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

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended March 31, 2021**

**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.)** |
| **353 Hatch Drive**<br>**Foster City, California** | **94404** |
| **(Address of principal executive offices)** | **(Zip Code)** |

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

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

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

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

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

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

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

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

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

As of May 7, 2021, the registrant had 51,378,730 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.

"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 report, 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 coverage and immunogenicity of our vaccine candidates;
- our expectations regarding our preclinical study results potentially being predictive of clinical study results;
- our belief that our pneumococcal conjugate vaccine candidates could receive regulatory approval based on a demonstration of non-inferiority to the standard of care using well-defined surrogate immune endpoints rather than requiring clinical field efficacy studies;
- the timing of the initiation, progress and potential results of our preclinical studies, clinical trials and our research and development programs;
- our ability to advance vaccine candidates into, and successfully complete, preclinical studies and clinical trials;
- the commercialization of our vaccine candidates, if approved;
- estimates of our future expenses, capital requirements and our needs for additional financing;
- our ability to compete effectively with existing competitors and new market entrants;
- our ability to establish and maintain intellectual property protection for our products or avoid claims of infringement;
- our and our third-party manufacturers’ manufacturing capabilities and the scalable nature of our manufacturing process;
- potential effects of extensive government regulation;
- the pricing, coverage and reimbursement of our vaccine candidates, if approved;
- our ability and the ability of our third-party contract manufacturers to operate and continue operations in light of the COVID-19 pandemic;
- our ability to hire and retain key personnel;
- our ability to obtain additional financing;
- the volatility of the trading price of our common stock; and
- our expectation regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act.

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 early stages of vaccine development and have a very limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant net losses since inception and anticipate that we will continue to incur substantial net losses for the foreseeable future. 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 have never been tested in human subjects and are in early, preclinical stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we are unable to complete development of or commercialize our vaccine candidates or experience significant delays in doing so, our business would be materially harmed.
- The U.S. Food and Drug Administration, or FDA, may disagree with our regulatory plan, and we may fail to obtain regulatory approval of our vaccine candidates.
- Our business is highly dependent on the success of VAX-24, which is in the early stages of development. If we are unable to obtain approval for VAX-24 and effectively commercialize VAX-24, our business would be significantly harmed.
- Our primary competitors have significantly greater resources and experience than we do, which may make it difficult for us to successfully develop our vaccine candidates, or may result in others discovering, developing or commercializing products before or more successfully than us.
- We may not be successful in our efforts to use our cell-free protein synthesis platform to expand our pipeline of vaccine candidates and develop marketable products.
- We currently rely on third-party manufacturing and supply partners, including Lonza Ltd., or Lonza, and Sutro Biopharma, Inc., or Sutro Biopharma, to supply raw materials and components for, and manufacture of, our preclinical and clinical supplies as well as our vaccine candidates. Our inability to procure necessary raw materials or to have sufficient quantities of preclinical and clinical supplies or the inability to have our vaccine candidates manufactured, including delays or interruptions at our third-party manufacturers, or our failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.
- Our business could be adversely affected by the effects of health epidemics, including the ongoing effects of the COVID-19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations. The COVID-19 pandemic could materially affect our operations, including at our headquarters in the San Francisco Bay Area, as well as the business or operations of our contract manufacturers or other third parties with whom we conduct business.
- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our vaccine candidates.
- If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

**PART I—FINANCIAL INFORMATION**

**Item 1. Financial Statements**

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

| | March 31, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 198,939 | $ 386,200 |
| Short-term investments | 122,180 | — |
| Prepaid expenses and other current assets | 3,595 | 2,804 |
| Total current assets | 324,714 | 389,004 |
| Property and equipment, net | 4,994 | 3,272 |
| Operating lease right-of-use assets | 1,028 | — |
| Long-term investments | 49,754 | — |
| Restricted cash | 871 | — |
| Other assets | 990 | 550 |
| Total noncurrent assets | 57,637 | 3,822 |
| Total assets | $ 382,351 | $ 392,826 |
| | | |
| **Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 31,864 | $ 29,785 |
| Accrued compensation | 1,007 | 284 |
| Accrued manufacturing expenses | 15,538 | 13,012 |
| Accrued expenses (including related party accrual of $1,874 and $677 as of March 31, 2021 and December 31, 2020, respectively) | 5,774 | 3,766 |
| Deferred rent — current | — | 14 |
| Operating lease liabilities — current | 833 | — |
| Total current liabilities | 55,016 | 46,861 |
| Deferred rent — long-term | — | 10 |
| Operating lease liabilities — long-term | 295 | — |
| Other liabilities | 103 | 112 |
| Total liabilities | 55,414 | 46,983 |
| | | |
| Commitments and contingencies (Note 6) | | |
| **Stockholders' Equity (Deficit)** | | |
| Preferred stock, $0.001 par value — 10,000,000 shares authorized at March 31, 2021 and December 31, 2020; no shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively | — | — |
| Common stock, $0.001 par value — 500,000,000 shares authorized at March 31, 2021 and December 31, 2020; 51,338,801 and 51,071,593 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively | 54 | 54 |
| Additional paid-in capital | 546,714 | 544,353 |
| Accumulated other comprehensive loss | (47) | — |
| Accumulated deficit | (219,784) | (198,564) |
| Total stockholders' equity (deficit) | 326,937 | 345,843 |
| Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit) | $ 382,351 | $ 392,826 |

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

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2021** | **2020** |
| Operating expenses: | | |
| Research and development (including related party expenses of $1,612 and $218 for the three months ended March 31, 2021 and 2020, respectively) | $ 17,258 | $ 24,315 |
| General and administrative | 5,885 | 3,281 |
| Total operating expenses | 23,143 | 27,596 |
| Loss from operations | (23,143) | (27,596) |
| Other income (expense), net: | | |
| Interest expense | — | (7) |
| Interest income | 61 | 135 |
| Grant income | — | 329 |
| Foreign currency transaction gains (losses) | 1,862 | (3) |
| Total other income (expense), net | 1,923 | 454 |
| Net loss | $ (21,220) | $ (27,142) |
| Net loss per share, basic and diluted | $ (0.41) | $ (6.70) |
| Weighted-average shares outstanding, basic and diluted | 51,174,978 | 4,049,848 |

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

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2021 | 2020 |
| **Net Loss** | $ (21,220) | $ (27,142) |
| Other comprehensive loss: | | |
| Unrealized loss on investments | (47) | — |
| **Comprehensive loss** | $ (21,267) | $ (27,142) |

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

**VAXCYTE, INC.**
**Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)**
*(in thousands, except share data)*
*(unaudited)*

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Loss | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance — December 31, 2020** | 51,071,593 | $ 54 | $ 544,353 | $ (198,564) | $ — | $ 345,843 |
| Exercise of stock options | 267,208 | — | 487 | — | — | 487 |
| Vesting of early exercised stock options | — | — | 9 | — | — | 9 |
| Stock-based compensation expense | — | — | 1,865 | — | — | 1,865 |
| Unrealized losses on investments | — | — | — | — | (47) | (47) |
| Net loss | — | — | — | (21,220) | — | (21,220) |
| **Balance — March 31, 2021** | 51,338,801 | $ 54 | $ 546,714 | $ (219,784) | $ (47) | $ 326,937 |

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

**VAXCYTE, INC.**
**Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)**
*(in thousands, except share data)*
*(unaudited)*

| | Series A Redeemable Convertible Preferred Stock | | Series B Redeemable Convertible Preferred Stock | | Series C Redeemable Convertible Preferred Stock | | Series D Redeemable Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | | | |
| **Balance — December 31, 2019** | 6,225,719 | $ 24,967 | 6,786,896 | $ 55,151 | 7,377,480 | $ 80,192 | — | $ — | 4,059,909 | $ 7 | $ 2,967 | $ (109,347) | $ (106,373) |
| Exercise of stock options | — | — | — | — | — | — | — | — | 28,837 | — | 49 | — | 49 |
| Issuance of common stock related to early exercised stock options | — | — | — | — | — | — | — | — | 14,819 | — | — | — | — |
| Vesting of early exercised stock options | — | — | — | — | — | — | — | — | — | — | 128 | — | 128 |
| Issuance of Series D redeemable convertible preferred stock, net of issuance cost of $125 | — | — | — | — | — | — | 8,220,242 | 109,875 | — | — | — | — | — |
| Stock-based compensation expense | — | — | — | — | — | — | — | — | — | — | 372 | — | 372 |
| Net loss | — | — | — | — | — | — | — | — | — | — | — | (27,142) | (27,142) |
| **Balance — March 31, 2020** | 6,225,719 | $ 24,967 | 6,786,896 | $ 55,151 | 7,377,480 | $ 80,192 | 8,220,242 | $ 109,875 | 4,103,565 | $ 7 | $ 3,516 | $ (136,489) | $ (132,966) |

