital equipment and/or any cancellation fees. Upon an extended force majeure event, neither party shall have any further liability to the other party (each term as defined in the 2023 Lonza DMSA).

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

Commercial Manufacturing and Supply Agreement

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

Pursuant to the Lonza Commercial Manufacturing and Supply Agreement, Lonza constructed and built out a dedicated suite (the "Suite") at Lonza's facilities in Visp, Switzerland to manufacture certain key components (including drug substance) for our proprietary PCV franchise and any other products or intermediates we may choose (collectively, the "Products"). Lonza is a preferred, non-exclusive, supplier of the Products to us, and we retain the right to procure the Products from one or more alternate and/or backup manufacturers of the Products (including at our own facilities).

Under the Lonza Commercial Manufacturing and Supply Agreement, prior to completion of construction and certification of the Suite for commercial operation, we contributed to the capital expenditure costs to construct the Suite (and own certain equipment in the Suite that was purchased or otherwise acquired by us), and paid Lonza a fixed-rate monthly service fee for Lonza's pre-commercial services prior to commencement of commercial operations. Following completion of construction and certification of the Suite for commercial operation, the Suite was transferred to the Lonza operations team in August 2026, at which time the lease was deemed to have commenced. Lonza now maintains and operates the Suite, utilizing their employees, to manufacture the Products on our behalf, including conducting related quality control and quality assurance activities. We are now obligated to pay Lonza (i) Suite fees based on allocations of certain of Lonza's costs to maintain the facility in which the Suite is located and to provide shared services to us and Lonza's other customers in such facility, (ii) service fees based upon Lonza's actual full-time equivalent employee ("FTE") costs to operate the Suite to manufacture the Products, and (iii) equipment expenditures and certain other pass-through costs, including for raw materials. In addition, we may be obligated to pay or reimburse Lonza for certain other fees and expenses under the Lonza Commercial Manufacturing and Supply Agreement. Lonza is eligible for certain financial bonuses, and subject to certain financial penalties, as incentives for the timely completion of certain scale-up activities, receipt of certain regulatory approvals for the Suite and manufacture of the Products in accordance with our commercial requirements.

Unless earlier terminated, the Lonza Commercial Manufacturing and Supply Agreement will remain in effect until December 31, 2038, subject to automatic renewal for up to three additional renewal periods of five years each, unless we elect not to renew (with 24 months advanced notice to Lonza). We are permitted to terminate the Lonza Commercial Manufacturing and Supply Agreement for convenience or for Lonza's uncured material breach, in each case subject to certain notice obligations. Lonza is permitted to terminate the Lonza Commercial Manufacturing and Supply Agreement in the event that we commit certain specified material breaches, including uncured failure to pay material and undisputed amounts of money due to Lonza, subject to certain notice obligations. Either party may terminate the Commercial Manufacturing and Supply Agreement in certain circumstances in the event of the other party's bankruptcy. In the event that we terminate the agreement for convenience, or Lonza terminates the agreement in the event that we commit certain specified material breaches, then certain termination consequences may be triggered, including that (i) we would forfeit any outstanding entitlement to credit from Lonza of the Repurposing Fee (as defined below), and (ii) we would be obligated to

pay Lonza a termination penalty equal to the greater of (a) CHF 70.0 million or (b) a prespecified number of months' FTE fees for the actual FTEs assigned to us as of the date of termination. Within 30 days of the Effective Date, we paid Lonza a repurposing fee (the "Repurposing Fee") of CHF 27.0 million that will be credited back to us over a 10-year period starting upon commencement of commercial production. In the event of a termination under certain circumstances, Lonza shall be obligated to provide certain wind-down and transition services to us for up to 12 months and 24 months, respectively.

2026 Development and Manufacturing Services Agreement

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

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

Sutro Biopharma

Amended and Restated License Agreement

We are party to an amended and restated license agreement with Sutro Biopharma, dated October 12, 2015, which was subsequently amended on May 9, 2018, May 29, 2018, September 28, 2023 and November 21, 2023 (as amended, the "Sutro Biopharma License Agreement"). Under the Sutro Biopharma License Agreement, we received an exclusive, worldwide, royalty-bearing, sublicensable license under Sutro Biopharma's patents and know-how relating to cell-free expression of proteins to (i) research, develop, use, sell, offer for sale, export, import and otherwise exploit specified vaccine compositions, such rights being sublicensable, for the treatment or prophylaxis of infectious diseases, excluding cancer vaccines, and (ii) manufacture, or have manufactured by an approved contract manufacturing organization, such vaccine compositions from extracts supplied by Sutro Biopharma pursuant to the Sutro Biopharma Supply Agreement (as described below). We are obligated to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize the vaccine compositions. In consideration of the rights granted under the Sutro Biopharma License Agreement, we are obligated to pay Sutro Biopharma a 4% royalty on worldwide aggregate annual net sales of our vaccine products for human health and a 2% royalty on such net sales of vaccine products for animal health. Such royalty rates are subject to specified reductions, including standard reductions for third-party payments and for expiration of relevant patent claims. We are also obligated to pay Sutro Biopharma any royalties due to Stanford University (the upstream licensor of Sutro Biopharma), to the extent the royalties payable by Sutro Biopharma to Stanford University are greater than the royalties payable by us to Sutro Biopharma. Royalties are payable on a vaccine composition-by-vaccine composition and country-by-country basis until the later of expiration of the last valid claim in the licensed patents covering such vaccine composition in such country and 10 years after the first commercial sale of such vaccine composition. The latest expiration date of a licensed Sutro Biopharma patent application, if issued, would be 2036, subject to any adjustment or extension of patent term that may be available in a particular country. In addition, we are obligated to pay Sutro Biopharma a percentage of net sublicensing revenue received in the low teen percentages. In addition, in the event we sublicense our non-manufacturing rights under the Sutro Biopharma License Agreement before a specified date, we are obligated to pay Sutro Biopharma a percentage, in the low double-digits, of the sublicensing revenue we receive under such agreement.

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

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

Supply Agreement

In May 2018, we entered into a supply agreement with Sutro Biopharma, which was subsequently amended on February 22, 2021 and November 21, 2023 (as amended, the "Sutro Biopharma Supply Agreement") pursuant to which we purchase from Sutro Biopharma extract and custom reagents for use in manufacturing non-clinical and certain clinical supply of vaccine compositions utilizing the technology licensed under the Sutro Biopharma License at prices not to exceed a specified percentage above Sutro Biopharma's fully burdened manufacturing cost. If any extracts or custom reagents do not meet the specifications and warranties provided, then we will not have an obligation to pay for the non-conforming product, and Sutro Biopharma will be obligated to replace the non-conforming product within the shortest possible time with conforming product at our cost. The term of the Sutro Biopharma Supply Agreement is from execution until the later of (i) July 31, 2022, or (ii) the date that we and Sutro Biopharma enter into the Phase 3/Commercial Supply Agreement and Sutro Biopharma is supplying to us each Product under the Phase 3/Commercial Supply Agreement (each term as defined in the Sutro Biopharma Supply Agreement). The Sutro Biopharma Supply Agreement may be terminated by either party for the other party's material breach uncured within 60 days' notice, by us at will with 60 days' notice, or by mutual agreement of the parties. In December 2019, we exercised our right to require Sutro Biopharma to establish a second supplier for extract and custom reagents to support our anticipated clinical and commercial needs.

Option Agreement

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

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

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

Manufacturing Rights Agreement

Concurrent with the payment of the first installment of the Option exercise price pursuant to the Option Agreement, on November 21, 2023, the manufacturing rights agreement (in the form of the Form Definitive Agreement) between us and Sutro Biopharma (the "Manufacturing Rights Agreement") became effective. Under the Manufacturing Rights Agreement, we received an exclusive (except as to Sutro Biopharma), perpetual (subject to termination), worldwide license, for no additional royalty (i.e., royalty-free, other than any royalties due under the Sutro Biopharma License Agreement), under Sutro Biopharma's relevant patents and know-how, to manufacture or have manufactured extract and improvements to

extract (in any form) solely for use in the research, development, use, production, sale, offering for sale, export, import, commercialization or other exploitation of Vaccine Compositions (as defined in the Sutro Biopharma License Agreement) as well as certain rights with respect to certain regulatory matters related to extract and its use in connection with such Vaccine Compositions. We have the right to extend our rights and obligations under the Manufacturing Rights Agreement to our affiliates and to sublicense our rights to manufacture extract and improvements to extract to certain third-party CMOs and other contractors (for our benefit and not for such third party's independent commercial use). For clarity, we are not permitted to manufacture extract for sale to third parties for the independent use of such third parties. Under the Manufacturing Rights Agreement, we have the obligation to protect the confidentiality of the extract manufacturing technology, and Sutro Biopharma has certain audit rights in connection therewith.

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

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

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

Thermo Fisher Scientific

Commercial Manufacturing and Supply Agreement

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

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

Impact of Certain Trends and Macroeconomic Environment

We operate in an industry that is subject to significant government regulation. Our operations are subject to significant risk and uncertainties, including financial, operational, technological, regulatory and political risks. Such factors include, but are not necessarily limited to, the results of clinical testing and trial activities; our ability to adequately demonstrate sufficient safety, tolerability and immunogenicity or efficacy of our vaccine candidates; our ability to enroll subjects in our ongoing and future clinical trials; our ability to successfully manufacture and supply our vaccine candidates for clinical trials or for future potential commercialization; our ability to obtain additional capital to finance our operations; our ability to obtain, maintain and protect our intellectual property rights; developments relating to our competitors and our industry, including competing vaccine candidates; the ability to obtain regulatory approval; the necessary requirements for regulatory approval; the ability to obtain favorable licensing, manufacturing or other agreements; the political and regulatory environment; general and market conditions; and other risks and uncertainties, including those more fully described in the "Risk Factors" section of this Quarterly Report on Form 10-Q.

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

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

Components of Results of Operations

Operating Expenses

Research and Development

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

Our PCV programs include VAX-31, VAX-24 and VAX-XL, and our non-PCV programs include VAX-A1, VAX-GI, and other discovery-stage programs. In August 2025, we announced that we paused the advancement, beyond preclinical development, of VAX-A1 and VAX-GI while remaining confident in their potential and preserving the option to advance the programs in the future. In June 2026, we initiated a Phase 1 adult study for VAX-A1. The majority of our external costs relate to our PCV programs compared to the costs related to non-PCV programs. Most of the external costs associated with our vaccine candidates, particularly our PCV programs, are common in nature, and can be deployed across multiple candidates or redeployed as our vaccine development strategy evolves; as a result, we do not track external costs by candidate, program or project. We do not allocate internal personnel-related costs by program or project because several of our departments support multiple vaccine candidate programs and the hours are not tracked separately by program.

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

Research and development expenses 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 expect our research and development expenses to remain high in absolute dollars for the foreseeable future as we advance our vaccine candidates into and through preclinical studies and clinical trials, manufacture drug product for our clinical trials and to support the potential initial commercial launch of VAX-31 in the adult population, scale up our manufacturing activities, establish additional manufacturing capacity to meet potential incremental supply requirements following the potential commercial launches of VAX-31 in the adult population and VAX-31 or VAX-24 in the pediatric population, pursue regulatory approval of our vaccine candidates and expand our pipeline of vaccine candidates. The process of conducting the necessary preclinical and clinical research and completing the manufacturing requirements to obtain regulatory approval is costly and time-consuming. The actual probability of success for our vaccine candidates may be affected by a variety of factors, including the safety and efficacy or immunogenicity of our vaccine candidates, clinical data, investment in our clinical programs, competition, manufacturing capabilities and commercial viability. We may never succeed in achieving regulatory approval for any of our vaccine candidates. As a result of the uncertainties discussed

above, we are unable to determine the duration and completion costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of our vaccine candidates.

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

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

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

- the costs and timing of our CMC activities, including fulfilling good manufacturing practice (“GMP”) related standards and compliance, and identifying and qualifying second suppliers;
- the costs related to raw materials we purchase directly or through our third-party manufacturing and supply partners;
- the cost of clinical trials of our vaccine candidates;
- changes in the standard-of-care on which a clinical development plan was based, which may require new or additional trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- delays in adding a sufficient number of trial sites and recruiting suitable volunteers to participate in our clinical trials;
- the number of subjects that participate in the trials;
- the number of doses that subjects receive;
- subjects dropping out of a study or lost in follow-up;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the cost and timing of manufacturing our vaccine candidates;
- the phase of development of our vaccine candidates;
- the costs of establishing additional manufacturing capacity to meet potential incremental supply requirements following the potential commercial launches of VAX-31 in the adult population and VAX-31 or VAX-24 in the pediatric population;
- the costs that may be required for secondary supply sources; and
- the immunogenicity or efficacy and safety and tolerability profile of our vaccine candidates.

General and Administrative

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

Other Income (Expense), Net

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

Interest Income

Interest income is earned from our cash and cash equivalents balances and short- and long-term investments. The cost of investment securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in other income, net. Realized gains and losses are also included in other income, net. When the fair value of a debt security declines below its amortized cost basis, any portion of that decline attributable to credit losses, to the extent expected to be nonrecoverable before the sale of the security, is recognized in our 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.