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

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2021** | **2020** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (21,220) | $ (27,142) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 347 | 384 |
| Stock-based compensation expense | 1,865 | 372 |
| Change in fair value of redeemable convertible preferred stock warrant | — | 179 |
| Amortization of operating right-of-use assets | 180 | — |
| Net amortization of premiums on investments | 151 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | (557) | (951) |
| Other assets | (441) | (89) |
| Operating lease liabilities | (105) | — |
| Accounts payable | 2,185 | (723) |
| Accrued compensation | 723 | (65) |
| Accrued manufacturing expenses | 2,525 | 13,159 |
| Accrued expenses | 1,142 | 1,245 |
| Deferred rent and other long-term liabilities | — | (2) |
| Net cash used in operating activities | (13,205) | (13,633) |
| **Cash flows from investing activities:** | | |
| Purchases of property and equipment | (1,246) | (349) |
| Purchases of investments | (172,145) | — |
| Net cash used in investing activities | (173,391) | (349) |
| **Cash flows from financing activities:** | | |
| Payments of capital lease obligations | — | (60) |
| Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs | — | 109,875 |
| Proceeds from exercise of common stock options | 487 | 49 |
| Proceeds from issuance of common stock related to early exercised stock options | — | 36 |
| Payments of deferred offering costs | — | (103) |
| Net cash provided by financing activities | 487 | 109,797 |
| **Effect of exchange rate changes on cash and cash equivalents** | (281) | — |
| Net increase (decrease) in cash, cash equivalents and restricted cash | (186,390) | 95,815 |
| Cash, cash equivalents and restricted cash, beginning of period | 386,200 | 58,976 |
| Cash, cash equivalents and restricted cash, end of period | $ 199,810 | $ 154,791 |
| **Supplemental disclosure of cash flow information:** | | |
| Cash paid for interest | $ — | $ 7 |
| **Supplemental disclosures of non-cash investing and financing activities:** | | |
| Purchases of property and equipment recorded in accounts payable and accrued expenses | $ 1,537 | $ 35 |
| Issuance costs for initial public offering included in accounts payable and accrued expenses | $ — | $ 142 |

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

## 1. Company Organization and Nature of Business

Vaxcyte, Inc. ("we," "us," "the Company," or "Vaxcyte"), headquartered in Foster City, California, was incorporated in the state of Delaware on November 27, 2013 as SutroVax, Inc. and we changed our name to Vaxcyte, Inc. on May 15, 2020. We are a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent or treat some of the most common and deadly infectious diseases worldwide. Our cell-free protein synthesis platform enables us to design and produce protein carriers and antigens, the critical building blocks of vaccines, in ways that we believe conventional vaccine technologies currently cannot. Our pipeline includes pneumococcal conjugate vaccine ("PCV") candidates that we believe are among the most broad-spectrum PCV candidates currently in development, targeting the $7 billion global pneumococcal vaccine market. Our lead vaccine candidate, VAX-24, is a 24-valent investigational PCV. We anticipate submitting our initial investigational new drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for VAX-24 between January and June 2022 and initiating our Phase 1/2 clinical proof-of-concept study in adults thereafter. We expect to announce topline data from this study between late 2022 and early 2023. Our second PCV candidate, VAX-XP, leverages our scalable and modular platform and builds on the technical proof of concept established by VAX-24 and is designed to expand the breadth of coverage to at least 30 strains without compromising immunogenicity due to carrier suppression. In addition to our PCV franchise, our pipeline includes VAX-A1, a novel conjugate vaccine candidate for Group A Strep; VAX-PG, a novel protein vaccine candidate targeting the keystone pathogen responsible for periodontitis; and other discovery-stage programs. Our primary activities since incorporation have been to: perform research and development, undertake preclinical studies and conduct manufacturing activities in support of our product development efforts; organize and staff the Company; establish our intellectual property portfolio; and raise capital to support and expand such activities.

### *Reverse Stock Split*

On June 5, 2020, we filed a certificate of amendment to our amended and restated certificate of incorporation to effect a one-for-1.6870 reverse stock split of our issued and outstanding common stock, preferred stock, stock options and warrants effective on June 5, 2020. Accordingly, all share and per share amounts for all periods presented in the financial statements and notes thereto have been retroactively adjusted.

### *Initial Public Offering*

On June 11, 2020, we completed an initial public offering ("IPO") in which we issued and sold 17,968,750 shares of common stock, including shares issued upon the exercise in full of the underwriters' option to purchase 2,343,750 additional shares of common stock, at a public offering price of $16.00 per share. We received $264.0 million in net proceeds, after deducting underwriting discounts and commissions of $20.1 million and offering expenses of $3.4 million.

Immediately prior to the completion of our IPO, all outstanding shares of redeemable convertible preferred stock were converted into 28,610,337 shares of common stock. Subsequent to the completion of the IPO, there were no shares of redeemable convertible preferred stock outstanding.

## 2. Basis of Presentation and Summary of Significant Accounting Policies

### Basis of Presentation

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

### *Unaudited Interim Condensed Financial Statements*

The condensed balance sheet as of March 31, 2021 and the condensed statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for the three months ended March 31, 2021 and 2020 are unaudited. The unaudited interim condensed financial statements have been prepared on the same basis as the audited annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair statement of our financial information. The financial data disclosed in the footnotes to the condensed financial statements related to the three months ended March 31, 2021 and 2020 are also unaudited. The results of operations for the three months ended March 31, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or for

any other future annual or interim period. These interim condensed financial statements should be read in conjunction with our audited financial statements and related notes thereto for the year ended December 31, 2020 included in our Annual Report on Form 10-K filed with the SEC on March 29, 2021.

***Use of Estimates***

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

***Cash, Cash Equivalents and Restricted Cash***

We consider all highly liquid investments purchased with original maturities of three months or less from the date of purchase to be cash and cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts and commercial paper and are stated at their fair values. Restricted cash consists of a standby letter of credit, which was issued in the first quarter of 2021, that serves as collateral for the lease agreement for our new corporate headquarters.

***Investments***

Our investments have been classified and accounted for as available-for-sale securities. Fixed income securities consist of U.S. Treasury securities, U.S. government agency securities, corporate debt and commercial paper. These securities are recorded on the condensed balance sheets at fair value. Unrealized gains and losses on these securities are included as a separate component of accumulated other comprehensive income. The cost of investment securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in other income (expense), net. Realized gains and losses and declines in fair value judged to be other-than-temporary, if any, are also included in other income (expense), net. We evaluate securities for other-than-temporary impairment at the balance sheet date. Declines in fair value determined to be other-than-temporary are included in other income (expense), net. We classify our investments as short or long term primarily based on the remaining contractual maturity of the securities.

***Net Loss Per Share***

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

***Deferred Offering Costs***

Deferred offering costs consist of fees and expenses incurred in connection with the sale of our common stock in equity transactions, including legal, accounting, printing and other issuance-related costs. Prior to the completion of such equity transactions, these deferred offering costs were included in Other assets on the condensed balance sheet. In connection with and as of the closing of such equity transactions, these costs were reclassified to Additional paid-in capital, representing a reduction to the gross proceeds. As of March 31, 2021, $3.4 million of IPO-related costs are included in the Additional paid-in capital line item on the condensed balance sheet. As of March 31, 2021 and December 31, 2020, we recorded deferred offering costs of $0 and $0.1 million, respectively, in Other assets on the condensed balance sheets.

***Leases***

Under Financial Accounting Standards Board (FASB) Accounting Standards Update (“ASU”) No. 2016-02, *Leases (Topic 842)* and its associated amendments (“ASC 842”), we determine if an arrangement is a lease at inception. In addition, we determine whether a lease meets the classification criteria of a finance or operating lease at the lease commencement date considering whether: (i) the lease transfers ownership of the underlying asset to the lessee at the end of the lease term; (ii) the lease grants the lessee an option to purchase the underlying asset that the lessee is reasonably certain to exercise; (iii) the lease term is for a major part of the remaining economic life of the underlying asset; (iv) the present value of the sum of the lease payments and residual value guaranteed by the lessee equals or exceeds substantially all of the fair value of the underlying asset; and (v) the underlying asset is such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. As of March 31, 2021, our lease population consisted of real estate operating leases. As of March 31, 2021, the Company did not have finance leases.

Operating leases are included in Operating lease right-of-use (ROU) assets, Operating lease liabilities — current and Operating lease liabilities — long term in our condensed balance sheet. ROU assets represent our right to use the underlying assets for the lease term and lease liabilities represent our obligation to make lease payments arising from the leases. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, if the rate implicit in the lease is not readily determinable, we use our incremental borrowing rate based on the information available at the lease commencement date. We determine the incremental borrowing rate based on an analysis of corporate bond yields with a credit rating similar to us. The determination of our incremental borrowing rate requires management judgment, including development of a synthetic credit rating and cost of debt, as we currently do not carry any debt. We believe that the estimates used in determining the incremental borrowing rate are reasonable based upon current facts and circumstances. Applying different judgment to the same facts and circumstances could yield a different incremental borrowing rate. The operating lease ROU assets also include adjustments for prepayments and accrued lease payments and exclude lease incentives. ROU assets and lease liabilities may include options to extend or terminate leases if it is reasonably certain that we will exercise such options. Lease payments which are fixed and determinable are amortized as rent and lease expense on a straight-line basis over the expected lease term. Variable lease costs, which are dependent on usage, a rate or index, including common area maintenance charges, are expensed as incurred. Lease agreements that include lease and non-lease components are accounted for as a single lease component. Lease agreements with non-cancelable terms of less than 12 months are not recorded on our condensed balance sheets.

***Concentration of Credit Risk and Other Risks and Uncertainties***

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

We are subject to supplier concentration risk from our suppliers. We source our critical raw materials from a sole source supplier, Sutro Biopharma, Inc. (“Sutro Biopharma”). We also use one contract manufacturing organization (“CMO”), Lonza Ltd. (“Lonza”), to handle most of our manufacturing activities. If we were to experience disruptions in raw materials supplied by Sutro Biopharma, or in manufacturing activities at Lonza, we may experience significant delays in our product development timelines and may incur substantial costs to secure alternative sources of raw materials or manufacturing.

Our future results of operations involve a number of other risks and uncertainties. Factors that could affect our future operating results and cause actual results to vary materially from expectations include, but are not limited to: our early stages of clinical vaccine development; our ability to advance vaccine candidates into, and successfully complete, clinical trials on the timelines we project; our ability to adequately demonstrate sufficient safety and efficacy of our vaccine candidates; our ability to enroll subjects in our ongoing and future clinical trials; our ability to successfully manufacture and supply our vaccine candidates for clinical trials; our ability to obtain additional capital to finance our operations; our ability to obtain, maintain and protect our intellectual property rights; developments relating to our competitors and our industry, including competing vaccine candidates; general and market conditions; and other risks and uncertainties, including those more fully described in the “Risk Factors” section of this Quarterly Report on Form 10-Q.

***Recently Adopted Accounting Pronouncements***

In February 2016, the FASB issued ASC 842, which requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. The new standard establishes a ROU model that requires a lessee to recognize a ROU asset and a lease liability on the balance sheet for all leases with a term longer than 12 months. Under ASC 842, leases will be classified as either finance leases or operating leases, with classification affecting the pattern and classification of expense recognition in the income statement.

The new standard is effective for us on January 1, 2022, with early adoption permitted. We early adopted the new standard effective January 1, 2021 using the modified retrospective transition approach. Upon adoption on January 1, 2021, we recognized ROU assets and lease liabilities totaling $0.9 million and $0.9 million, respectively, to reflect the present value of remaining lease payments under existing lease arrangements. The difference between the leased assets and lease liabilities represents the existing deferred rent liabilities balance resulting from historical straight-lining of operating leases for our facilities, which was reclassified upon adoption to reduce the measurement of the leased assets. The balance of our deferred rent liabilities, which was reclassified to reduce the ROU assets upon adoption, was immaterial. We applied the modified retrospective transition approach and did not recast prior periods. Although we applied this approach, we did not have a cumulative effect adjustment to the opening balance of our retained deficit upon adoption. As permitted by the standard, we elected the transition practical expedient package, which among other things, allows the carryforward of historical lease classifications.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)*. The amendments in ASU 2019-12 simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify U.S. GAAP or other areas of Topic 740 by clarifying and amending existing guidance. The new standard was effective for us on January 1, 2021 and for interim periods within 2021. The adoption of ASU 2019-12 did not have a material impact on our financial statements.

***Recently Issued Accounting Pronouncements – Not Yet Adopted***

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* and has subsequently issued related amendments, collectively referred to as "Topic 326." Topic 326 requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The measurement of expected credit losses is based on historical experience, current conditions and reasonable and supportable forecasts that affect collectability. Topic 326 also eliminates the concept of "other-than-temporary" impairment when evaluating available-for-sale debt securities and instead focuses on determining whether any impairment is a result of a credit loss or other factors. An entity will recognize an allowance for credit losses on available-for-sale debt securities rather than an other-than-temporary impairment that reduces the cost basis of the investment. Topic 326 is effective for fiscal years beginning after December 15, 2022 and interim periods within those fiscal years. Early adoption is permitted. We are currently assessing the impact of this standard to our financial statements and related disclosures.

**3. Fair Value Measurements and Fair Value of Financial Instruments**

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

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

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

***Level 3*—**Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. We recognize transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs.

Level 1 securities consist of highly liquid money market funds for which the carrying amounts approximate their fair values due to their short maturities. U.S. Treasury securities are valued using Level 1 inputs based on unadjusted, quoted prices in active markets that are observable at the measurement date for identical assets or liabilities. Level 2 securities, consisting of corporate debt, commercial paper and U.S. government agency securities, are measured based on other observable inputs, including broker or dealer quotations or alternative pricing sources. When quoted prices in active markets for identical assets or liabilities are not available, we rely on non-binding quotes from our investment managers, which are based on proprietary valuation models of independent pricing services. These models generally use inputs such as observable market data, quoted market prices for similar instruments or historical pricing trends of securities relative to our peers. To validate the fair value determinations provided by our investment managers, we review the pricing movement in the context of overall market trends and trading information from our

investment managers. In addition, we assess the inputs and methods used in determining the fair value in order to determine the classification of securities in the fair value hierarchy. We had no Level 3 securities either as of March 31, 2021 or December 31, 2020.

There were no transfers within the hierarchies during the three months ended March 31, 2021 or the year ended December 31, 2020.

We invested in money market funds as of December 31, 2020. In January 2021, we started to invest some of our funds in corporate debt, commercial paper, U.S. Treasury securities and U.S. agency securities in addition to money market funds. The following tables set forth our financial instruments measured at fair value on a recurring basis by level within the fair value hierarchy at March 31, 2021 and December 31, 2020:

| | | March 31, 2021 | | | |
|---|---|---|---|---|---|
| | Fair Value Hierarchy Level | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| **Assets** | | (in thousands) | | | |
| Cash and cash equivalents: | | | | | |
| Cash | Level 1 | $ 26,226 | $ — | $ — | $ 26,226 |
| Money market funds[1] | Level 1 | 113,718 | — | — | 113,718 |
| Commercial paper[1] | Level 2 | 58,997 | — | (2) | 58,995 |
| Total cash and cash equivalents | | $ 198,941 | — | $ (2) | 198,939 |
| Investments: | | | | | |
| U.S. Treasury securities | Level 1 | 35,431 | — | (5) | 35,426 |
| Commercial paper | Level 2 | 89,931 | — | (12) | 89,919 |
| Corporate debt | Level 2 | 37,517 | — | (28) | 37,489 |
| U.S. government agency securities | Level 2 | 9,100 | — | — | 9,100 |
| Total investments | | 171,979 | — | (45) | 171,934 |
| Total assets measured at fair value | | $ 370,920 | $ — | $ (47) | $ 370,873 |

| | | December 31, 2020 | | | |
|---|---|---|---|---|---|
| | Fair Value Hierarchy Level | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| **Assets** | | (in thousands) | | | |
| Cash and cash equivalents: | | | | | |
| Cash | Level 1 | $ 4,788 | $ — | $ — | $ 4,788 |
| Money market funds[1] | Level 1 | 381,412 | — | — | 381,412 |
| Total assets measured at fair value | | $ 386,200 | $ — | $ — | $ 386,200 |

(1) Included within cash and cash equivalents on the condensed balance sheets.

The following table presents the contractual maturities of our investments as of March 31, 2021 (in thousands):

| | March 31, 2021 |
|---|---|
| | Fair Value |
| Due in less than one year | $ 122,180 |
| Due in one to five years | 49,754 |
| Total | $ 171,934 |

**4. Balance Sheet Details**

**Property and Equipment, Net**

Property and equipment, net as of March 31, 2021 and December 31, 2020 consisted of the following:

| | March 31, 2021 | December 31, 2020 |
|---|---|---|
| | (in thousands) | |
| Furniture and equipment | $ 397 | $ 397 |
| Computers and computer software | 111 | 111 |
| Lab equipment | 7,027 | 4,739 |
| Leasehold improvements | 1,903 | 1,903 |
| Construction in progress | — | 219 |
| Total property and equipment | 9,438 | 7,369 |
| Less: accumulated depreciation and amortization | (4,444) | (4,097) |
| Property and equipment, net | $ 4,994 | $ 3,272 |

Depreciation and amortization expense for the three months ended March 31, 2021 and 2020 was $0.3 million and $0.4 million, respectively. None of the amortization expense for the three months ended March 31, 2021 or 2020 relates to capital lease amortization expense.

**Accrued Expenses**

Accrued expenses as of March 31, 2021 and December 31, 2020 consisted of the following:

| | March 31, 2021 | December 31, 2020 |
|---|---|---|
| | (in thousands) | |
| Preclinical studies | $ 4,178 | $ 2,844 |
| Professional fees | 925 | 490 |
| Other accrued expenses | 671 | 432 |
| Total | $ 5,774 | $ 3,766 |

**5. Leases**

**Operating Lease Obligations**

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

In January 2021, we entered into a lease agreement for our new corporate headquarters facility to be located in San Carlos, California and a license agreement for temporary lab and office space in Palo Alto, California. The lease term for our new corporate headquarters facility began on January 22, 2021 and will expire 48 months from the first day of the first full month following the earlier to occur of (i) January 21, 2022 or (ii) the date that the tenant improvements are substantially completed. We have two 60-month renewal options. The license agreement for temporary space in Palo Alto will terminate when the San Carlos office leasehold improvements are completed and we move into our new corporate headquarters. These two leases are accounted for as a combined lease because the contracts were negotiated as a package with the same commercial objective.