Grant Income

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

Our vaccine development program for VAX-GI, a novel preclinical vaccine candidate being developed as a preventative treatment for dysentery and shigellosis, which is caused by Shigella bacteria, is currently funded in part by two grants obtained from the NIH administered by the University of Maryland, Baltimore. Our first grant from the NIH was awarded in April 2021 and provides for potential funding up to five years totaling approximately $0.5 million. In June 2023, we received another grant from the NIH that provides for potential funding up to five years totaling approximately $4.6 million. As of September 30, 2026, we have received and expect to continue to receive funding under each of these grants.

We are currently working on a discovery program with the University of North Carolina at Chapel Hill and the University of Chicago to develop a vaccine candidate for the prevention of Chlamydia, which is funded in part by a grant from the National Institute of Allergy and Infectious Diseases that provides potential funding up to five years totaling approximately $9.5 million. As of September 30, 2026, we have received and expect to continue to receive funding under this grant.

Income from grants is recognized in the period during which the related specified expenses are incurred, provided that the conditions under which the grants were provided have been met. The amount of grant income was not material during the three and nine months ended September 30, 2026 and September 30, 2025. Grant income is included as a component of Other income, net in the condensed consolidated statements of operations.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2026 and 2025

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2026	2025	$	%	2026	2025	$	%
	(in thousands)				(in thousands)			
Operating expenses:								
Research and development	$ 270,326	$ 209,933	$ 60,393	28.8 %	$ 850,956	$ 552,246	$ 298,710	54.1 %
General and administrative	37,948	32,447	5,501	17.0 %	105,943	97,146	8,797	9.1 %
Total operating expenses	308,274	242,380	65,894	27.2 %	956,899	649,392	307,507	47.4 %
Loss from operations	(308,274)	(242,380)	(65,894)	27.2 %	(956,899)	(649,392)	(307,507)	47.4 %
Other income, net:								
Interest income	23,189	29,259	(6,070)	(20.7)%	75,554	93,267	(17,713)	(19.0)%
Other (expense) income	(11,977)	291	(12,268)	*	(20,641)	36,004	(56,645)	(157.3)%
Total other income, net	11,212	29,550	(18,338)	(62.1)%	54,913	129,271	(74,358)	(57.5)%
Net loss	$ (297,062)	$ (212,830)	$ (84,232)	39.6 %	$ (901,986)	$ (520,121)	$ (381,865)	73.4 %

** not meaningful*

Operating Expenses

Research and Development Expenses

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2026	2025	$	%	2026	2025	$	%
	(in thousands)				(in thousands)			
External costs:								
Product manufacturing costs	$ 130,858	$ 110,656	$ 20,202	18.3 %	$ 405,942	$ 258,785	$ 147,157	56.9 %
Clinical trials-related expenses	38,378	19,664	18,714	95.2 %	143,372	54,179	89,193	164.6 %
Research expenses	20,980	16,136	4,844	30.0 %	73,657	52,677	20,980	39.8 %
Facility and other allocated costs	12,628	11,007	1,621	14.7 %	35,109	32,829	2,280	6.9 %
Other external costs	6,183	3,807	2,376	62.4 %	16,222	11,335	4,887	43.1 %
Total external costs	209,027	161,270	47,757	29.6 %	674,302	409,805	264,497	64.5 %
Internal costs:								
Personnel-related expenses	61,299	48,663	12,636	26.0 %	176,654	142,441	34,213	24.0 %
Total research and development expenses	$ 270,326	$ 209,933	$ 60,393	28.8 %	$ 850,956	$ 552,246	$ 298,710	54.1 %

Research and development expenses increased by $60.4 million, or 28.8%, during the three months ended September 30, 2026, compared to the corresponding period in 2025. The increase was largely driven by external costs, which grew by $47.8 million primarily due to increased activities related to clinical trials and product manufacturing in connection with our PCV programs. Product manufacturing costs increased by $20.2 million primarily driven by increased manufacturing activities to support potential future commercial launches. Clinical trials-related expenses increased by $18.7 million primarily due to the activities associated with the VAX-31 OPUS-1, OPUS-2 and OPUS-3 Phase 3 studies. Research expenses increased by $4.8 million driven by research and assay services, and other external costs increased by $2.4 million. The increase was further driven by internal personnel-related costs, which grew by $12.6 million, primarily due to headcount growth to support our research and development efforts.

Research and development expenses increased by $298.7 million, or 54.1%, during the nine months ended September 30, 2026 compared to the corresponding period in 2025. The increase was largely driven by external costs, which grew by $264.5 million primarily due to increased activities related to product manufacturing and clinical trials in connection with our PCV programs. Product manufacturing costs increased by $147.2 million due to an increase in manufacturing activities in preparation for potential future commercial launches. Clinical trials-related expenses increased by $89.2 million primarily due to the initiation of and enrollment in the VAX-31 OPUS-1, OPUS-2 and OPUS-3 Phase 3 studies. Research expenses increased by $21.0 million, primarily due to higher contracted research services utilized and increased expensed lab equipment costs, reflecting the expansion of research activities. Other external costs increased by $4.9 million, primarily driven by a $1.9 million increase in consulting and contractor services utilized and a $2.6 million increase in

shipment costs associated with our expanded PCV programs. The increase was further driven by internal personnel-related costs, which grew by $34.2 million largely due to headcount growth to support our research and development efforts.

General and Administrative Expenses

General and administrative expenses increased by $5.5 million, or 17.0%, during the three months ended September 30, 2026 compared to the corresponding period in 2025, which was driven primarily by a $3.3 million increase in internal personnel-related costs due to headcount growth and a $2.2 million increase in professional and consulting services.

General and administrative expenses increased by $8.8 million, or 9.1%, during the nine months ended September 30, 2026 compared to the corresponding period in 2025 due primarily to an increase in internal personnel-related costs due to headcount growth.

Other Income, Net

Other income, net decreased by $18.3 million, or 62.1%, during the three months ended September 30, 2026 compared to the corresponding period in 2025. The decrease was primarily attributable to a $12.0 million reduction in unrealized and realized foreign currency gains due to fluctuations in foreign currency exchange rates and a $6.1 million decrease in interest income, due to lower average investment balances and lower interest rates.

Other income, net decreased by $74.4 million, or 57.5%, during the nine months ended September 30, 2026 compared to the corresponding period in 2025. The decrease was primarily attributable to a $57.7 million reduction in unrealized and realized foreign currency gains due to fluctuations in foreign currency exchange rates and a $17.7 million decrease in interest income due to lower average investment balances and lower interest rates.

Liquidity and Capital Resources

From inception through September 30, 2026, 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 $5.3 billion in aggregate gross proceeds and $5.1 billion net of underwriting discounts, commissions and offering expenses. As of September 30, 2026, we had $0.1 billion in cash and cash equivalents, $2.1 billion in investments and an accumulated deficit of $3.1 billion.

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

ATM Program

In July 2021, we entered into an Open Market Sales Agreement℠ (the “Original ATM Sales Agreement”) with Jefferies LLC (“Jefferies”), which provided that, upon the terms and subject to the conditions and limitations set forth in the Original ATM Sales Agreement, we had the right to issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $150.0 million through Jefferies acting as our sales agent or principal. As of February 27, 2023, we had sold 4,995,709 shares of our common stock under the Original ATM Sales Agreement at a weighted average price of $27.57 per share for aggregate gross proceeds of $137.8 million. On February 27, 2023, we and Jefferies entered into an amendment to the Original ATM Sales Agreement (as amended, the “Amended ATM Sales Agreement”) pursuant to which we had the right to issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $400.0 million. Effective as of February 24, 2026, we terminated the Amended ATM Sales Agreement. Prior to termination, we sold 4,211,367 shares of our common stock under the Amended ATM Sales Agreement at a weighted average price of $64.19 per share for aggregate gross proceeds of $270.3 million ($264.2 million net of commissions and offering expenses).

On February 24, 2026, we entered into a Sales Agreement (the "2026 ATM Sales Agreement") with Leerink Partners LLC ("Leerink Partners"), to issue and sell, from time to time at our discretion, shares of our common stock at an aggregate offering price up to $500.0 million through Leerink Partners as our sales agent. We will pay Leerink Partners a commission

of up to 3.0% of the gross sales proceeds of any common stock sold through Leerink Partners under the 2026 ATM Sales Agreement; however, we are not obligated to make any sales of common stock. As of September 30, 2026, we have not sold any shares of our common stock under the 2026 ATM Sales Agreement.

Underwritten Follow-on Public Offerings

From January 2022 through September 2024, we successfully completed a number of underwritten public offerings, which included pre-funded warrants to purchase a total of 10,458,434 shares of our common stock. 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. Each pre-funded warrant has an exercise price of $0.001 per share. 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.

During the three and nine months ended September 30, 2026, 3,946,094 shares underlying the pre-funded warrants were exercised to receive 3,946,020 shares of common stock, net of exercise costs. During the three months ended September 30, 2025, no shares underlying the pre-funded warrants were exercised. During the nine months ended September 30, 2025, 4,140,705 shares underlying the pre-funded warrants were exercised, to receive 4,140,644 shares of common stock, net of exercise costs. As of September 30, 2026 and December 31, 2025, a total of 1,517,699 and 5,463,793 shares underlying pre-funded warrants were outstanding, respectively.

In February 2026, we completed an underwritten public offering of 12,650,000 shares of our common stock, which included the full exercise of the underwriters' option to purchase an additional 1,650,000 shares, at a price of $50.00 per share. In aggregate, we received $601.8 million in net proceeds after deducting underwriting discounts, commissions and other offering expenses payable by us. We did not have any public offerings during the three and nine months ended September 30, 2025.

In October 2026, we completed concurrent underwritten public offerings of 8,584,375 shares of common stock at a public offering price of $64.00 per share, pre-funded warrants to purchase 400,000 shares of common stock at a public offering price of $63.999 per pre-funded warrant and $575 million aggregate principal amount of 1.50% convertible senior notes due 2032 (the "2032 Notes"). These offerings included the exercise in full by the underwriters of their option to purchase up to 1,171,875 additional shares of common stock at the public offering price per share and their option to purchase up to an additional $75 million aggregate principal amount of 2032 Notes at the public offering price, solely to cover over-allotments, in each case less underwriting discounts and commissions. The aggregate net proceeds to us from these offerings were approximately $1.1 billion, after deducting underwriting discounts and commissions and other offering expenses payable by us.

The exercise price of each pre-funded warrant equals $0.001 per share and each pre-funded warrant is exercisable from the date of issuance until fully exercised, subject to an ownership limitation.

The 2032 Notes were issued pursuant to, and are governed by, an indenture (the "Base Indenture"), dated as of October 9, 2026, between us and U.S. Bank Trust Company, National Association, as trustee (the "Trustee"), as supplemented by a First Supplemental Indenture (the "Supplemental Indenture," and the Base Indenture, as supplemented by the Supplemental Indenture, the "Indenture"), dated as of October 9, 2026, between us and the Trustee.

The 2032 Notes are senior, unsecured obligations and will accrue interest at a rate of 1.50% per annum, payable semi-annually in arrears on April 15 and October 15 of each year, beginning on April 15, 2027. The 2032 Notes will mature on October 15, 2032 unless earlier repurchased, redeemed or converted. Before July 15, 2032, noteholders will have the right to convert their 2032 Notes only upon the occurrence of certain events. From and after July 15, 2032, noteholders may

convert their 2032 Notes at any time at their election until the close of business on the second scheduled trading day immediately before the maturity date. We will settle conversions by paying or delivering, as applicable, cash, shares of our common stock or a combination of cash and shares of common stock, at our election. The initial conversion rate is 11.1607 shares of common stock per $1,000 principal amount of 2032 Notes, which represents an initial conversion price of approximately $89.60 per share of common stock. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. In addition, if certain corporate events that constitute a "Make-Whole Fundamental Change" (as defined in the Indenture) occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

The 2032 Notes will be redeemable (a "provisional redemption"), in whole or in part (subject to certain limitations described below), at our option at any time, and from time to time, on or after October 22, 2029 and on or before the 20th scheduled trading day immediately before the maturity date, at a cash redemption price equal to the principal amount of the 2032 Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, but only if the last reported sale price per share of common stock exceeds 130% of the conversion price on (x) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date we send the related redemption notice; and (y) the trading day immediately before the date we send such notice. However, we may not redeem less than all of the outstanding 2032 Notes pursuant to a provisional redemption unless at least $75.0 million aggregate principal amount of 2032 Notes are outstanding and not called for redemption as of the time we send the related redemption notice. In addition, calling any 2032 Note for provisional redemption will constitute a Make-Whole Fundamental Change with respect to that 2032 Note, in which case the conversion rate applicable to the conversion of that 2032 Note will be increased in certain circumstances if it is converted after it is called for provisional redemption.