We early adopted ASC 842 and its associated amendments as of January 1, 2021 using the modified retrospective transition approach by applying the new standard to all leases existing at the date of the initial adoption and not restating comparative periods. We elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carryforward the historical lease classification of those leases in place as of January 1, 2021. The adoption

of ASC 842 resulted in an increase to total assets and liabilities due to the recording of operating lease ROU assets and operating lease liabilities of $0.9 million and $0.9 million, respectively, as of January 1, 2021. ROU assets and lease liabilities are recognized based on the present value of the fixed and in-substance fixed lease payments over the lease terms at their respective commencement dates. The ROU assets also include any initial direct costs incurred and lease payments made at or before the commencement date and are reduced by lease incentives. In determining the present value of lease payments, since the rate implicit in the lease is generally not readily determinable, we use our incremental borrowing rate, which requires management's judgment, including for the development of a synthetic credit rating and the cost of debt as we currently do not carry any debt. Variable lease costs, which are dependent on usage, a rate or index, including common area maintenance charges for our real estate leases, are expensed as incurred.

Upon commencement of the Palo Alto lease in March 2021, we recorded a right-of-use asset and lease liability of $0.3 million and $0.3 million, respectively. The right-of-use asset and lease liability associated with the San Carlos lease will be recorded upon the date that the tenant improvements are substantially completed, which we anticipate will occur by the end of 2021 or early 2022. Because the Palo Alto and the San Carlos leases are accounted for as a combined lease, lease payments and lease incentives are allocated between the two leases.

Information related to our ROU assets and related lease liabilities was as follows (dollar amounts in thousands):

| | March 31, 2021 |
|---|---|
| Cash paid for operating lease liabilities | $ 223 |
| Right-of-use assets recognized in exchange for new lease obligations | 1,028 |
| Current operating lease liabilities | 833 |
| Non-current operating lease liabilities | 295 |
| Weighted-average remaining lease term (in years) | 0.89 |
| Weighted-average discount rate | 6.50% |

Maturities of lease liabilities as of March 31, 2021 were as follows:

| Years ending December 31, | (in thousands) |
|---|---|
| Remainder of 2021[1] | $ (251) |
| 2022 | 487 |
| 2023 | 379 |
| 2024 | 388 |
| 2025 | 398 |
| Thereafter | — |
| Total future undiscounted lease payments | 1,401 |
| Less: Imputed interest | (273) |
| Total lease liabilities | $ 1,128 |

(1) Maturities for 2021 is net of lease incentives of $0.9 million allocated to the Palo Alto office.

Future minimum payments required under operating leases as of December 31, 2020 were as follows:

| Years ending December 31, | (in thousands) |
|---|---|
| 2021 | $ 742 |
| 2022 | 190 |
| Total future minimum payments | $ 932 |

Rent expense recognized under the leases was $0.4 million and $0.2 million for the three months ended March 31, 2021 and 2020, respectively.

**6. Commitments and Contingencies**
**Legal Contingencies**

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

**Guarantees and Indemnifications**

In the normal course of business, we enter into agreements that contain a variety of representations and provide for general indemnification. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. As of March 31, 2021, we did not have any material indemnification claims that were probable or reasonably possible and consequently have not recorded related liabilities.

**Indemnification**

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

**Development and Manufacturing Services Agreement**

On October 21, 2016, we entered into a development and manufacturing services agreement, as amended, with Lonza (the "Lonza DMSA"), pursuant to which Lonza is obligated to perform services including manufacturing process development and the manufacture of components for VAX-24, including the polysaccharide antigens, our proprietary eCRM protein carrier and conjugated drug substances.

In September 2017, we and Lonza agreed to defer the completion payments for any stage that commences after December 31, 2019 or has not been completed by December 31, 2019 until the earlier of the completion of all Investigational New Drug ("IND")-enabling activities or December 31, 2020. In March 2020, Lonza agreed to defer the completion payments until the earlier of the completion of all IND-enabling activities or April 30, 2021. In April 2021, Lonza further agreed to defer 50% of the completion payments until the earlier of the completion of all IND-enabling activities or December 31, 2021.

In June 2018, we and Lonza entered into a letter agreement pursuant to which we agreed to certain terms for potential future payments in shares of our common stock as partial satisfaction of future obligations to Lonza. This agreement states that the initial pre-IND cash payments will be subject to a specified dollar cap (the "Initial Cash Cap"). After the Initial Cash Cap has been reached, we have the option to make any further pre-IND payments owed to Lonza in cash, in shares of our common stock at then market prevailing prices, or a combination of both, at our election, provided that (i) Lonza may elect to receive up to 25% of pre-IND payments in shares of our common stock, up to a maximum of $2.5 million, and (ii) we may issue no more than $10.0 million of pre-IND payments in shares of our common stock. The Initial Cash Cap had not been reached as of March 31, 2021. As such, no amount has been recorded with respect to the potential future payments above the Initial Cash Cap at March 31, 2021 and December 31, 2020. In April 2021, we reached the Initial Cash Cap and notified Lonza that we would be exercising our option to issue approximately $10.0 million in shares of our common stock as payment for a portion of pre-IND payments due April 30, 2021.

In October 2018, we entered into a second development and manufacturing services agreement with Lonza (the "Lonza 2018 DMSA," and together with the Lonza DMSA, the "Lonza Agreements"), pursuant to which Lonza is obligated to perform services including manufacturing process development and the manufacture and supply of VAX-24 finished drug product.

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

**7. Redeemable Convertible Preferred Stock**

There were no shares of redeemable convertible preferred stock authorized or outstanding as of March 31, 2021.

In connection with our IPO in June 2020, the outstanding shares of our Series A, Series B, Series C and Series D Redeemable Convertible Preferred Stock automatically converted into 28,610,337 shares of common stock.

In March 2020, we sold an aggregate of 8,220,242 shares of our Series D redeemable convertible preferred stock at a purchase price of $13.3816 per share for an aggregate purchase price of $110.0 million.

**8. 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 51,338,801 and 51,071,593 shares were issued and outstanding as of March 31, 2021 and December 31, 2020, respectively. The holders of our common stock are also entitled to receive dividends whenever funds are legally available, when and if declared by our board of directors. As of March 31, 2021 and December 31, 2020, no dividends have been declared. Each share of common stock is entitled to one vote.

Common stock reserved for future issuance under the 2020 Equity Incentive Plan (the "2020 Plan") and the 2014 Equity Incentive Plan (the "2014 Plan") was as follows, and excludes 66,982 shares issued outside of the 2014 Plan and 2020 Plan:

| | March 31, 2021 | December 31, 2020 |
|---|---|---|
| Options issued and outstanding | 4,863,399 | 5,188,531 |
| Shares available for future stock option grants | 7,262,652 | 4,651,149 |
| Total | 12,126,051 | 9,839,680 |

**9. Warrants**

In connection with our IPO in June 2020, our outstanding warrants were automatically net exercised for an aggregate 46,869 shares of common stock.

**10. Equity Incentive Plans**

**2020 and 2014 Equity Incentive Plans**

In June 2020, our board of directors adopted, and our stockholders approved, the 2020 Plan, which became effective on June 11, 2020. Under the 2020 Plan, we may grant stock options, appreciation rights, restricted stock and restricted stock units to employees, consultants and directors. Stock options granted under the 2020 Plan may be either incentive stock options or nonqualified stock options. Incentive stock options may be granted only to our employees, including officers and directors who are also employees. Nonqualified stock options may be granted to our employees, officers, directors, consultants and advisors. The exercise price of stock options granted under the 2020 Plan must be at least equal to the fair market value of the common stock on the date of grant, except that an incentive stock option granted to an employee who owns more than 10% of the shares of our common stock shall have an exercise price of no less than 110% of the fair value per share on the grant date and expire five years from the date of grant. The maximum term of stock options granted under the 2020 Plan is 10 years, unless subject to the provisions regarding 10% stockholders. Our stock options granted to new employees generally vest over four years at a rate of 25% upon the first anniversary of the vesting commencement date and monthly thereafter. Our other stock options granted to employees generally vest on terms consistent with stock options granted to new employees or monthly over four years from the vesting commencement date. A total of 10,150,000 shares of common stock were approved to be initially reserved for issuance under the 2020 Plan. The number of shares that remained available for issuance under the 2014 Plan as of the effective date of the 2020 Plan and shares subject to outstanding awards under the 2014 Plan as of the effective date of the 2020 Plan that are subsequently canceled, forfeited or repurchased by us will be added to the shares reserved under the 2020 Plan. In addition, the number of shares of common stock available for issuance under the 2020 Plan will be automatically increased on the first day of each calendar year during the ten-year term of the 2020 Plan, beginning with January 1, 2021 and ending with January 1, 2030, by an amount equal to 5% of the outstanding number of shares of our common stock on December 31 of the preceding calendar year or such lesser amount as determined by our board of directors. Effective January 1, 2021, the number of shares of common stock available under the 2020 Plan increased by 2,553,579 shares pursuant to the evergreen provision. As of March 31, 2021, an aggregate of 7,262,652 shares of common stock were available for issuance under the 2020 Plan.

Our 2014 Plan permitted the granting of incentive stock options, non-statutory stock options, restricted stock and other stock-based awards. Subsequent to the adoption of the 2020 Plan, no additional equity awards can be made under the 2014 Plan. As of March 31, 2021, 4,395,417 shares and 401,000 shares of common stock were subject to outstanding options under the 2014 Plan and 2020 Plan, respectively.

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

At March 31, 2021 and December 31, 2020, 10,189 and 15,056 shares, respectively, remained subject to our right of repurchase as a result of the early exercised stock options. The remaining liabilities related to early exercised shares as of March 31, 2021 and December 31, 2020 were both less than $0.1 million and were recorded in other liabilities.