In addition, we will also have the right to redeem (a "cleanup redemption") all, but not less than all, of the 2032 Notes, at any time, at a cash redemption price equal to the principal amount of the 2032 Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, but only if the principal amount of the 2032 Notes outstanding at the time we send the related redemption notice is less than 10% of the aggregate principal amount of the 2032 Notes originally issued. Calling the 2032 Notes for cleanup redemption will constitute a Make-Whole Fundamental Change, which will require us to increase the conversion rate in certain circumstances for a specified period of time.

If certain corporate events that constitute a "Fundamental Change" (as defined in the Indenture) occur, then, subject to a limited exception for certain cash mergers, noteholders may require us to repurchase their 2032 Notes at a cash repurchase price equal to the principal amount of the 2032 Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. The definition of Fundamental Change includes certain business combination transactions involving us and certain de-listing events with respect to the common stock.

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 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 commercial launches of VAX-31 in the adult population and VAX-31 or VAX-24 in the pediatric population;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, which may require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the cost of building a sales force in anticipation of any product commercialization;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our vaccine candidates for which we receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- exchange rate fluctuations due to exposure of foreign operations and foreign currency fluctuations and translations;
- any product liability or other lawsuits related to our products;
- the revenue, if any, received from commercial sales, or sales to foreign governments, of our vaccine candidates for which we may receive marketing approval;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing our patents or other intellectual property rights;
- expenses needed to attract, hire and retain skilled personnel; and
- the impact of macroeconomic factors, including potential effects of changes in federal government regulation, rising inflation which may impact labor costs, research and development costs, tariffs, and supply chain constraints, as well as civil and political unrest in certain countries and regions, which may exacerbate the magnitude of the factors discussed above.

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

Cash Flows

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

	Nine Months Ended September 30,	
	2026	2025
	(in thousands)	
Net cash used in operating activities	$ (737,177)	$ (430,745)
Net cash provided by investing activities	85,080	322,229
Net cash provided by (used in) financing activities	601,958	(394)
Effect of exchange rate changes on cash and cash equivalents	1,435	2,263
Net decrease in cash, cash equivalents and restricted cash	$ (48,704)	$ (106,647)

Net Cash Flows from Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2026 was $737.2 million, an increase of $306.4 million compared to the nine months ended September 30, 2025. The increase was primarily due to higher cash expenditures to support our business growth, including increased development and manufacturing activities in connection with the adult and infant PCV programs to support the potential future commercial launches, as well as timing of payments.

Net Cash Flows from Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2026 was $85.1 million, a decrease of $237.1 million compared to net cash provided by investing activities for the nine months ended September 30, 2025. The change was primarily attributable to a $170.3 million increase in purchases of investments and a $91.1 million decrease in maturities and sales of investments, which were partially offset by a $22.9 million decrease in cash used for purchases of manufacturing facility and equipment construction-in-progress.

Net Cash Flows from Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2026 was $602.0 million, an increase of $602.4 million compared to the nine months ended September 30, 2025. The increase was primarily due to $601.8 million in net proceeds from the follow-on offering during the nine months ended September 30, 2026, whereas no such offerings occurred during the nine months ended September 30, 2025.

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 and a finance lease agreement for our manufacturing activities. As of September 30, 2026, we had total operating lease payment obligations of $154.6 million, of which $14.1 million is payable within one year. As of September 30, 2026, we had total finance lease payment obligations of $131.2 million, of which $14.9 million is payable within one year.

Option Agreement

In November 2023 (the “Option Exercise Date”), we exercised the Option pursuant to the Option Agreement by submitting written notice thereof to Sutro Biopharma and paid Sutro Biopharma an aggregate of $75.0 million in cash for the Option exercise price, with the final payment made in May 2024. Upon the occurrence of certain regulatory milestones, we would be obligated to pay Sutro Biopharma certain additional milestone payments totaling up to $60.0 million in cash. In the event that we undergo a change of control, certain rights and payments may be accelerated.

Purchase Commitments

We have certain payment obligations under various license agreements. Under these agreements, we are required to make milestone payments upon successful completion and achievement of certain intellectual property, clinical, regulatory and sales milestones. The payment obligations under the license agreements are contingent upon future events such as our achievement of specified development, clinical, regulatory and commercial milestones, and we will be required to make development milestone payments and royalty payments in connection with the sale of products developed under these agreements. As the achievement and timing of these future milestone payments are not probable or estimable, such amounts have not been included in our condensed consolidated balance sheets as of September 30, 2026 or December 31, 2025.

We enter into agreements in the normal course of business with CMOs and other vendors for manufacturing services and raw materials purchases. We rely on several third-party manufacturers for our manufacturing requirements. As of September 30, 2026, we had the following amounts of non-cancelable purchase commitments related to manufacturing services and raw materials purchased due to our key manufacturing partners. These amounts represent our minimum contractual obligations, including termination fees. If we terminate certain firm orders with our key manufacturing partners, we will be required to pay for the manufacturing services scheduled or raw materials purchased under our arrangements. The actual amounts we pay in the future to the vendors under such agreements may differ from the purchase order amounts.

Years ending December 31,	**(in thousands)**
Remainder of 2026	$ 203,435
2027	231,149
2028	79,301
2029	10,500
Thereafter	—
Total non-cancelable purchase commitments due to our key manufacturing partners	$ 524,385

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements have been prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Actual results could differ materially from those estimates due to risks and uncertainty in the current economic environment. To the extent that there are material differences between these estimates and our actual results, our future consolidated financial statements will be affected.

We believe the critical accounting estimates discussed under Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025 reflect our more significant estimates, assumptions, and judgments that have the most significant impact on our condensed consolidated financial statements. There have been no significant changes to our critical accounting estimates as filed in such report.

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 September 30, 2026 and December 31, 2025 consisted of readily available checking and money market funds. As of September 30, 2026 and December 31, 2025, we also invested in U.S. Treasury securities, U.S. government agency securities, corporate debt, commercial paper, certificates of deposit, 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

September 30, 2026 and December 31, 2025, we had approximately $2.3 billion and $2.4 billion in cash, cash equivalents and investments, respectively. For the three and nine months ended September 30, 2026, we had interest income of $23.2 million and $75.6 million, respectively. The following table shows the impact of a hypothetical 10% increase or decrease in interest rates on our net assets as of September 30, 2026 and our net loss for the nine months ended September 30, 2026:

	Impact on Net Assets as of September 30, 2026	Impact on Net Loss for the Nine Months Ended September 30, 2026
Hypothetical Change in Interest Rates	**(in thousands)**	
10% increase	$ 11,050	$ 7,689
10% decrease	$ (11,050)	$ (7,689)

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 U.S. Treasury securities, U.S. government agency securities, corporate debt, commercial paper, certificates of deposit, 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. Our investment policy limits investments to money market funds, certain types of debt securities issued by the U.S. Government and its agencies, corporate debt, commercial paper and asset-backed securities, and places restrictions on the credit ratings, maturities and concentration by type and issuer. We believe that our exposure to credit risks is not significant and that a hypothetical 10% change in credit rates would not have a significant impact on our portfolio.

Foreign Currency Risk

We are exposed to market risk related to changes in foreign currency exchange rates, mainly relating to our contracts with Lonza, our CMO in Switzerland. We have also entered into a limited number of contracts with other parties with payments denominated in foreign currencies. Payments under these contracts are made in foreign currencies and are subject to fluctuations in foreign currency rates. We do not currently have a formal program in place to hedge foreign currency risks. However, from time to time, we buy Swiss Francs ("CHF"), which is the majority of our foreign currency exposure, at market and hold CHF in our bank accounts. As of September 30, 2026 and December 31, 2025, we had approximately $62.0 million and $38.9 million of CHF cash and cash equivalents, respectively, held at three financial institutions. As of September 30, 2026 and December 31, 2025, we had foreign currency denominated accounts payable and accrued expenses of $310.3 million and $129.0 million, respectively. As of September 30, 2026 and December 31, 2025, we had foreign currency denominated property, plant and equipment of $210.0 million and $223.7 million, respectively. As of September 30, 2026 and December 31, 2025, we had foreign currency denominated other assets of $312.5 million and $148.1 million, respectively. To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements.

The following table shows the impact of a hypothetical 10% increase or decrease in current exchange rates on our net assets as of September 30, 2026 and our net loss for the nine months ended September 30, 2026:

	Impact on Net Assets as of September 30, 2026	Impact on Net Loss for the Nine Months Ended September 30, 2026
Hypothetical Change in Currency Exchange Rates	**(in thousands)**	
10% increase	$ 27,317	$ 28,575
10% decrease	$ (27,317)	$ (28,575)

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

Effects of Inflation

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

Item 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 September 30, 2026. Based on this evaluation, our CEO and CFO have concluded that our disclosure controls and procedures as of September 30, 2026 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 September 30, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

RISK FACTORS

Our business involves significant risks, some of which are described below. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the 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 certain of these activities on our behalf. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

We have incurred significant net losses since inception and anticipate that we will continue to incur substantial net losses for the foreseeable future. We currently have no source of product revenue and may never achieve profitability. Our stock is a highly speculative investment.

We are a clinical-stage biotechnology vaccine company. Investment in clinical-stage companies and vaccine development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential vaccine candidate will not gain regulatory approval or become commercially viable. We do not have any products approved for sale and have not generated any revenue from product sales. As a result, we are not profitable and have incurred losses in each year since inception. Our net losses were $766.6 million and $463.9 million for the years ended December 31, 2025 and 2024, respectively, $297.1 million and $212.8 million for the three months ended September 30, 2026 and 2025, respectively, and $902.0 million and $520.1 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $3.1 billion.

We expect to continue to spend significant resources to fund research and development of, and seek regulatory approvals for, our vaccine candidates. We expect to incur substantial operating losses over the next several years as our research,

development, manufacturing, commercial readiness, preclinical testing and clinical trial activities remain high. 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. 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 September 30, 2026, we had cash, cash equivalents and investments of $2.3 billion. 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, changes in interest rates and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide, including the trading price of common stock, resulting from civil and political unrest in certain countries and regions. Our future capital requirements will depend on many factors, including:

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

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

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

Due to the significant resources required for the development of our vaccine candidates, we must decide which vaccine candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, management and financial resources toward particular vaccine candidates may not lead to the development of any viable commercial vaccines and may divert resources away from better opportunities. For example, although we allocated resources for the development of VAX-24 in the adult population through a Phase 1/2 program, we made the determination to suspend further development of VAX-24 for the adult indication because we chose to advance exclusively VAX-31 for an adult Phase 3 program following the positive results of the VAX-31 adult Phase 1/2 study. Additionally, in August 2025, we announced that as part of our continued focus on strategic capital deployment and in order to prioritize our resources towards our PCV franchise, we had paused the advancement, beyond preclinical development, of VAX-GI while remaining confident in its potential and preserving the option to advance the program in the future. We also discontinued further development of VAX-PG, a vaccine candidate we were developing for periodontal disease, which demonstrated an acceptable safety profile but not sufficient efficacy signals to warrant further investment. Similarly, our potential decisions to delay, terminate, license or collaborate with third parties in respect of certain vaccine candidates may subsequently also prove to be less than optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our vaccine candidates or misread trends in the biopharmaceutical industry, in particular for vaccines, our business could be seriously harmed. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other vaccine candidates that may later prove to have greater commercial potential than those we choose to pursue or relinquish valuable rights to such vaccine candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development, manufacturing and commercialization rights.

Risks Related to Our Business and Industry

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

We are developing a pipeline of vaccine candidates utilizing our cell-free protein synthesis platform, which is comprised of the XpressCF® platform exclusively licensed from Sutro Biopharma, Inc. ("Sutro Biopharma") and our proprietary know-how for vaccine applications against infectious disease. Our future success depends on the successful application of this approach to vaccine development. We are in the clinical or preclinical stages of developing our vaccine candidates and there can be no assurance that any development problems we may experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be overcome. For example, although we have achieved proof-of-concept for our carrier-sparing approach with VAX-31 and VAX-24, our approach may not be validated for our other vaccine candidates or subsequent trials of VAX-31 or VAX-24. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to manufacturing partners, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all. In addition, since we have not yet completed clinical development on any of our product candidates, we do not know the specific doses that may be effective in the clinic or, if approved, commercially. Finding a suitable dose may delay our anticipated clinical development timelines. We may also encounter difficulty recruiting sufficient participants for our clinical studies, or the FDA may impose additional requirements on us regarding trial size or a long-term safety study that will significantly slow or forestall our development program.

Furthermore, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our vaccine candidates and learn more about these critical factors. Conjugate vaccine development is highly complex, and development of broad-valency pneumococcal conjugate vaccines ("PCVs") is further complicated by the

number of components, analytical assays and potential for adjustments, including, but not limited to, changes in raw materials, composition, formulation, manufacturing methods and dosing, which could result in drug substances and/or drug product that may vary between preclinical and clinical studies over time. Over the course of the development and manufacturing of VAX-24, we previously encountered process-related matters that required us to make adjustments to our processes. For example, in 2020 we encountered such process-related matters during our drug substance manufacturing campaign for VAX-24 at Lonza, Ltd. ("Lonza"). The cumulative impact of the time required to make adjustments to our processes led to a delay of our drug substance manufacturing campaign due to scheduling conflicts and capacity constraints at Lonza. There can be no assurance that we or Lonza will be able to successfully manufacture drug substances in a timely manner in the future, or at all. Such process changes and manufacturing delays have caused a change in our Investigational New Drug ("IND") application timelines in the past and future changes or delays could impact future timelines for VAX-31, VAX-24 or for our other product candidates. In addition, if we encounter similar manufacturing issues after product approval, it will require inspection and approval of the new manufacturing site and submission of a Biologics License Application ("BLA") supplement, which may further impede or delay commercialization.

In addition, the preclinical and clinical trial requirements of the FDA, European Medicines Agency ("EMA") and other regulatory agencies and the criteria these regulators use to determine the safety and immunogenicity or efficacy of a vaccine candidate are determined according to the type, complexity, novelty and intended use and market of the potential products, taking into consideration the benefits and risks for the intended population who will receive the vaccine, as well as the disease(s) to be prevented. Regulatory agencies also evaluate a sponsor's data to determine whether the manufacturing and facility information assure product quality and consistency. Approvals by the FDA and EMA for existing pneumococcal vaccines, such as Pfizer Inc.'s ("Pfizer") Prevnar 13® ("PCV13") and Prevnar 20® ("PCV20"), and Merck & Co., Inc.'s ("Merck") VAXNEUVANCE™ ("PCV15"), Capvaxive® ("PCV21") and Pneumovax® 23 ("PPSV23"), may not be indicative of what these regulators may require for approval of our vaccine candidates. For example, in the adult population, these existing pneumococcal vaccines were previously approved based on several criteria, including the establishment of non-inferiority of OPA responses relative to the then current standard of care vaccine(s) for the serotypes in common with such standard-of-care vaccine(s), on a strain-by-strain basis, where non-inferiority was defined as greater than or equal to 0.50 of the lower limit of the two-sided 95% confidence interval of the OPA geometric mean titer ratio. Following discussions with the FDA, the non-inferiority standard in our VAX-31 adult OPUS-1 Phase 3 pivotal, noninferiority trial is set at 0.667. In the infant population, existing pneumococcal vaccines were previously approved based on several criteria, including, for the post-dose 4 assessment, the establishment of non-inferiority of IgG responses relative to the then current standard-of-care vaccine(s) for the serotypes in common with such standard-of-care vaccine(s), on a strain-by-strain basis, where non-inferiority was defined as greater than or equal to 0.50 of the lower limit of the two-sided 95% confidence interval of the IgG geometric mean ratio. In October 2026, Pfizer announced that it would use a noninferiority standard of 0.667 in its infant Phase 3 trial of its 25-valent PCV candidate ("PCV25"). The noninferiority standard for our infant Phase 3 program will not be determined until at least the time we have our End-of-Phase 2 meeting with the FDA, but given Pfizer's PCV25 trial decision, we expect that the FDA will also require our infant Phase 3 trial to use the 0.667 noninferiority standard.

The FDA may challenge our VAX-31 Phase 3 Chemistry, Manufacturing and Controls ("CMC") strategy, which could cause significant delays or unanticipated costs. Additionally, novel aspects of our vaccine candidates and manufacturing processes may create further challenges in obtaining regulatory approval. The regulatory approval process for our novel vaccine candidates can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other vaccine candidates. More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new vaccine candidates. Moreover, our vaccine candidates may not perform successfully in clinical trials. Evolving regulatory approaches to vaccine approval decisions may present additional hurdles to development that would necessitate a change to our approach to meet regulatory expectations.

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

Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing our vaccine candidates, either alone or with third parties, and we cannot guarantee that we will ever obtain regulatory approval for any of our vaccine candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA, and we may never be able to obtain marketing approval for any of our product candidates. Before obtaining regulatory approval for the commercial distribution of our vaccine candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate the safety and immunogenicity or efficacy of our vaccine candidates.

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

- negative or inconclusive results from our preclinical or clinical trials, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon a program;
- product-related adverse effects experienced by volunteers in our clinical trials;
- difficulty achieving successful development of our manufacturing processes, including process development and scale-up activities to supply products for preclinical studies, clinical trials and commercial sale, if approved;
- timely completion of our preclinical studies and clinical trials, including any field efficacy studies that may be required, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- inability of us or any third-party contract manufacturer to scale up manufacturing of our vaccine candidates to supply the needs of preclinical studies, clinical trials and commercial sales, and to manufacture such products in conformity with regulatory requirements;
- delays in submitting IND applications or comparable foreign applications or delays or failures in obtaining necessary authorizations from regulators to commence a clinical trial, or suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or similar foreign authorities regarding the scope or design of our clinical trials, including any requirements to perform field efficacy studies;
- challenges by the FDA to our clinical or regulatory strategies;
- changes in FDA personnel that alter the FDA's advice with respect to our development strategy;
- delays in enrolling subjects in our clinical trials;
- inadequate supply or quality of vaccine candidate components or materials or other supplies necessary for conducting clinical trials;
- inability to obtain alternative sources of supply for which we have a single source for vaccine candidate components;
- the availability of coverage and adequate reimbursement and pricing from third-party payors, including government authorities, pertaining to the vaccine candidate, once approved, and patients' willingness to pay out-of-pocket if third-party payor reimbursement is limited or not available;
- greater than anticipated costs of our clinical trials, including CMC activities related to our clinical trials;
- harmful side effects or inability of our vaccine candidates to meet immunogenicity or efficacy endpoints;
- unfavorable FDA or other regulatory agency inspection and review of one or more of our clinical trial sites or our contract manufacturers' facilities;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology or vaccine candidates in particular; or
- varying interpretations of our data by the FDA and comparable foreign regulatory authorities.

In addition, changes to the standard-of-care or the approval standards for new vaccines have, and could again in the future, change the threshold for achievement of non-inferiority using the established surrogate immune endpoints that our PCVs will need to meet in our clinical trials.

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

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

by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our vaccine candidates.

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

Our business and future success depends on our ability to successfully develop, obtain regulatory approval of, and then commercialize our PCV candidates, which include VAX-31, our 31-valent clinical PCV candidate in development for both the adult and pediatric populations, VAX-24, our 24-valent clinical PCV candidate in development for the pediatric population, and VAX-XL, our third-generation PCV candidate designed to provide the broadest coverage of any PCV currently in development. VAX-31 and VAX-24 will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient clinical and commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We cannot provide any assurance that we will be able to successfully advance our PCV candidates through the development process.

The clinical and commercial success of VAX-31, VAX-24, and future vaccine candidates will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete IND-enabling studies and successfully submit IND or comparable applications;
- the ability of third parties with whom we contract to manufacture adequate clinical study and commercial supplies of our lead vaccine candidates or any future vaccine candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices ("cGMP") and do so in a timely manner;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials, including field efficacy studies, long-term safety studies, or other studies beyond those planned to support the approval and commercialization of our vaccine candidates or any future vaccine candidates;
- acceptance of our proposed indications and primary surrogate endpoint assessments for our PCV candidates by the FDA and similar foreign regulatory authorities;
- any changes to the required threshold for the achievement of non-inferiority using established surrogate immune endpoints that our PCVs will need to meet in our clinical trials;
- our ability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities the safety and immunogenicity or efficacy and acceptable risk to benefit profile of our PCV candidates and any future vaccine candidates;
- the pace and prevalence of serotype replacement following the introduction of our PCV candidates or other vaccines targeting pneumococcal disease;
- any vaccine-vaccine interference studies that may be required, particularly with the standard-of-care pediatric vaccine regimen;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our vaccine candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA or comparable foreign regulatory authorities;
- achieving, maintaining and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to our lead vaccine candidates or any future vaccine candidates or approved products, if any;
- obtaining and maintaining Advisory Committee on Immunization Practices ("ACIP"), comparable foreign regulatory authority, professional society, or other clinical recommendation of our vaccine candidates and the willingness of physicians, operators of clinics and patients to utilize or adopt any of our future vaccine candidates to prevent or treat age-associated diseases;
- our ability to successfully develop a commercial strategy and thereafter commercialize our vaccine candidates or any future vaccine candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- the convenience of our treatment or dosing regimen;
- acceptance by physicians, payors and patients of the benefits, safety and immunogenicity or efficacy of our vaccine candidates or any future vaccine candidates, if approved, including relative to alternative and competing treatments;

- patient demand for our vaccine candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our vaccine candidates or any future vaccine candidates;
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims;
- our ability to set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors; and
- macroeconomic factors that may exacerbate the magnitude of the factors discussed above.

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

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

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

Vaccine candidates that we successfully develop and commercialize may compete with existing vaccines and new vaccines that may become available in the future. Many of our competitors have substantially greater financial, lobbying, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior vaccines, including the potential that our competitors may develop chemical processes or utilize novel technologies for developing vaccines that may be superior to those we employ. In addition, many of these competitors have significantly greater experience than we have in undertaking preclinical studies and clinical trials of new products and in obtaining regulatory approvals, including for many vaccine franchises. Accordingly, our competitors may succeed in obtaining FDA approval or a preferred recommendation from ACIP for their products. For example, PCV13 obtained FDA approval for the prevention of invasive pneumococcal disease ("IPD") in infants based on non-inferior IgG antibody responses relative to Prevnar, using the surrogate immune endpoints established by the prior Prevnar field efficacy study. Pfizer implemented a similar approach to the development of its 20-valent PCV vaccine candidate, PCV20, which was approved by the FDA in June 2021 for use in adults and in April 2023 for use in infants and children. Pfizer previously announced that it was developing PCV25, which was in adult and pediatric Phase 2 clinical trials, and that it was working on a 30-plus valent PCV candidate that was in preclinical development. Pfizer announced in November 2025 that it planned to initiate adult and pediatric pivotal trials evaluating PCV25 in 2026. In May 2026, Pfizer announced the initiation of a Phase 3 pediatric program evaluating PCV25 and the termination of its adult 25-valent program in favor of a preclinical 35-valent candidate, which it expects will enter clinical development in 2026. In October 2026, Pfizer announced results from its Phase 2 trial evaluating PCV25 in infants, and that it plans to complete its PCV25 infant Phase 3 study in the second quarter of 2029 with regulatory submission planned in 2029. Merck received approval for PCV15, its 15-valent PCV, in July 2021 for use in adults and in June 2022 for use in infants and children. Merck announced in June 2024 that PCV21, its 21-valent PCV, received approval from the FDA for use in adults. In September 2025, Merck announced positive results from its Phase 3 study evaluating PCV21 in children aged 2–17 with increased risk for pneumococcal disease. In June 2026, Merck announced that the FDA approved an additional indication for PCV21 in children aged 2–17 with increased risk of pneumococcal disease who have previously completed a primary pediatric pneumococcal series. Merck is also advancing additional next-generation PCV candidates through multiple early-phase clinical studies evaluating different formulations. In addition, Sanofi and SK bioscience have partnered to develop a 21-valent PCV and, in June 2023, announced positive results from their Phase 2 clinical trials in infants. In December 2024, Sanofi and SK bioscience announced the initiation of a global pediatric Phase 3 clinical program of their 21-valent PCV candidate, as well as an expanded agreement to develop, license and commercialize "next-generation" PCVs for both pediatric and adult populations. In February 2026, SK bioscience announced that it expected topline results from this Phase 3 study to be available in 2027, and that a next-generation PCV candidate, also co-developed with Sanofi, was in preclinical development with clinical trial entry expected in 2026. In March 2026, SK bioscience announced that it was targeting 2029 for commercialization of its 21-valent PCV candidate, which it is co-developing with Sanofi. GSK, which previously acquired Affinivax, was previously developing a 24-valent affinity-bound pneumococcal vaccine candidate in adults and infants. In October 2024, GSK announced the termination of their adult 24-valent program in favor of a

preclinical 30-plus valent candidate. In October 2025, GSK announced the initiation of a Phase 1 study in Australia evaluating its 30-plus valent candidate in adults. In the fourth quarter of 2025, GSK removed its pediatric 24-valent candidate, which had previously advanced into a Phase 2 clinical trial program, from its publicly disclosed pipeline. GSK's disclosed pipeline lists a 30-plus valent pediatric candidate in Phase 1.

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

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

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

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

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

- manufacturing our vaccine candidates to our specifications, including process development, analytical development and quality control testing, and in a timely manner to support our preclinical and clinical trials and, if approved, commercialization;
- maintaining a cGMP-compliant facility and passing a pre-approval inspection;
- sourcing the raw materials used to manufacture our vaccine candidates for preclinical, clinical and, if approved, commercial supplies; and
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of our vaccines.