Activity under our 2020 Plan and 2014 Plan, which excludes options to purchase 66,982 shares granted outside of the 2020 Plan and 2014 Plan, was as follows:

| | | Options Outstanding | | | |
|---|---|---|---|---|---|
| Stock Option Activity | Options Available for Grant | Number of Options | Weighted-Average Exercise Price Per Share | Weighted-Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value |
| Balances — December 31, 2020 | 4,651,149 | 5,121,549 | $ 4.99 | | |
| Additional shares authorized | 2,553,579 | — | | | |
| Options granted | (79,000) | 79,000 | $ 26.56 | | |
| Options exercised | — | (267,208) | $ 1.82 | | |
| Options forfeited | 136,924 | (136,924) | $ 21.73 | | |
| Balances — March 31, 2021 | 7,262,652 | 4,796,417 | $ 5.05 | 7.95 | $ 73,165 |
| Vested and expected to vest — March 31, 2021 | | 4,796,417 | $ 5.05 | 7.95 | $ 73,165 |
| Exercisable at March 31, 2021 | | 2,141,639 | $ 2.37 | 6.97 | $ 37,225 |

During the three months ended March 31, 2021 and 2020, 267,208 and 43,657 shares of stock options, respectively, were exercised for cash at a weighted-average price per share of $1.82 and $1.94, respectively. The weighted-average grant date fair value of options granted for the three months ended March 31, 2021 and 2020 was $17.70 and $2.58, respectively. The intrinsic value of the stock options exercised was $6.4 million and $0.1 million for the three months ended March 31, 2021 and 2020, respectively.

**2020 Employee Stock Purchase Plan**

In June 2020, our board of directors adopted, and our stockholders approved, the 2020 Employee Stock Purchase Plan (the “2020 ESPP”), which became effective on June 11, 2020. The 2020 ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. Employees enrolled in the 2020 ESPP purchase shares of common stock at a price per share equal to 85% of the lower of the fair market value at the start or end of the six-month purchase periods within the two-year offering period. A total of 650,000 shares of common stock were approved to be initially reserved for issuance under the 2020 ESPP. In addition, the number of shares of common stock available for issuance under the 2020 ESPP will be automatically increased on the first day of each calendar year during the ten-year term of the 2020 Plan, beginning with January 1, 2021 and ending with January 1, 2030, by an amount of 1% of the outstanding number of shares of our common stock on December 31st of the preceding calendar year or such lesser amount as determined by our board of directors. Effective January 1, 2021, the number of shares of common stock available under the 2020 ESPP increased by 510,715 shares pursuant to the evergreen provision. As of March 31, 2021, 1,133,250 shares of common stock were available for issuance under the 2020 ESPP.

**Stock-based Compensation**

We estimated the fair value of employee stock options using the Black-Scholes option-pricing model for the three months ended March 31, 2021 and 2020 using the following weighted-average assumptions:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2021 | 2020 |
| **Fair Value Assumptions** | | |
| Expected volatility | 81.0% - 82.5% | 81.2% - 81.3% |
| Expected dividend yield | 0% | 0% |
| Expected term (in years) | 5.5 | 6.0 - 6.1 |
| Risk-free interest rate | 0.5% - 1.0% | 1.4% |

We estimated the fair value of shares under the 2020 ESPP using the Black-Scholes option-pricing model for the three months ended March 31, 2021 and 2020 using the following weighted-average assumptions:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2021 | 2020 |
| **Fair Value Assumptions** | | |
| Expected volatility | 105.8% - 158.2% | N/A |
| Expected dividend yield | 0% | N/A |
| Expected term (in years) | 0.4 - 2.0 | N/A |
| Risk-free interest rate | 0.1% - 0.2% | N/A |

We recorded total stock-based compensation expense for the three months ended March 31, 2021 and 2020 related to the 2014 Plan, the 2020 Plan and the 2020 ESPP in the condensed statements of operations and allocated the amounts as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2021 | 2020 |
| | (In thousands) | |
| Research and development | $ 683 | $ 149 |
| General and administrative | 1,182 | 223 |
| Total | $ 1,865 | $ 372 |

**11. Funding Arrangement**

In July 2019, we received a cost-reimbursement research award from Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (“CARB-X”), a public-private partnership funded under a Cooperative Agreement from Assistant Secretary for Preparedness and Response/Biomedical Advanced Research and Development Authority (“BARDA”) and by awards from Wellcome Trust, Germany’s Federal Ministry of Education and Research, the United Kingdom Global Antimicrobial Resistance Innovation Fund and the Bill & Melinda Gates Foundation. In connection with this funding, we entered into a cost-reimbursement sub-award agreement with the Trustees of Boston University, the administrator of the program. The initial award provided the potential for funding up to four years to develop a universal vaccine to prevent infections caused by Group A Strep bacteria, which include pharyngitis, impetigo and necrotizing fasciitis, at an amount equal to 50% of reimbursable expenses up to specified amounts. The initial award committed initial funding of up to $1.6 million and, subject to a CARB-X decision to extend the options, up to $15.1 million in total funding available upon achievement of development milestones over the next four years. Specified research expenditures are reimbursable expenses associated with agreed-upon activities needed to advance the research project supported by the grant. These expenditures can include labor, laboratory supplies, travel, consulting and third-party vendor research and development support costs.

In July 2020, the CARB-X agreement was amended to increase the funding percentage for reimbursable expenses during the initial funding period from 50% to 90%. As a result, the initial funding amount increased from $1.6 million to $2.7 million. We anticipate that the increase in the funding percentage for reimbursable expenses may apply to future funding periods and, if so, the total funding amount over the four-year period, if the options to extend are exercised by CARB-X, would increase from the $15.1 million in the original agreement. In December 2020, we reached the maximum CARB-X funding limit for the initial funding period for our VAX-A1 program. We have submitted our funding proposal to CARB-X for the next period under our agreement.

Income from grants is recognized in the period during which the related specified expenses are incurred, provided that the conditions under which the grants were provided have been met. We recognized $0 and $0.3 million of grant income under this award and recorded the amounts in Other income (expense), net in the condensed statement of operations during the three months ended March 31, 2021 and 2020, respectively. A grant receivable of $0 and $0.3 million representing unreimbursed, eligible costs incurred under the CARB-X agreement was recorded and included in prepaid expenses and other current assets in the condensed balance sheets as of March 31, 2021 and December 31, 2020, respectively.

**12. Net Loss Per Share**

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2021 | 2020 |
| Net loss (in thousands) | $ (21,220) | $ (27,142) |
| Weighted-average shares outstanding used in computing net loss per share, basic and diluted | 51,174,978 | 4,049,848 |
| Net loss per share, basic and diluted | $ (0.41) | $ (6.70) |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2021 | 2020 |
| Stock options | 4,863,399 | 3,470,732 |
| Redeemable convertible preferred stock: | | |
| Series A | — | 6,225,719 |
| Series B | — | 6,786,896 |
| Series C | — | 7,377,480 |
| Series D | — | 8,220,242 |
| Common stock warrant | — | 31,857 |
| Redeemable convertible preferred stock warrant | — | 59,276 |
| Total | 4,863,399 | 32,172,202 |

**13. Income Taxes**

In determining quarterly provisions for income taxes, we use the annual estimated effective tax rate applied to the actual year-to-date profit or loss, adjusted for discrete items arising in that period. Our annual estimated effective tax rate differs from the U.S. federal statutory rate primarily as a result of state taxes and changes in our valuation allowance against our deferred tax assets. For all periods presented, we have incurred net pre-tax losses in the United States. During the three months ended March 31, 2021, there were no material changes to our unrecognized tax benefits, and we do not expect to have any significant changes to unrecognized tax benefits through the end of the fiscal year. For the three months ended March 31, 2021, we reported zero tax provision. We do not have any tax audits or other issues pending.

On March 27, 2020, the President of the United States signed into law the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The CARES Act, among other things, includes certain income tax provisions for individuals and corporations; however, these benefits do not impact our current tax provision.

On December 21, 2020, the President of the United States signed into law the “Consolidated Appropriations Act, 2021” which includes further COVID-19 economic relief and extension of certain expiring tax provisions. The relief package includes a tax provision clarifying that businesses with forgiven Paycheck Protection Program (“PPP”), loans can deduct regular business expenses that are paid for with the loan proceeds. Additional pandemic relief tax measures include an expansion of the employee retention credit, enhanced charitable contribution deductions and a temporary full deduction for business expenses for food and beverages provided by a restaurant. These benefits do not have a material impact on our current tax provision.