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

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

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

- receiving the U.S. Centers for Disease Control and Prevention ("CDC"), ACIP, comparable foreign regulatory authority, professional society, or other clinical recommendation for use;
- prevalence and severity of the disease targets for which our vaccine candidates are approved;
- physicians, hospitals, third-party payors and patients considering our vaccine candidates as safe and effective;
- the potential and perceived advantages of our vaccine candidates over existing vaccines, including with respect to spectrum of coverage or immunogenicity;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory and advisory bodies;
- limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory and advisory bodies;
- the timing of market introduction of our vaccine candidates as well as competitive products;
- the cost in relation to alternatives;
- the availability of coverage and adequate reimbursement and pricing by third-party payors, including government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors, including government authorities;
- relative convenience and ease of administration, including as compared to competitive vaccines and alternative treatments; and
- the effectiveness of our sales and marketing efforts.

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

New pediatric vaccines that receive an ACIP preferred recommendation are almost universally adopted, and adult vaccines that receive a preferred recommendation are widely adopted. Recent changes to federal vaccine policy have introduced new uncertainties regarding the regulatory, legal, and reimbursement landscape for vaccines in the United States. Such changes have resulted in the American Academy of Pediatrics and other recommending bodies or organizations to generate their own recommended pediatric vaccine schedule. We may need to engage with additional professional societies or organizations to secure access for both adults and infants.

The ACIP's composition and decisions could influence the pathway for new vaccines to receive a positive recommendation or the impact of a positive recommendation. If our vaccine candidates are approved but fail to receive CDC, ACIP, comparable foreign authority, professional society, or other clinical recommendations, or fail to achieve market acceptance among physicians, healthcare providers, patients, third-party payors or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

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

The success of our business depends in large part upon our ability to identify, develop and commercialize products based on our cell-free protein synthesis platform. In addition to our PCV franchise, our pipeline includes VAX-A1, a clinical vaccine candidate for Group A Streptococcus ("Group A Strep"), and VAX-GI, a preclinical vaccine candidate for dysentery and shigellosis. Our research programs may fail to identify potential vaccine candidates for clinical development for a number of reasons or we may focus our efforts and resources on potential programs or vaccine candidates that ultimately prove to be successful in a smaller subset of patients than expected or completely unsuccessful. In addition, we

cannot provide any assurance that we will be able to successfully advance any of our existing or future vaccine candidates through the development process.

For example, we announced in August 2025 that preclinical data for VAX-PG demonstrated an acceptable safety profile but not sufficient efficacy signals to support further investment, and we therefore discontinued further development of that candidate.

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

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

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

We currently rely on third-party manufacturing and supply partners to supply raw materials and components for, and the manufacture of, our preclinical and clinical supplies as well as our vaccine candidates. Our inability to procure necessary raw materials or to have sufficient quantities of preclinical and clinical supplies or the inability to have our vaccine candidates manufactured, including delays or interruptions at our third-party manufacturers, or our failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

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

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

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

If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, or if they cannot pass a pre-approval inspection, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our vaccine candidates. Moreover, we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fail to comply with such requirements or to perform their obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills, raw materials or technology required to manufacture our vaccine candidates may be unique or proprietary to the original manufacturer or supplier, and we may have difficulty applying such skills or technology or sourcing such raw materials ourselves, or in transferring such skills, technology or raw materials to another third party, or such transfer may be subject to certain consent obligations and payment terms to the original manufacturer. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our vaccine candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines, and we may be required to repeat some of the development program and submit a supplement to our application. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop vaccine candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers and suppliers if we receive regulatory approval for any PCV or any other vaccine candidates. For example, in October 2023, we entered into a pre-commercial services and commercial manufacturing supply agreement (the "Lonza Commercial Manufacturing and Supply Agreement") with Lonza, pursuant to which Lonza (i) constructed and built out a dedicated suite ("Suite") at Lonza's facilities in Visp, Switzerland to manufacture certain key components (including drug substance) for our proprietary PCV franchise and any other products or intermediates we may choose (collectively, the "Products"), and (ii) maintains and operates the Suite (utilizing Lonza's employees) to manufacture the Products as a service provided to us, including conducting related quality control and quality assurance operations. In September 2025, we also entered into a master services agreement with Patheon Manufacturing Services LLC, part of Thermo Fisher Scientific (collectively, "Thermo Fisher"), pursuant to which Thermo Fisher will commercially manufacture and supply drug product for our PCV candidates, if approved (the "Thermo Fisher Commercial Manufacturing and Supply Agreement").

To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. In November 2023, we entered into a manufacturing rights agreement (the "Manufacturing Rights Agreement") with Sutro Biopharma pursuant to which we obtained exclusive rights to independently, or through certain third parties, develop, improve and manufacture cell-free extract for use in connection with our vaccine candidates. If the independent alternate CMO or the designated third parties are unable to provide a sufficient supply of cell-free extract, our third-party manufacturers may be delayed in their production of intermediate components, which may lead to delays of our drug substance manufacturing campaigns.

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

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

In addition, because VAX-31, VAX-24 and our other vaccine candidates are also based on our cell-free protein synthesis platform, if our vaccine candidates encounter safety and immunogenicity or efficacy problems, manufacturing problems,

developmental delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

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

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

Adverse effects or other undesirable or unacceptable side effects caused by our vaccine candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In such an event, our clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our vaccine candidates. Such side effects could also affect trial recruitment or the ability of enrolled subjects to complete the clinical trial or result in potential product liability claims. An independent data safety monitoring board ("DSMB") may also suspend or terminate a clinical trial at any time on various grounds, including a finding that the research volunteers are being exposed to an unacceptable health risk. Vaccine-related side effects could also affect recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, any vaccine to be approved in pediatric populations may need to undergo extensive vaccine-vaccine interference studies with the standard-of-care pediatric vaccine regimen. Further, to the extent field efficacy studies are required, prophylactic vaccines typically require clinical testing in thousands to tens of thousands of healthy volunteers to define an approvable benefit-risk profile. The need to show a high degree of safety and tolerability when dosing healthy individuals could result in rare and even spurious safety findings, negatively impacting a program prior to or after commercial launch. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

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

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

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

Our timing of submitting the IND applications for our product candidates is dependent on preclinical and manufacturing success, and if we experience additional delays, we may fail to meet our anticipated timelines. In addition, we cannot be sure that submission of an IND application or IND application amendment will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. Additionally, even if regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

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

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

and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include, but are not limited to:

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

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

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

We may experience difficulties in enrolling subjects in any clinical trials we may conduct for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of subjects who remain in the study until its conclusion. The enrollment of subjects depends on many factors, including, but not limited to:

- the eligibility and exclusion criteria defined in the protocol;

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

Based on our VAX-31 End-of-Phase 2 meeting with the FDA, we believe there is confirmation that the immunogenicity analyses are sufficient to support licensure, and an efficacy study is therefore not required. In the event that we are required to conduct any field efficacy studies for VAX-31 or any of our other product candidates, enrollment of a sufficient number of subjects may require additional time and resources given widespread vaccination rates in the United States, particularly in the pediatric population. As a result, we may be required to conduct any such trials outside the United States, which could cause additional complexity and delay. Delays in enrollment may result in increased costs or may affect the timing or outcome of any clinical trials we may conduct, which could prevent completion of these trials and adversely affect our ability to advance the development of our vaccine candidates.

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

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

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

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

We have in the past and may in the future seek BTD or Fast Track designation for some of our vaccine candidates. For instance, in August 2022 we announced that the FDA granted Fast Track designation to VAX-24 in adults ages 18 and older, in January 2023 we announced that the FDA granted a BTD for VAX-24 for the prevention of IPD in adults, in November 2024 we announced that the FDA granted a BTD for VAX-31 for the prevention of IPD in adults, and in August 2025 we announced that the FDA extended the BTD for VAX-31 to include the prevention of pneumonia caused by *Streptococcus pneumoniae* in adults. A sponsor may seek FDA designation of its vaccine candidate as a breakthrough therapy if the vaccine candidate is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or

more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For vaccines that have been designated as Breakthrough Therapies, the FDA may take actions to expedite the development and review of the application, and interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

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

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

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

We have only recently begun to build our marketing and sales organization, and as an organization we have never marketed any products. If we are unable to further 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 have only recently begun to build our sales, marketing and distribution organization and, as a company, have never marketed any products. Although we have begun hiring sales and marketing personnel, we have not yet established a fully developed organization in these areas. Continuing to develop these capabilities will require significant expenses, management resources and time, and we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to further 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 further 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 further develop in-house sales and distribution capabilities or enter into relationships with third-party collaborators on acceptable terms or at all, we may not be able to successfully commercialize our products. If we are not successful in commercializing our products or any future products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

A variety of risks associated with our current and potential international operations and collaborations could materially adversely affect our business.

As we pursue approval and commercialization for our vaccine candidates overseas and conduct CMC and other operations overseas, we will be subject to additional risks related to operating in foreign countries, including, but not limited to:

- differing regulatory requirements in foreign countries;
- significant changes in trade policies, price and exchange controls and other regulatory requirements;

- increased difficulties in managing the logistics and transportation of storing and shipping vaccine candidates abroad;
- import and export requirements and restrictions;
- differing and changing data protection and privacy regimes and requirements;
- economic weakness, including inflation and interest rates, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended, or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

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

These and other risks associated with our international operations and our collaborations with Lonza, based in Switzerland, may materially adversely affect our ability to attain or maintain profitable operations.

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

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

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

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

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

As our discovery, development, manufacturing and commercialization plans and strategies develop, we have rapidly expanded our employee base and expect to continue to add managerial, operational, sales, research and development,

marketing, financial and other personnel. Current and future growth imposes significant added responsibilities on members of management, including, but not limited to:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Remote and hybrid work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we

may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- decreased demand for our vaccine candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any vaccine candidate; and
- a decline in our share price.

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

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

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

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

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

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

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

Our ability to utilize our net operating loss ("NOL") carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. As of December 31, 2025, we had federal and state NOL carryforwards of $796.1 million and $1,907.7 million, respectively. The federal and state loss carryforwards, except the federal loss carryforward arising in tax years beginning after December 31, 2017, begin to expire in 2034 unless previously utilized. Federal NOLs arising in tax years beginning after December 31, 2017 have an indefinite carryforward period and do not expire. As of December 31, 2025, we also had federal and state research credit carryforwards of $40.3 million and $12.3 million, respectively. The federal research and development tax credit carryforwards expire beginning in 2039 unless previously utilized, and the state research and development tax credits can be carried forward indefinitely. In general, a corporation that undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We have experienced ownership changes in the past. There were no ownership changes identified in 2025, as such we have determined that no federal research credits will expire unutilized or are excluded from our research credits carryforwards as of December 31, 2025. Subsequent ownership changes may affect the limitation in future years. As a result, if, and to the extent that we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations.

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

Although we intend to maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any vaccine candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Conditions in the insurance markets relating to nearly all areas of traditional corporate insurance change rapidly and may result in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

Risks Related to Our Reliance on Third Parties

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

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

We will need to negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol and legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for vaccine candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will require a large number of test subjects. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of subjects may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our preclinical studies and clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our vaccine candidates. As a result, our financial results and the commercial prospects for our vaccine candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

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

We do not have the infrastructure or capability internally to manufacture supplies for our vaccine candidates or the materials necessary to produce our vaccine candidates for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our vaccine candidates on a preclinical, clinical or commercial scale. Pursuant to the Manufacturing Rights Agreement with Sutro Biopharma, we obtained exclusive rights to independently, or through certain third parties, develop, improve and manufacture cell-free extract for use in connection with our vaccine candidates. We have engaged Lonza to perform manufacturing process development and clinical manufacture and supply of components for our PCV candidates. Lonza is currently in the process of manufacturing certain components of our vaccine candidates on a clinical scale. In addition, we entered into the Lonza Commercial Manufacturing and Supply Agreement pursuant to which Lonza (i) constructed and built out a Suite at Lonza's facilities in Visp, Switzerland to manufacture the Products, and (ii) maintains and operates the Suite (utilizing Lonza's employees) to manufacture the Products as a service provided to us. In September 2025, we also entered into the Thermo Fisher Commercial Manufacturing and Supply Agreement, pursuant to which Thermo Fisher will commercially manufacture and supply drug product for our PCV candidates, if approved.

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

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

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

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any;
- Our third-party suppliers and manufacturers might be unable to timely formulate and manufacture or supply raw materials for our vaccine candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any. For example, if the independent alternate CMO or the designated third parties under the Manufacturing Rights Agreement are unable to provide a sufficient supply of cell-free extract, our third-party manufacturers may be delayed in their production of intermediate components, which may lead to delays of our drug substance manufacturing campaigns. Additionally, if Lonza is unable to identify a timely or manageable

solution for handling cell-free extract during our clinical studies, such studies may be delayed, and we will incur additional costs;

- Contract manufacturers may not be able to execute our manufacturing procedures appropriately;
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products; and
- Our third-party suppliers and manufacturers could breach or terminate their agreement with us.

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

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

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

Risks Related to Government Regulation

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

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products, including biologics such as conjugate vaccines, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We expect that our vaccine candidates will be regulated by the FDA as biologics. We are not permitted to market any biological drug product in the United States until we receive approval of a BLA from the FDA. We have not previously submitted a BLA to the FDA, or similar requests for marketing authorization to comparable foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the vaccine candidate's safety, purity, and potency for each desired indication. The BLA must also include significant information regarding the CMC for the product, including with respect to chain of identity and chain of custody of the product and various comparability assessments. The FDA's review of our BLA may be significantly delayed if the FDA views that the CMC information included in our submission is not adequate or requests additional CMC information or data.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our vaccine candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our vaccine candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety and immunogenicity or efficacy results between different clinical trials of the same vaccine candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout

among clinical trial participants. Vaccine candidates in later stages of clinical trials may fail to show the desired safety and immunogenicity or efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of immunogenicity or efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most vaccine candidates that begin clinical trials are never approved by regulatory authorities for commercialization. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit a BLA or other marketing application.

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

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

We could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our vaccine candidates in lieu of using existing vaccines that have established safety and immunogenicity or efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a vaccine candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial or based on a recommendation by the DSMB. If we experience termination of, or delays in the completion of, any clinical trial of our vaccine candidates, the commercial prospects for our vaccine candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

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

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

The general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from two Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Phase 3 clinical trials typically involve thousands of patients, have significant costs and are time consuming. While we are still in the process of having discussions with the FDA regarding our Phase 3 regulatory plans, including discussions regarding our CMC strategy, the FDA may ultimately disagree with our regulatory strategy or we may be unable to successfully complete development to the FDA's satisfaction. We believe our previously reported topline results from the VAX-31 OPUS-1 pivotal adult Phase 3 trial support an approvable profile for VAX-31 in adults, but there can be no assurance that this will be sufficient for regulatory approval.

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

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

are studying. This may result in the FDA or other regulatory agencies requesting additional studies to show that our vaccine candidate is non-inferior or superior to the new products.

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our vaccine candidates are safe and effective;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our vaccine candidates' clinical and other benefits outweigh their safety risks;
- any changes to the required threshold for the achievement of non-inferiority using established surrogate immune endpoints that our PCVs will need to meet in our clinical trials;
- any vaccine to be approved in pediatric populations may need to undergo extensive vaccine-vaccine interference studies with the standard-of-care pediatric vaccine regimen;
- the need to perform superiority or field efficacy trials, which can be larger, longer and more costly, if an existing vaccine is approved for a disease indication;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our vaccine candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities will inspect the commercial manufacturing facilities we may utilize and may not approve such facilities; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

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

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

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

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") established an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA and the FDA will not accept an application for a biosimilar product based on the reference biological product until four years after the date of first licensure of the reference product, and will not approve a biosimilar until 12 years after the date of first licensure. These periods of exclusivity can be extended by six months by obtaining pediatric exclusivity. In addition, if the reference product is protected by patents, the biosimilar manufacturer and reference product manufacturer must engage in a complex process called the "patent dance." The FDA has not yet approved a biosimilar vaccine.

In addition, there is a risk that any exclusivity period we receive for any of the vaccine candidates we develop that is approved in the United States as a biological product under a BLA could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject vaccine candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. In October 2025, the FDA announced that it will no longer require comparative efficacy studies to establish biosimilarity. In addition, although it has not announced a formal policy, the FDA is no longer requiring switching studies for interchangeable products. In addition, the FDA's updated guidance no longer requires an interchangeability statement on labeling. The FDA's more expansive

view of interchangeability may allow more biosimilars to be automatically substituted for the reference product upon approval.

Our relationships with customers, physicians and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, health information privacy and security laws and other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we could face substantial penalties.

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of government funds, including Medicare and Medicaid, that are false or fraudulent, or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Actions under the civil False Claims Act may be brought by the federal government or as a qui tam or whistleblower action by a private individual in the name of the government. Pharmaceutical manufacturers have been investigated and have reached substantial financial settlements under the civil False Claims Act for causing false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim, including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, regardless of the payor (e.g., public or private), or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (the "HITECH") and its implementing regulations, which also impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, including health plans, healthcare clearinghouses and certain healthcare providers, and their business associates that perform certain services involving the use or disclosure of individually identifiable health information for or on their behalf, as well as their covered subcontractors. HITECH also created tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the Federal Food, Drug, and Cosmetic Act and its implementing regulations, which prohibit, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners),

and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers; and
- laws governing the privacy and security of certain protected information, such as the EU GDPR, and the CCPA, which impose obligations and restrictions on the collection, use and disclosure of personal data (including health data) relating to individuals located in the European Economic Area ("EEA") and California, respectively.

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

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

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

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

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

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

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

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

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our vaccine candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our vaccine candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for administering the product.

Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from third-party payors and reduce the willingness of physicians to use our vaccine candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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

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

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

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of vaccine candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any vaccine candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), was passed, which substantially changed the way

healthcare is financed by both the government and private insurers and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things: (i) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations; (ii) created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (iii) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in specific government healthcare programs; (iv) expanded the eligibility criteria for Medicaid programs; (v) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; (vi) created a Medicare Part D coverage gap discount program (now replaced by the IRA); and (vii) established a Center for Medicare & Medicaid Innovation ("CMMI") at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drugs.

There have been executive, judicial and Congressional efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA, some of which have been successful. For example, the Tax Act included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress.

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

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

Further, in the United States, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug and biological product pricing, reduce the cost of prescription drugs and biological products under government payor programs and review the relationship between pricing and manufacturer patient programs. For example, the IRA, among other things, (i) enables the Department of Health and Human Services ("HHS") to assert control over the prices of certain single-source drugs and biologics covered under Medicare, (ii) subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, (iii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation, and (iv) redesigns the funding and benefit structure of the Medicare Part D program, potentially increasing manufacturer liability while capping annual out-of-pocket drug expenses for Medicare beneficiaries. The IRA also eliminates patient cost sharing for FDA-approved adult vaccines that are recommended by the ACIP and covered under Medicare Part D, and mandates that all state Medicaid programs cover FDA-approved adult vaccines that are recommended by the ACIP and their administration without cost sharing. In addition, in January 2026, the HHS announced the list of 15 drugs that will be subject to the third round of price negotiations.

The IRA is currently subject to legal challenges and it is unclear how the IRA will be effectuated or changed in the future. However, the IRA does not change either the CDC's Vaccines for Children program ("VFC") or the provisions added in 2010 under the ACA. The VFC was established to give first-dollar coverage to children up to 18 years of age whose families could not pay for vaccinations while the ACA guaranteed coverage of vaccines without cost sharing for Americans who are either privately insured or newly covered in states that expanded Medicaid. Further, many vaccines are excluded from Medicare Part B rebate requirements.

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

At the state level, legislatures and regulatory agencies have increasingly passed legislation and implemented regulations designed to control drug pricing, including restrictions on pricing or reimbursement at the state government level,

limitations on discounts to patients, advance notices of price increases, marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. The OBBBA will also reduce funds for Medicaid programs, which are administered by the states.

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

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

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

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

Changes in policies or actions that impact the funding, staffing, or operations of regulatory agencies, including changes to the user fee reauthorization process or a failure to reauthorize user fee programs in a timely manner, could lead to changes in review periods or response times. This, in turn, could affect the development and regulatory timelines for approval of new products and related services and have a material adverse effect on our business.

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

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

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

In the United States, federal, state, and local governments have enacted numerous data privacy and data security laws beyond HIPAA and other healthcare privacy laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the CCPA imposes obligations on covered businesses, including, but not limited to, providing specific

disclosures in privacy notices and affording California residents certain rights related to their personal data. In addition, the CPRA expanded the CCPA's requirements, including by adding new rights allowing individuals to opt out of the sharing (as defined under the CCPA) of and correct their personal data and limit the use and disclosure of their sensitive personal data, as well as by establishing a new California Privacy Protection Agency to implement and enforce, alongside the California Attorney General, the CCPA. Other U.S. states have also recently enacted comprehensive data privacy laws — including Virginia, Connecticut, Utah, Colorado, Delaware, Indiana, Iowa, Kentucky, Maryland, Minnesota, Montana, New Hampshire, New Jersey, Nebraska, Oregon, Rhode Island, Tennessee, and Texas — and other local, state, and federal laws are currently under consideration. Certain states also impose stricter requirements, such as conducting data privacy impact assessments, for processing certain personal data, including sensitive information. These state laws allow for statutory fines for noncompliance. For example, the CCPA allows for fines of up to $7,500 per intentional violation and allows for private litigants affected by certain data breaches to recover significant statutory damages. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon which we rely. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors).

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

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

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

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

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon which we rely may fail (or be perceived to have failed) to comply with such obligations, which could negatively impact our business operations and compliance posture. If we or the third parties on which we rely fail, or are perceived to have failed, to address or

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future vaccine candidates.

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

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

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

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our PCV candidates or any future vaccine candidate, or the XpressCF® platform, our competitors might be able to enter the market, which would have an adverse effect on our business.

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

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent

infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing vaccine candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our vaccine candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

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

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

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

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

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, written description, or lack of patentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The

outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future vaccine candidates. Such a loss of patent protection could harm our business.

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

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

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

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of PTA for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in future and whether patent expiration dates may be impacted. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications may, upon grant of a patent, become a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC may be opted out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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

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

In addition, any proprietary name we propose to use with our current or any other vaccine candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

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

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

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

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

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

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

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks Related to Ownership of Our Common Stock

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

The market price of our common stock has been and may continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In

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

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

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

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

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

The focus of certain investors and other key stakeholders concerning corporate responsibility, specifically related to environmental, social and governance ("ESG") factors has been changing, and ESG laws and regulations regarding disclosure, reporting and diligence requirements continue to evolve. Some parties have placed an increased emphasis on corporate responsibility ratings and a number of third parties provide reports on companies in order to measure and assess corporate responsibility performance. In addition, the ESG factors by which companies' corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. On the other hand, state attorneys general and other governmental authorities may take action against certain ESG policies or practices. We risk damage to our brand and reputation if our corporate responsibility procedures or standards do not meet the standards set by various constituencies or comply with new laws and regulations or changes to legal or regulatory requirements concerning ESG. We may be required to make investments to comply with various ESG and anti-ESG practices and regulations, which could be significant and adversely impact our results of operations. Furthermore, if our competitors' corporate responsibility performance is perceived to be greater than ours, potential or current investors may elect to invest with our competitors instead. In addition, if we communicate certain initiatives and goals regarding ESG matters, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors and other key stakeholders or our initiatives are not executed as planned or

do not meet evolving legal and regulatory standards, our reputation and financial results could be materially and adversely affected.

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

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

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors ("Board") is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board. Among other things, these provisions:

- establish a classified Board such that not all members of the Board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our Board;
- limit the manner in which stockholders can remove directors from the Board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- authorize our Board to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board; and
- require the approval of the holders of at least 66 ⅔% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

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

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

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case, to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated bylaws provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors and executive officers. With certain exceptions, these agreements provide for indemnification for related expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in connection with any action, proceeding or investigation. We believe that these amended and restated certificate of incorporation and amended and restated bylaws provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will, to the fullest extent permitted by applicable law, be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware), to the fullest extent permitted by applicable law, is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and
- any action or proceeding asserting a claim against us by any of our directors, officers or other employees governed by the internal affairs doctrine.

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

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

General Risk Factors

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

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

Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under the 2032 Notes.

As of the date of this Quarterly Report on Form 10-Q, we have $575.0 million principal amount of indebtedness outstanding under our 1.50% Convertible Senior Notes due 2032 (the "2032 Notes"). We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the 2032 Notes; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the 2032 Notes, and our cash needs may increase in the future. In addition, future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full.

We may be unable to raise the funds necessary to repurchase the 2032 Notes for cash following a fundamental change or to pay any cash amounts due upon maturity or conversion of the 2032 Notes, and our other indebtedness may limit our ability to repurchase the 2032 Notes or to pay any cash amounts due upon their maturity or conversion.

Holders of the 2032 Notes may, subject to a limited exception, require us to repurchase their 2032 Notes following a "fundamental change" (as defined in the indenture governing the 2032 Notes) at a cash repurchase price generally equal to the principal amount of the 2032 Notes to be repurchased, plus accrued and unpaid interest, if any. Upon maturity of the 2032 Notes, we must pay their principal amount and accrued and unpaid interest in cash, unless they have been previously repurchased, redeemed or converted. In addition, upon conversion, we will satisfy part or all of our conversion obligation in cash unless we elect to settle conversions solely in shares of our common stock. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the 2032 Notes or pay any cash amounts due upon their maturity or conversion. In addition, applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the 2032 Notes or to pay any cash amounts due upon their maturity or conversion. Our failure to repurchase 2032 Notes or to pay any cash amounts due upon their maturity or conversion when required will constitute a default under the indenture governing the 2032 Notes. A default under the indenture governing the 2032 Notes or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the 2032 Notes.

Provisions in the indenture governing the 2032 Notes could delay or prevent an otherwise beneficial takeover of us.