**14. Related Party Transactions**

We have an ongoing relationship with Sutro Biopharma. In 2013, Sutro Biopharma provided support to facilitate the establishment of our Company. As of March 31, 2021 and December 31, 2020, Sutro Biopharma owned approximately 1.6 million shares of our common stock. As of December 31, 2019, Sutro Biopharma also owned warrants to purchase 31,857 shares of our common stock (the "Common Stock Warrant") at an exercise price of $0.79289 per share and 59,276 shares of our Series C redeemable convertible stock (the "Preferred Stock Warrant") at an exercise price of $11.5215 per share. The Common Stock Warrant and the Preferred Stock Warrant were automatically net exercised pursuant to their terms for 30,278 shares and 16,591 shares, respectively, of our common stock in connection with the IPO. In the agreements and amendments identified herein, we licensed certain intellectual property and acquired certain supply rights from Sutro Biopharma, including the right to use the XpressCF platform to discover and develop vaccine candidates for the treatment or prophylaxis of infectious diseases. On October 12, 2015, we and Sutro Biopharma ("the Parties") entered into the Sutro Biopharma License Agreement, which amended and restated an agreement dated August 1, 2014. The Sutro Biopharma License Agreement was subsequently amended on May 9, 2018 ("License Amendment A1") and May 29, 2018 ("License Amendment A2"). In consideration for the License Amendment A2, we issued to Sutro Biopharma the Preferred Stock Warrant to purchase 59,276 shares of Series C redeemable convertible preferred stock at a purchase price of $11.5215 per share. We also entered into a separate supply agreement with Sutro Biopharma on May 29, 2018 (the "Sutro Biopharma Supply Agreement").

Under the Sutro Biopharma License Agreement, Sutro Biopharma granted us an exclusive, worldwide license to research, develop, manufacture and commercialize vaccine products addressing infectious disease, which are discovered or produced based on the use of Sutro Biopharma's proprietary cell-free protein expression technology, known as XpressCF, which utilizes extracts derived from strains of *E. coli*. In connection with the Sutro Biopharma License Agreement, under the Sutro Biopharma Supply Agreement, Sutro Biopharma has agreed to manufacture and supply extracts and reagents for us on a cost-plus basis. In consideration for the rights licensed, we are obligated to pay 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. In addition, for a certain period of time, if we grant a sublicense to a third party to further develop or sell a vaccine product discovered or generated by us, we are obligated to pay Sutro Biopharma a percentage, in the low single digits, of any net sublicense fees received. Our obligation to pay single-digit royalties to Sutro Biopharma expires on a country-by-country basis on the later of the expiration of the last to expire patent covering the manufacture, use, offer for sale or importation of the applicable vaccine product and ten years from first commercial sale of the applicable vaccine product. Our obligation to pay sublicense fees to Sutro Biopharma expired in July 2020. In License Amendment A1, the Parties amended the license agreement to remove a pre-IND regulatory meeting as a diligence milestone and to agree that certain other diligence milestones had been satisfied. In License Amendment A2, the Parties amended the license agreement to add certain terms confirming our obligation to purchase Sutro Biopharma's proprietary extract from *E. coli* ("Extract") from Sutro Biopharma. In addition, the Parties amended the license agreement to specify our rights to a transfer of certain know-how relating to the manufacture of Extract in the event of a declaration of bankruptcy by Sutro Biopharma. Finally, the Parties agreed to terms providing for injunctive relief in the event of a breach or threatened breach by the other party.

In the Sutro Biopharma Supply Agreement, the Parties agreed to terms for the supply of manufactured Extract and custom reagents by Sutro Biopharma for us to use in manufacturing vaccine compositions in non-clinical research or in Phase 1 or Phase 2 clinical trials. The term of the Sutro Biopharma Supply Agreement is from execution until the later of July 31, 2021 and the date the parties enter into and commence activities under the supply agreement unless extended through a subsequent supply agreement for the supply of Extract and custom reagents for vaccine compositions for Phase 3 and commercial uses as contemplated in the Supply Agreement. In February 2021, we entered into an amendment to the Sutro Biopharma Supply Agreement and extended the term to July 31, 2022.

We recognized expense related to the Supply Agreement of $1.6 million and $0 for the three months ended March 31, 2021 and 2020, respectively. In addition, we recorded $0 and $0.2 million in changes in the fair value of the Preferred Stock Warrant for the three months ended March 31, 2021 and 2020, respectively. The expense related to the changes in the fair value of the warrant is included in research and development expenses in the condensed statements of operations and comprehensive loss. Accrued expenses payable to Sutro Biopharma were $1.9 million and $0.7 million as of March 31, 2021 and December 31, 2020, respectively.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed financial statements and related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto for the year ended December 31, 2020 filed with the Securities and Exchange Commission, or the SEC, on March 29, 2021. This discussion and analysis contains forward-looking statements based upon our current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. You should carefully read the "Risk Factors" section of this Quarterly Report on Form 10-Q to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements."*

**Overview**

We are a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent or treat some of the most common and deadly infectious diseases worldwide. Our cell-free protein synthesis platform enables us to design and produce protein carriers and antigens, the critical building blocks of vaccines, in ways that we believe conventional vaccine technologies currently cannot. Our pipeline includes pneumococcal conjugate vaccine, or PCV, candidates that we believe are among the most broad-spectrum PCV candidates currently in development, targeting the $7 billion global pneumococcal vaccine market. Our lead vaccine candidate is VAX-24, a 24-valent investigational PCV. We anticipate submitting our initial investigational new drug, or IND, application to the U.S. Food and Drug Administration, or FDA, for VAX-24 between January and June 2022 and initiating our Phase 1/2 clinical proof-of-concept study in adults thereafter. We expect to announce topline data from this study between late 2022 and early 2023. Our second PCV candidate, known as VAX-XP, leverages our scalable and modular platform and builds on the technical proof of concept established by VAX-24 and, if approved, would expand the breadth of coverage to at least 30 strains without compromising immunogenicity due to carrier suppression. In addition to our PCV franchise, we are developing VAX-A1, a novel conjugate vaccine candidate for Group A Strep, and VAX-PG, a novel protein vaccine candidate targeting the keystone pathogen responsible for periodontitis, and other discovery-stage programs.

Since January 1, 2021, key developments affecting our business include the following:

- ***Advanced VAX-24 IND-Enabling Activities:*** We continued to progress several initiatives for VAX-24 in connection with our anticipated IND application submission to the FDA and ensuing Phase 1/2 clinical proof-of-concept study initiation. Among other activities, we made substantive progress toward completion of the final stage of production of the 24 good manufacturing practice, or GMP, conjugated drug substances.

- ***Progressed and reported new data for VAX-XP program:*** As part of our strategy to maximize the optionality and value of our PCV franchise, we have continued to advance VAX-XP, our broader-spectrum PCV candidate designed to cover at least 30 strains. In March, we announced new data for VAX-XP that further demonstrate the potential benefits of our scalable technology platform and the reproducibility of data with conjugates produced at larger scale. Results from a preclinical proof-of-concept study showed that in rabbit models for VAX-XP compared to more than 30 different pneumococcal serotypes, including all of those contained in Prevnar 13, the VAX-XP IgG immune responses were superior to polysaccharide-only serotypes and comparable to Prevnar 13 in the common 13 strains.

- ***Advanced and published data for VAX-A1 program:*** We advanced VAX-A1, our novel conjugate vaccine candidate designed to prevent infections from Group A Strep, a human pathogen causing pharyngitis, or strep throat, and certain severe invasive infections such as sepsis, toxic shock syndrome and necrotizing fasciitis. Based on the progress of the program, and consistent with target timelines, we nominated the final VAX-A1 vaccine candidate in the first quarter of 2021. In January 2021, we announced the publication of preclinical data in the journal *Infectious Microbes & Diseases*, which showed that VAX-A1 demonstrated meaningful protection against systemic and soft tissue infection after challenge with no evidence of cross-reactivity with human tissue.

- ***Published New Research Supporting VAX-24 and our Technology Platform:*** Since the beginning of 2021, we published preclinical VAX-24 data as well as research supporting our technology platform.

    - The paper, "*Non-clinical Immunological Comparison of a Next-Generation 24-Valent Pneumococcal Conjugate Vaccine (VAX-24) Using Site-Specific Carrier Protein Conjugation to the Current Standard of Care (PCV13 and*

*PPV23),"* published in May in the journal *Vaccine*, uses a rabbit model to evaluate the immune response of Vaxcyte's 24-valent PCV candidate compared to Prevnar13® (PCV13) and Pneumovax®23 (PPV23). In this study, all serotype conjugates (pneumococcal strains) in VAX-24 met the primary objective to elicit immune responses that were more robust compared to PPV23 and at least comparable to PCV13.

- The paper, *"Site-specific antigen-adjuvant conjugation using cell-free protein synthesis enhances antigen presentation and CD8+ T-cell response,"* was published in March in the journal *Scientific Reports*, and demonstrated an enhanced CD8 positive T-cell response by directly conjugating an adjuvant to a candidate antigen. This expansion of our site-specific technology platform has potential application in viral vaccines where an enhanced CD8 T-cell response is required.