Certain provisions in the 2032 Notes and the indenture governing the 2032 Notes could make a third-party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then, subject to a limited exception, holders of the 2032 Notes will have the right to require us to repurchase their 2032 Notes for cash. In addition, if a takeover constitutes a "make-whole fundamental change" (as defined in the indenture governing the 2032 Notes), then we may be required to temporarily increase the conversion rate. In either case, and in other cases, our obligations under the 2032 Notes and the indenture governing the 2032 Notes could increase the cost of acquiring us or otherwise discourage a third party from acquiring us, including in a transaction that holders of the 2032 Notes or holders of our common stock may view as favorable.

The accounting method for the 2032 Notes could adversely affect our reported financial condition and results.

The accounting method for reflecting the 2032 Notes on our balance sheet, accruing interest expense for the 2032 Notes and reflecting the underlying shares of our common stock in our reported diluted earnings per share may adversely affect our reported earnings and financial condition.

We are currently assessing the accounting effects of the 2032 Notes on our consolidated financial statements. In accordance with applicable accounting standards, we expect that the 2032 Notes will be reflected as a liability on our balance sheets, with the initial carrying amount equal to the principal amount of the 2032 Notes, net of issuance costs. The issuance costs would be treated as a debt discount for accounting purposes, which would be amortized into interest expense over the term of the 2032 Notes. As a result of this amortization, the interest expense that we expect to recognize for the 2032 Notes for accounting purposes could be greater than the cash interest payments we will pay on the 2032 Notes, which would result in lower reported income.

Furthermore, if any of the conditions to the convertibility of the 2032 Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the 2032 Notes as a current, rather than a long-term, liability. This reclassification could be required even if no noteholders convert their 2032 Notes and could materially reduce our reported working capital.

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

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

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

or future banks will not face similar risks as SVB or that we will be able to recover in full our deposits in the event of similar closures. If one or any of the financial institutions in which we hold our funds for working capital and operating expense needs were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner.

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

International trade policies are subject to periodic revision and may change in response to economic, geopolitical or national security considerations. The U.S. government and certain foreign governments have recently announced new or increased tariffs on imported goods, and additional tariffs or increases in tariffs could be assessed in the future. Pharmaceuticals have historically been exempt from tariffs. However, pursuant to Section 232 of the Trade Expansion Act of 1962, the U.S. government has imposed a 100% tariff on patented pharmaceutical products and ingredients manufactured outside the U.S., subject to certain exemptions and reduced rates, including delayed implementation, reduced rates for imports from certain countries, exemptions for specific product categories, and pathways to mitigate tariffs through onshoring and pricing agreements with the U.S. government. It is possible that the imposition of tariffs on a range of pharmaceutical products and ingredients may negatively impact certain aspects of our manufacturing process for our clinical trial product materials and supplies, the level of expenses related to our vaccine candidates or preclinical and clinical development programs, and our business.

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

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

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

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

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

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

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

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

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

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

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

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have control over these analysts. If securities or industry analysts do not publish research or reports about our business, the trading price for our stock would likely be negatively impacted. If one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Item 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

During the three months ended September 30, 2026, none of our directors or Section 16 officers adopted, modified or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 3, 2026, the Company entered into an amendment to the Executive Change in Control and Severance Agreement between the Company and Mikhail Eydelman, its Senior Vice President, General Counsel (as so amended, the "Amended Agreement"). In connection with certain organizational changes implemented as of August 31, 2026 impacting Mr. Eydelman's role, Mr. Eydelman and the Company have formally agreed that he will remain employed until at least the earlier of (i) May 31, 2027 (the "Scheduled Date"), or (ii) the date on which an Early Termination Event occurs (the period between August 31, 2026 and the earlier to occur of the Scheduled Date or Early Termination Event, the "Continued Employment Period"). During the Continued Employment Period, Mr. Eydelman will continue to vest in his Company equity awards and to earn base salary and annual incentives as currently in effect. The Amended Agreement also preserves Mr. Eydelman's Good Reason severance rights for the duration of the Continued Employment Period. Unless Mr. Eydelman's employment continues past the Scheduled Date, upon his termination of employment for Good Reason, Mr. Eydelman will be entitled to receive the severance benefits that apply upon a termination of his employment for Good Reason under the Change in Control and Severance Agreement as previously disclosed, except that, pursuant to the Amended Agreement, the severance benefits to apply to Mr. Eydelman upon a Qualifying Termination are modified such that the references to 12 months have been reduced to 9 months.

Capitalized terms not otherwise defined herein have the meanings set forth in the Amended Agreement.

The foregoing description of the Amended Agreement is only a summary and is qualified in its entirety by the Second Amendment to Change in Control and Severance Agreement between Vaxcyte, Inc. and Mikhail Eydelman, dated November 3, 2026, disclosed herewith.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Schedule Form	File Number	Exhibit	Filing Date
3.1	Second Amended and Restated Certificate of Incorporation of Vaxcyte, Inc.	10-K	001-39323	3.1	February 24, 2026
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
4.6	Form of Pre-Funded Warrant.	8-K	001-39323	4.1	September 6, 2024
10.1#	Second Amendment to Executive Change in Control and Severance Agreement entered into by and between the Registrant and Mikhail Eydelman.				X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
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.				X
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.				

X Filed herewith.

# Indicates a management contract or compensatory plan or arrangement.

† The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as

amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Vaxcyte, Inc.

Date: November 4, 2026 By: /s/ Grant E. Pickering

Grant E. Pickering

Chief Executive Officer

Date: November 4, 2026 By: /s/ Andrew Guggenhime

Andrew Guggenhime

President and Chief Financial Officer

SECOND AMENDMENT TO

EXECUTIVE CHANGE IN CONTROL AND SEVERANCE AGREEMENT

This Second Amendment to Executive Change in Control and Severance Agreement (this "**Amendment**") is entered into by and between Mikhail Eydelman ("**Executive**") and Vaxcyte, Inc., a Delaware corporation (the "**Company**"), effective as of the date of the last signature below (the "**Amendment Effective Date**").

A. The Company and Executive are parties to a certain Executive Change in Control and Severance Agreement dated as of April 1, 2022, as amended by that certain First Amendment to Executive Change in Control and Severance Agreement effective December 31, 2025 (collectively, the "**Agreement**").

B. The Company initiated organizational changes that include, without limitation, any one or more of the following: the hiring of a new Chief Legal Officer, changes to Executive's reporting relationship, and/or modifications to Executive's duties, authority, or responsibilities (collectively, whether occurring individually or in combination, the "**Organizational Changes**").

C. The Company and Executive acknowledge and agree that the Organizational Changes (in whole or in part), constitute "Good Reason" under the Agreement.

D. The Company has determined that it is in the best interests of the Company and its stockholders to provide Executive with certain enhanced protections to induce Executive to continue his employment notwithstanding the occurrence of the Organizational Changes.

E. The Company and Executive desire to enter into this Amendment to establish the terms of Executive's continued employment for nine (9) months following the Organizational Changes, including Executive's title, compensation, equity vesting, and benefits, and to preserve Executive's Good Reason resignation right and related severance entitlements under the Agreement as set forth herein.

F. The Company intends, and the Company and Executive acknowledge, that this Amendment is being entered into in connection with a specific, discrete set of Organizational Changes and is tailored to address Executive's unique role, tenure, and contributions to the Company in the context of those particular changes.

G. The parties intend that the enhanced protections and terms set forth in this Amendment reflect the Company's recognition of Executive's significant value to the organization during this transitional period and are designed to facilitate a smooth and orderly transition in connection with Organizational Changes.

Now, therefore, in consideration of the mutual promises, covenants and agreements contained herein, and in consideration of the continuing employment of Executive by the Company, the parties agree as follows:

Section 1. Continued Employment Period.

(a) Establishment. During the period (the "**Continued Employment Period**") that begins on August 31, 2026 (the "**Trigger Date**") and continues until (and includes) the earlier of (x) May 31, 2027 (the "**Scheduled End Date**") or (y) the date on which an Early Termination Event (as defined below) occurs, the Company shall continue to employ Executive and Executive shall remain employed by the Company on the terms set forth in this Amendment. The Company shall not terminate Executive's employment before the Scheduled End Date except pursuant to an Early Termination Event, and any purported termination in violation of this Section 1(a) shall be void and of no effect. An "**Early Termination Event**" means the termination of Executive's employment with the Company due to (a) Executive's termination for Cause, (b) a Mutual Termination (as defined in Section 1(d) below), (c) a CIC Termination (as defined in Section 1(e) below), or (d) Executive's death.

(b) Company Right to Place on Garden Leave. During the Continued Employment Period, the Company may, in its sole discretion, relieve Executive from the performance of active duties and place Executive on paid garden leave. Placement of Executive on garden leave pursuant to this Section 1(b) does not constitute a reduction in title, duties, or responsibilities or breach of agreement for purposes of the Agreement or any other agreement between Executive and the Company or any Company policy or plan applicable to Executive. Further, any such placement on garden leave shall not constitute a Separation, a termination of employment, or a cessation of "Continuous Service" under the Company's 2020 Equity Incentive Plan (the "**Plan**") or any successor plan. During any period of garden leave, Executive shall remain a W-2 employee of the Company, shall continue to receive Executive's full base salary in accordance with the Company's standard payroll practices, and remain eligible for an annual target bonus of forty-five percent (45%) of Executive's annualized base salary. Executive's employment during any garden leave shall constitute "Continuous Service" under the Plan for all purposes, including equity vesting. If Executive is on garden leave as of the end of the Continued Employment Period, then, immediately upon the expiration of the Continued Employment Period, Executive's employment with the Company shall terminate and such termination shall be deemed to constitute a Qualifying Termination or CIC Qualifying Termination, as applicable, for purposes of the Agreement and Executive's right to receive severance under the Agreement in such event shall be subject to the release requirement of Section 4 of the Agreement.

(c) Termination for Cause. The Company retains the right to terminate Executive's employment for Cause at any time, including during and after the Continued Employment Period. In the event of a termination for Cause Executive shall be entitled only to (i) the Accrued Compensation and Expenses and Accrued Benefits (each as defined in Section 5 of the Agreement) and (ii) if such termination occurs during the Continued Employment Period, a lump-sum cash payment, subject to and solely in

consideration of Executive's execution, delivery and non-revocation of a general release of claims on a form provided by the Company within fifteen (15) days of such termination and as otherwise provided in Section 4 of the Agreement, in the amount equal to the sum of: (x) nine (9) months of Executive's base salary as of the date of such termination, (y) the cost of (9) months of family COBRA continuation coverage, and (z) an amount equal to 45% of Executive's then-current annual base salary, multiplied by a fraction, the numerator of which is the number of days Executive was employed during the calendar year through the termination date and the denominator of which is the total number of days in that calendar year, payable on the first business day occurring after the sixtieth (60th) day following Executive's termination for Cause, provided such release has become effective and irrevocable. For avoidance of doubt, the payment set forth in clause (ii), if payable, is made solely in consideration of Executive's release of claims and does not constitute severance under the Agreement. Except as expressly provided in the immediately preceding sentence, if Executive is terminated for Cause, (x) all severance benefits, equity acceleration, and other entitlements under this Amendment and the Agreement shall be forfeited; (y) any unvested Equity Awards shall terminate and be forfeited as of the date of such termination; and (z) the Stipulated Good Reason Event shall be deemed extinguished and Executive shall have no further right to resign for Good Reason. For purposes of this Section 1(c), Cause includes acts or omissions by Executive occurring before the Amendment Effective Date that come to light after the Amendment Effective Date. Executive represents that, to his reasonable belief after reasonable inquiry, he has not committed Cause prior to the Amendment Effective Date. The Company represents it is not currently aware of any acts or omissions by Executive that would constitute Cause.

(d) Mutual Termination. At any time during the Continued Employment Period, the Company and Executive may mutually agree in writing to terminate Executive's employment with the Company (a "**Mutual Termination**"). Upon a Mutual Termination, the Continued Employment Period shall immediately terminate and such termination shall be deemed to constitute a Qualifying Termination or CIC Qualifying Termination, as applicable, for purposes of the Agreement and Executive's right to receive severance under the Agreement in such event shall be subject to the release requirement of Section 4 of the Agreement.

(e) Change in Control Termination. If a Change in Control occurs during the Continued Employment Period, (i) the Company may terminate Executive's employment without Cause at any time before the end of the Continued Employment Period and (ii) if such Change in Control occurs within sixty (60) days before the Scheduled End Date, Executive may resign for Good Reason effective as of the Scheduled End Date (without regard to the sixty (60)-day notice requirement set forth in Section 2(b)) by delivering written notice of such resignation to the Company on or before the Scheduled End Date (any such termination, a "**CIC Termination**"). If Executive incurs a CIC Termination, then, subject to satisfaction of the release conditions set forth in Section 4 of the Agreement, such CIC Termination shall be deemed to constitute a CIC Qualifying Termination for purposes of the Agreement and Executive shall be entitled to the severance benefits set forth in Section 3 of the Agreement. For the avoidance of doubt, upon a CIC Termination: (i) Executive shall be entitled solely to the CIC Qualifying Termination benefits under Section 3 of the Agreement, and (ii) no additional severance, salary continuation, or other

compensation shall be payable under this Amendment or Section 2 of the Agreement in connection with such CIC Termination.