- ***Strengthened leadership team and advisory board with key appointments:*** In April 2021, we appointed Janet Graesser as Vice President of Corporate Communications and Investor Relations. Mrs. Graesser brings to us over 20 years of healthcare communications experience and expertise across a variety of areas, including corporate communications and strategy, public relations and organizational communications. She dedicated 13 years of her career working at leading healthcare communications firms, ultimately serving as an Executive Vice President, delivering communications strategy and implementation to biotech, pharmaceutical and consumer health companies, including Amgen, GlaxoSmithKline ("GSK"), Johnson & Johnson ("J&J"), Pfizer and Merck. She went on to hold an operating role at J&J with responsibility for internal and external communications across seven J&J medical device companies, including Cordis. Mrs. Graesser remained in a senior leadership role with Cordis when it was acquired by Cardinal Health, ultimately serving as the Vice President of Global Communications and Strategy Implementation. Mrs. Graesser went on to establish her own consulting practice that successfully supported both large and small biotech companies. In February 2021, we added William Hausdorff, PhD to our Scientific Advisory Board. Dr. Hausdorff has worked on the development, clinical evaluation, registration, implementation and post-marketing assessment of a variety of vaccines over the past 30 years. Since 2018, Dr. Hausdorff has served as the Lead, Public Health Value Propositions for Vaccines at PATH, a global organization that works to accelerate health equity by bringing together public institutions, businesses, social enterprises, and investors to solve the world's most pressing health challenges. Prior to joining PATH, he worked for 12 years at GSK Vaccines, eight years at Wyeth Vaccines and was previously at the Centers for Disease Control and Prevention. In his roles at GSK Vaccines and Wyeth Vaccines, he was involved in the development of Synflorix® and Prevnar 13®, respectively. Dr. Hausdorff received his PhD in Biology from The Johns Hopkins University and his BA in Biology from Carleton College.

Since our inception in November 2013, we have devoted substantially all of our resources to performing research and development, undertaking preclinical studies and enabling manufacturing activities in support of our product development efforts, acquiring and developing our technology and vaccine candidates, organizing and staffing our company, establishing our intellectual property portfolio and raising capital to support and expand such activities. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from the sales of our redeemable convertible preferred stock and our initial public offering, or IPO. Through March 31, 2021, we have raised approximately $569.5 million in gross proceeds from the sale of our capital stock. We will continue to require additional capital to develop our vaccine candidates and fund operations for the foreseeable future. Accordingly, until such time as we can generate significant revenue from sales of our vaccine candidates, if ever, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.

We have incurred net losses in each year since inception and expect to continue to incur net losses in the foreseeable future. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending in large part on the timing of our preclinical studies, clinical trials and manufacturing activities, and our expenditures on other research and development activities. Our net loss was $21.2 million for the three months ended March 31, 2021. As of March 31, 2021, we had an accumulated deficit of $219.8 million. As of March 31, 2021, we had cash, cash equivalents and investments of $370.9 million, which we believe will be sufficient to fund our operating expenses and capital expenditure requirements through at least the completion and announcement of the topline data from our Phase 1/2 clinical proof-of-concept study of VAX-24 in adults, which we expect between late 2022 and early 2023, and to continue to advance our pipeline of other vaccine candidates.

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

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

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

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

***Certain Significant Relationships***

*Sutro Biopharma*

Vaxcyte was formed through its relationship with Sutro Biopharma, Inc., or Sutro Biopharma, in 2013 by our co-founders with the goal of utilizing Sutro Biopharma's proprietary XpressCF platform for protein synthesis in the field of vaccines addressing infectious diseases.

In addition to receiving funding, we entered into a license agreement with Sutro Biopharma, or the Sutro License, on August 1, 2014. The Sutro License was amended on October 12, 2015 and again on May 9, 2018 and May 29, 2018. Under this license, 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 License, we are obligated to pay Sutro Biopharma a 4% royalty on worldwide aggregate net sales of 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. Royalties are payable on a vaccine composition-by-vaccine composition and country-by-country basis until the later of expiration of the last valid claim in the licensed patents covering such vaccine composition in such country and ten years after the first commercial sale of such vaccine composition. In addition, we are obligated to pay Sutro Biopharma a percentage in the low-double digits of any net sublicensing revenue received for sublicense agreements executed before July 2020. Our obligation to pay sublicense fees to Sutro Biopharma expired in July 2020.

In May 2018, we entered into a supply agreement, which we refer to as the Sutro Biopharma Supply Agreement, with Sutro Biopharma pursuant to which we purchase from Sutro Biopharma extract and custom reagents for use in manufacturing non-clinical and certain clinical supply of vaccine compositions utilizing the technology licensed under the Sutro License at prices not to exceed a specified percentage above Sutro Biopharma's fully burdened manufacturing cost. If any extracts or custom reagents do not meet the specifications and warranties provided, then we will not have an obligation to pay for the non-conforming product, and Sutro Biopharma will be obligated to replace the non-conforming product within the shortest possible time with conforming product at our cost. The term of the Sutro Biopharma Supply Agreement is from execution until the later of July 31, 2021 and the date the parties enter into and commence activities under the supply agreement unless extended through a subsequent supply agreement for the supply of Extract and custom reagents for vaccine compositions for Phase 3 and commercial uses as contemplated in the Supply Agreement. In February 2021, we entered into an amendment to the Sutro Biopharma Supply Agreement and extended the term to July 31, 2022.

For additional details regarding our relationship with Sutro Biopharma, see Note 14, "Related Party Transactions," to our condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

*Lonza*

In October 2016, we entered into a development and manufacturing services agreement, as amended, with Lonza Ltd. ("Lonza") (the "Lonza DMSA"), pursuant to which Lonza is obligated to perform services including manufacturing process development and the manufacture of components for VAX-24, including the polysaccharide antigens, our proprietary eCRM protein carrier and conjugated drug substances.

In September 2017, we and Lonza agreed to defer the completion payments for any stage that commences after December 31, 2019 or has not been completed by December 31, 2019 until the earlier of the completion of all IND-enabling activities or December 31, 2020. In March 2020, Lonza agreed to defer the completion payments until the earlier of the completion of all IND-enabling activities or April 30, 2021. In April 2021, Lonza further agreed to defer 50% of the completion payments until the earlier of the completion of all IND-enabling activities or December 31, 2021.

In June 2018, we entered into a letter agreement with Lonza, pursuant to which we agreed to certain terms for potential future payments in shares of our common stock as partial satisfaction of future obligations to Lonza. Specifically, we and Lonza agreed that the initial pre-IND cash payments made by us to Lonza are subject to a specified dollar cap, which we refer to as the Initial Cash Cap. After the Initial Cash Cap has been reached, then at our election, we can make any further pre-IND payments owed to Lonza in cash, in shares of our common stock at then market prevailing prices, or a combination of both, provided that (i) Lonza may elect to receive up to 25% of pre-IND payments in shares of our common stock, up to a maximum of $2.5 million, and (ii) we may issue no more than $10 million of pre-IND payments in shares of our common stock. The Initial Cash Cap had not been reached as of March 31, 2021. In April 2021, we reached the Initial Cash Cap and notified Lonza that we would be exercising our option to issue approximately $10.0 million in shares of our common stock as payment for a portion of pre-IND payments due April 30, 2021.

In October 2018, we entered into a second development and manufacturing services agreement with Lonza (the "Lonza 2018 DMSA," and together with the Lonza DMSA, the "Lonza Agreements"), pursuant to which Lonza is obligated to perform services including manufacturing process development and the manufacture and supply of VAX-24 finished drug product.

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

***Impact of COVID-19***

We are continuing to closely monitor the impact of the global COVID-19 pandemic on our business and are taking proactive efforts designed to protect the health and safety of our employees and to maintain business continuity. We believe that the measures we have implemented and continue to implement are appropriate, and we will continue to monitor and seek to comply with guidance from governmental authorities and adjust our activities as appropriate. Based on guidance issued by federal, state and local authorities, we transitioned to a remote work model for our non-lab based employees in March 2020, while maintaining essential in-person laboratory functions in order to advance key research and development initiatives, supported by the implementation of updated onsite safety procedures, including routine testing of employees.

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

In addition, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic could result in significant and prolonged disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the continued spread of COVID-19 could materially affect our business and the potential value of our common stock.

The extent of the impact of the COVID-19 pandemic on our development and regulatory efforts, our ability to raise sufficient additional capital on acceptable terms, if at all, and the value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, and the effectiveness of actions taken globally to contain and treat COVID-19. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, financial condition and results of operations, see the section titled "Risk Factors."

**Components of Results of Operations**

***Operating Expenses***

*Research and Development*

Research and development expenses represent costs incurred in performing research, development and manufacturing activities in support of our own product development efforts and include personnel-related costs (such as salaries, employee benefits and stock-based compensation) for our personnel in research and development functions; costs related to acquiring, developing and manufacturing supplies for preclinical studies, clinical trials and other studies, including fees paid to contract manufacturing organizations; costs and expenses related to agreements with contract research organizations, investigative sites and consultants to conduct non-clinical and preclinical studies and clinical trials; professional and consulting services costs; research and development consumables costs; laboratory supplies and equipment costs; and facility and other allocated costs.

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

We expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance our vaccine candidates into and through preclinical studies and clinical trials, pursue regulatory approval of our vaccine candidates and expand our pipeline of vaccine candidates. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our vaccine candidates may be affected by a variety of factors, including the safety and efficacy of our vaccine candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our vaccine candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or 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, that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors 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 clinical development costs may vary significantly based on factors such as:

- the costs and timing of our chemistry, manufacturing and controls, or CMC, activities, including fulfilling GMP-related standards and compliance, and identifying and qualifying a second supplier;
- the costs related to raw materials estimates from our third-party manufacturing and supply partners;
- the cost of clinical trials of our vaccine candidates being greater than we anticipate;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- delays in adding a sufficient number of trial sites and recruiting suitable volunteers to participate in our clinical trials;
- the number of subjects that participate in the trials;
- the number of doses that subjects receive;
- subjects dropping out of a study or lost in follow-up;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the cost and timing of manufacturing our vaccine candidates;
- the phase of development of our vaccine candidates; and
- the efficacy and safety profile of our vaccine candidates.