(f) Cooperation. Upon the receipt of reasonable notice from the Company (or its agents, including outside counsel), Executive agrees that during the Continued Employment Period and for six (6) months thereafter, Executive will reasonably and timely respond and provide information with regard to matters of which Executive has knowledge as a result of his employment with the Company, and will provide reasonable and timely assistance to the Company, its affiliates and their respective representatives in review of any investigative matters, defense or prosecution of any claims, or assistance in other proceedings (collectively, "**Claims**"). Upon presentation of appropriate documentation, the Company will pay or reimburse the Executive for all reasonable and necessary out-of-pocket travel expenses incurred by Executive in complying with this Section 1(f) provided that the Company has preapproved them in writing before being incurred by Executive. In addition, the Company will pay Executive an hourly fee, in the amount of $300.00, measured in quarter-hour increments, for services rendered by Executive in complying with this Section 1(f); *provided* that no such payment will be required by the Company under this Section 1(f) during the Continued Employment Period; *provided further* that no fee shall be paid in relation to any time spent by Executive in providing testimony in any legal proceeding.

Section 2. Good Reason Stipulation and Severance.

(a) Acknowledgment and Stipulation. The Company and Executive acknowledge and agree that the occurrence of the Organizational Changes (in whole or in part) constitute a "Good Reason" event under the Agreement (the "**Stipulated Good Reason Event**"). For all purposes of this Amendment, the Company and Executive acknowledge and agree that the Stipulated Good Reason Event shall be deemed to have occurred on the Trigger Date. Subject to Section 1(c) of this Amendment, this stipulation is binding, irrevocable, and may not be rescinded, modified, or challenged by the Company.

(b) Good Reason Termination. Executive may provide written notice of Executive's voluntary resignation to the Company at any time during the Continued Employment Period, *provided* that (i) the effective date of Executive's resignation is the Scheduled End Date and (ii) such written notice is provided at least sixty (60) days before the Scheduled End Date. If Executive resigns pursuant to and in accordance with this Section 2(b) (a "**Good Reason Resignation**"), such Good Reason Resignation shall be deemed to constitute a Qualifying Termination or CIC Qualifying Termination, as applicable, for purposes of the Agreement and Executive's right to receive severance under the Agreement in such event shall be subject to the release requirement of Section 4 of the Agreement.

Section 3. Title, Salary, Bonus, Modified Severance and Benefits.

(a) Title. During the Continued Employment Period, Executive shall, unless placed on garden leave pursuant to Section 1(b), hold a title no less senior than Senior Vice President, General Counsel.

(b) Base Salary. During the Continued Employment Period, Executive's annualized base salary shall be no less than Five Hundred Twenty-Four Thousand Dollars ($524,000) per annum, payable in accordance with the Company's standard payroll practices.

(c) Annual Target Bonus. During the Continued Employment Period, Executive shall remain eligible for an annual target bonus of no less than forty-five percent (45%) of Executive's annualized base salary, to be determined and paid on the same terms and conditions applicable to similarly situated executives of the Company. For the avoidance of doubt, Executive's target bonus opportunity is neither enhanced nor reduced by this Amendment nor by placement of Executive on garden leave, and nothing herein alters the discretionary nature of bonus determinations or the terms of any applicable bonus plan.

(d) Employee Benefits. During the Continued Employment Period, Executive shall continue to participate in all employee benefit plans and programs (including health, dental, vision, life insurance, disability, and 401(k) plans) on the same terms and conditions applicable to active, full-time executives of the Company. During any period of garden leave pursuant to Section 1(b), Executive's eligibility for employee benefit plans and programs shall be determined under the terms of the applicable plans. If Executive is no longer covered by the Company's benefit plans as an active full-time employee and such cessation of coverage triggers Executive's right to elect COBRA continuation coverage, Executive shall be obligated to elect COBRA benefits for such benefits to continue and the Company shall reimburse Executive for all such COBRA costs during the period of garden leave.

(e) Modified Severance. Notwithstanding any other provision of this Amendment or the Agreement, with respect to any Qualifying Termination that occurs on or after the Trigger Date and on or before the Scheduled End Date (including, for greater clarity, a Good Reason Resignation, Mutual Termination, or termination pursuant to Section 1(b)), references to "twelve (12) months" in Section 2(a)(i) of the Agreement and "twelve (12)-month" in Section 2(b) of the Agreement are hereby deleted in their entirety and replaced with "nine (9) months" and "nine (9)-month," respectively. For the avoidance of doubt, salary, bonus, benefits, and equity awards received by Executive during the Continued Employment Period constitute compensation for Executive's employment (including any period of garden leave) and shall not be offset against, reduce, or serve as a credit toward any severance benefits payable under the Agreement or this Amendment.

Section 4. Treatment of Equity Awards.

(a) Annual Equity Awards. During the Continued Employment Period, Executive shall be eligible to receive Annual Equity Awards (as defined below) that are substantially comparable in the aggregate to the Annual Equity Awards granted to other executives of the Company holding the title of Senior Vice President, including with respect to grant frequency, target grant value, vesting schedules, and other material terms and conditions. Nothing in this Section 4(a) shall require the Company to make any particular grant or guarantee any specific award value; *provided*, *however*, that the Company shall not exclude, bypass, or discriminate against Executive in the allocation of Annual Equity Awards, and Executive's status during the Continued Employment Period, placement on garden leave pursuant to

Section 1(b), or the existence of this Amendment shall not constitute a basis for reducing the target grant value or frequency of Annual Equity Awards below the level that would otherwise apply to Executive. Any new Annual Equity Awards granted to Executive during the Continued Employment Period shall be subject to the vesting, acceleration, and Continuous Service provisions set forth in this Section 4 and the Plan. For purposes of this Agreement, "**Annual Equity Awards**" means ordinary-course annual equity awards granted by the Company to Senior Vice Presidents and excludes, for avoidance of doubt, new-hire, sign-on, or make-whole equity awards and any individually negotiated promotional, retention, or similar off-cycle equity awards.

(b) Vesting During the Continued Employment Period. All outstanding Equity Awards (as defined in the Agreement) held by Executive as of the Trigger Date or received pursuant to Section 4(a) above shall continue to vest on their original vesting schedules throughout the Continued Employment Period, as if Executive remained in active, full-time service with the Company. If the Company places Executive on garden leave pursuant to Section 1(b), all outstanding Equity Awards shall continue to vest through the expiration of the Continued Employment Period as if Executive had remained in active service.

(c) Company Covenant Regarding Plan Administration. The Company covenants and agrees to take, and to cause the Plan Administrator (as defined in the Plan) to take, all actions necessary to ensure that Executive's service is treated as "Continuous Service" under the Plan throughout the Continued Employment Period, including during any period of garden leave, and that no Equity Award is terminated, forfeited, or otherwise adversely affected by reason of Executive's removal from active duties during the Continued Employment Period.

Section 5. Employment Following Scheduled End Date.

(a) General. This Section 5 sets forth the terms of Executive's employment with the Company, effective as of immediately following the Scheduled End Date, if Executive (i) remains actively employed with the Company through the Scheduled End Date, (ii) is not on garden leave when the Scheduled End Date occurs, and (iii) has not provided notice of resignation prior to the Scheduled End Date in accordance with Section 2(b) of this Amendment.

(b) At Will Employment; Salary; Bonus; Title. Executive's employment relationship with the Company shall be "at will". Executive's annualized base salary shall initially be equal to Executive's annualized base salary in effect as of the Scheduled End Date, and Executive's annual target bonus opportunity shall initially be equal to Executive's annual target bonus opportunity in effect immediately prior to the Scheduled End Date. The Company reserves the right to reduce Executive's base salary or target annual bonus at any time following the Scheduled End Date. Following the Scheduled End Date, Executive shall no longer have the title Senior Vice President, General Counsel.

(c) Waiver of Right to Resign for Stipulated Good Reason. Executive shall be deemed to have forever and irrevocably waived any right to resign for Good Reason based on the Stipulated Good

Reason Event, any of the Organizational Changes, or any fact or circumstance that occurred before the Scheduled End Date. Moreover, the Stipulated Good Reason Event shall be deemed extinguished for all purposes of the Agreement and this Amendment.

(d) Modified Good Reason. Effective as of immediately following the Scheduled End Date, the definition of "Good Reason" shall be amended and restated in its entirety to read as follows:

> ""**Good Reason**" means the occurrence, after June 1, 2027, of any of the following without Executive's consent: (i) a relocation of Executive's principal workplace by more than 35 miles unless such relocation is within 35 miles of Executive's principal residence; (ii) a material reduction in Executive's base pay or target bonus in excess of 10%, other than in connection with across-the-board reductions in base pay or bonus based on the Company's financial performance similarly affecting all or substantially all of the Company's executives; (iii) a diminution of Executive's title to a position below that of a Senior Vice President; (iv) any requirement that Executive engage in any conduct he or she reasonably believes is illegal; or (v) a material breach by the Company of this Agreement or any other agreement between Executive and the Company. A condition shall not be considered "Good Reason" unless Executive gives the Company written notice of such condition within ninety (90) days after such condition comes into existence or Executive knew or should have known with reasonable diligence of its existence, and the Company fails to remedy such condition within thirty (30) days after receiving Executive's written notice. Executive must resign Executive's employment no later than fifteen (15) days following expiration of the Company's thirty (30) day cure period or written receipt from the Company of its intent not to cure."

(e) Other Terms of Employment. Executive shall continue to be covered by the Agreement (as amended by Section 5(d) of this Amendment) and any other written agreement(s) then in effect between Executive and the Company. For the avoidance of doubt, the modified severance set forth in Section 3(e) of this Amendment shall only be applicable to a Qualifying Termination that occurs after the Trigger Date and on or before the Scheduled End Date and not to a Qualifying Termination that occurs after the Scheduled End Date in accordance with Section 5 of this Amendment.

Section 6. Post-Trigger Protections.

(a) No Unilateral Modification. The Company may not amend, terminate, modify, or waive any provision of this Amendment or the Continued Employment Period without Executive's prior written consent.

(b) Successor Obligation. Section 7(a) of the Agreement is hereby supplemented to provide that the successor assumption obligation extends to all provisions of this Amendment.

Section 7. General Provisions.

(a) Conflicts. In the event of a conflict between the terms of the Agreement (including Amendment No. 1) and the terms of this Amendment, the terms of this Amendment shall control.

(b) Choice of Law. This Amendment shall be governed by and construed in accordance with the laws of the State of California, excluding laws relating to conflicts or choice of law, consistent with Section 9(c) of the Agreement.

(c) Authorization, Non-Challenge, and Irrevocability. The Company represents and warrants that the individual signing this Amendment has been duly authorized by the Company to execute this Amendment and to bind the Company to all obligations set forth herein. The Company covenants that it shall not, directly or indirectly, challenge, contest, or seek to invalidate this Amendment on any ground. The Company may not rescind, terminate, or unilaterally modify this Amendment after execution, and any attempt to do so shall be void and of no effect.

(d) Severability. If any provision of this Amendment is held invalid or unenforceable, the remaining provisions shall remain in full force and effect, and any invalid provision shall be modified to the minimum extent necessary to make it valid and enforceable.

(e) Entire Amendment. This Amendment constitutes the entire agreement of the parties with respect to the subject matter hereof and supersedes all prior discussions, negotiations, and agreements relating to the subject matter hereof, including the Organizational Changes, the Stipulated Good Reason Event, the Continued Employment Period, and employment following the Scheduled End Date. Except as expressly modified by this Amendment all terms and conditions of the Agreement (as amended by Amendment No. 1) remain in full force and effect.

(f) Counterparts. This Amendment may be executed in counterparts and by electronic means, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument.

(g) Taxes. All payments made under the Agreement or the terms of this Amendment shall be subject to applicable withholding and income taxes. Further, all payments under this Amendment shall be subject to Section 9(a) of the Agreement.

IN WITNESS WHEREOF, each of the parties has executed this Amendment, in the case of the Company by its duly authorized officer, as of the date of the last signature below. This Amendment may be signed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

EXECUTIVE

By: /s/ Mikhail Eydelman
Name: Mikhail Eydelman
Title: SVP, General Counsel
Date: 11/3/2026

VAXCYTE, INC.

By: /s/ Grant E. Pickering
Name: Grant E. Pickering
Title: Chief Executive Officer
Date: 11/2/2026

[Signature Page to Second Amendment to Executive Change in Control and Severance Agreement]

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: November 4, 2026

By: /s/ Grant E. Pickering

Grant E. Pickering

Chief Executive Officer

Exhibit 31.2

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

I, Andrew Guggenhime, certify that:

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

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

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

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

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 4, 2026 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 September 30, 2026, 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: November 4, 2026

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

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

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