*General and Administrative*

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

*Other Income (Expense), Net*

Other income (expense), net includes interest expense incurred on our capital leases for lab equipment, interest income earned from our cash, cash equivalents and investments, grant income, foreign currency transaction gains (losses) related to our Swiss Franc cash and liability balances and changes in the fair value of our redeemable convertible preferred stock tranche liability (see Note 2, “Basis of Presentation and Summary of Significant Accounting Policies,” Note 3, “Fair Value Measurements and Fair Value of Financial Instruments,” and Note 7, “Redeemable Convertible Preferred Stock,” to our condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for more detail).

*Grant Income*

In July 2019, CARB-X awarded us up to $1.6 million in initial funding to advance the development of a universal vaccine to prevent infections caused by Group A Strep Bacteria. In July 2020, the CARB-X agreement was amended to increase the funding percentage for reimbursable expenses during the initial funding period from 50% to 90%. As a result, the initial funding amount increased from $1.6 million to $2.7 million. Income is recognized as we incur and pay qualifying expenses over a period that ends on December 31, 2020. Qualifying expenses under this funding arrangement are recorded as a receivable when we have both incurred and paid the expenses. We recognized $0 and $0.3 million in grant income for funding research and development under this award during the three months ended March 31, 2021 and 2020, respectively. Grant income is included as a component of Other income (expense), net in the condensed statements of operations and comprehensive loss.

**Results of Operations**

***Comparison of the Three Months Ended March 31, 2021 and 2020***

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

| | Three Months Ended March 31, | | Change | |
|---|---|---|---|---|
| | 2021 | 2020 | $ | % |
| | (in thousands) | | | |
| Operating expenses: | | | | |
| Research and development | $ 17,258 | $ 24,315 | $ (7,057) | (29.0)% |
| General and administrative | 5,885 | 3,281 | 2,604 | 79.4% |
| Total operating expenses | 23,143 | 27,596 | (4,453) | (16.1)% |
| Loss from operations | (23,143) | (27,596) | 4,453 | (16.1)% |
| Other income (expense), net: | | | | |
| Interest expense | — | (7) | 7 | (100.0)% |
| Interest income | 61 | 135 | (74) | (54.8)% |
| Grant income | — | 329 | (329) | (100.0)% |
| Foreign currency transaction gains (losses) | 1,862 | (3) | 1,865 | * |
| Total other income (expense), net | 1,923 | 454 | 1,469 | 323.6% |
| Net loss | $ (21,220) | $ (27,142) | $ 5,922 | (21.8)% |

* *not meaningful*

**Operating Expenses**

***Research and Development Expenses***

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

| | Three Months Ended March 31, | | Change | |
|---|---|---|---|---|
| | 2021 | 2020 | $ | % |
| | (in thousands) | | | |
| Product and clinical development (1) | $ 8,362 | $ 19,727 | $ (11,365) | (57.6)% |
| Personnel-related | 4,009 | 1,956 | 2,053 | 105.0% |
| Professional and consulting services | 1,035 | 1,052 | (17) | (1.6)% |
| Research and development consumables | 1,823 | 95 | 1,728 | * |
| Facility related and other allocated | 1,219 | 743 | 476 | 64.1% |
| Laboratory supplies and equipment | 621 | 359 | 262 | 73.0% |
| Other (2) | 189 | 383 | (194) | (50.7)% |
| Total research and development expenses | $ 17,258 | $ 24,315 | $ (7,057) | (29.0)% |

(1) Includes expenses for third-party manufacturing and outsourced contract services, including preclinical studies and outsourced assays.
(2) Includes travel-related expenses, warrant expense and other miscellaneous office expenses.
* *not meaningful*

Research and development expenses decreased by $7.1 million, or 29.0%, during the three months ended March 31, 2021 compared to the corresponding period in 2020. The decrease was primarily attributable to a decrease of $11.4 million in product and clinical development expenses mainly related to our lead vaccine candidate, VAX-24, driven by decreases of $10.2 million in outsourced manufacturing activities and $1.1 million in outsourced research services due to the completion of the eCRM and polysaccharide GMP campaigns in 2020, partially offset by increases in VAX-24 drug substance and drug product activities and VAX-XP activities. The increase in personnel-related expenses of $2.1 million was primarily due to increased salaries, benefits and stock-based compensation expense related to the increase in the number of employees to support the expanded activities in research and development. The increase of $1.7 million in research and development consumables was primarily due to expenses related to extracts and reagents incurred during the first quarter of 2021 for our VAX-XP program.

***General and Administrative Expenses***

General and administrative expenses increased by $2.6 million, or 79.4%, during the three months ended March 31, 2021 compared to the corresponding period in 2020. The increase was mainly due to increases of $2.1 million in personnel-related expenses related to higher stock-based compensation expense resulting from an increase in the number of options granted and an increase in the fair value of our common stock affecting the valuation of new option grants during 2020, as well as growth in the number of employees in our general and administrative functions, and $0.5 million in other expenses primarily due to an increase in directors and officers liability insurance expense as a public company.

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

Other income (expense), net increased by $1.5 million, or 323.6%, during the three months ended March 31, 2021 compared to the corresponding period in 2020. The increase was primarily due to unrealized gains from increases in Swiss Franc payables and accrued liabilities and the appreciation of the U.S. dollar against the Swiss Franc. This increase was partially offset by a decrease of $0.3 million in grant income for the CARB-X program, which reached its funding limit in December 2020.

**Liquidity and Capital Resources**

We have incurred losses and negative cash flows from operations from inception through March 31, 2021. We have funded our operations to date primarily through equity financings totaling approximately $569.5 million in aggregate gross proceeds and $545.2 million net of underwriting discounts, commissions and offering expenses. As of March 31, 2021, we had $198.9 million of cash and cash equivalents, $171.9 million in investments and an accumulated deficit of $219.8 million.

***Future Funding Requirements***

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to advance our vaccine candidates, expand our corporate infrastructure, including the costs associated with being a public company, further our research and development initiatives for our vaccine candidates 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 the completion and announcement of the topline data from our Phase 1/2 clinical proof-of-concept study of VAX-24 in adults, which we expect between late 2022 and early 2023, and to continue to advance our pipeline of other vaccine candidates. However, we will need to raise additional capital prior to commencing pivotal trials for any of our vaccine candidates. Until we can generate a sufficient amount of revenue from the commercialization of our vaccine candidates or from collaboration agreements with third parties, if ever, we expect to finance our future cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. The sale of equity or convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financings may subject us to covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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 and non-clinical studies and clinical trials, including any impacts related to the COVID-19 pandemic;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies for our PCV candidates, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the cost of building a sales force in anticipation of any product commercialization;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our vaccine candidates for which we receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the revenue, if any, received from commercial sales, or sales to foreign governments, of our vaccine candidates for which we may receive marketing approval;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing our patents or other intellectual property rights;
- expenses needed to attract, hire and retain skilled personnel;
- the costs of operating as a public company; and
- the impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

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

***Cash Flows***

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2021 | 2020 |
| | (in thousands) | |
| Net cash used in operating activities | $ (13,205) | $ (13,633) |
| Net cash used in investing activities | (173,391) | (349) |
| Net cash provided by financing activities | 487 | 109,797 |
| Effect of exchange rate changes on cash and cash equivalents | (281) | — |
| Net (decrease) increase in cash, cash equivalents and restricted cash | $ (186,390) | $ 95,815 |

***Cash Flows from Operating Activities***

Net cash used in operating activities for the three months ended March 31, 2021 was $13.2 million, which primarily resulted from a net loss of $21.2 million, partially offset by a net change in our operating assets and liabilities of $5.5 million and non-

cash charges of $2.5 million. The net change in operating assets and liabilities of $5.5 million was primarily due to increases in accrued manufacturing expenses of $2.5 million related to outsourced manufacturing activities, accounts payable of $2.2 million resulting from the deferral of completion payments until April 2021 and December 2021 in accordance with our contract with Lonza (see Note 6, "Commitments and Contingencies" under Item 1 of this Quarterly Report on Form 10-Q for further details), and accrued expenses of $1.1 million related primarily to increases in contract research services related to the VAX-24 program. Non-cash charges primarily consisted of $1.9 million in stock-based compensation expense and $0.3 million in depreciation and amortization.

Net cash used in operating activities for the three months ended March 31, 2020 was $13.6 million, which primarily resulted from a net loss of $27.1 million, partially offset by a net change in operating assets and liabilities of $12.6 million and non-cash charges of $0.9 million. The net change in operating assets and liabilities of $12.6 million was primarily due to increases in accrued manufacturing expenses of $13.2 million related to outsourced manufacturing activities and accrued expenses of $1.2 million resulting primarily from increases in legal fees from our Series D preferred stock financing and patent filings, partially offset by a $1.0 million increase in prepaid expenses and other current assets related to prepaid license fees of various systems and prepaid costs related to contract manufacturing activities and a $0.7 million decrease in accounts payable due to timing of payments. Non-cash charges primarily consisted of $0.4 million in depreciation and amortization and $0.4 in stock-based compensation expense.

***Cash Flows from Investing Activities***

Cash used in investing activities for the three months ended March 31, 2021 was $173.4 million which related primarily to $172.1 million of purchases of investments and $1.2 million of purchases of lab equipment.

Cash used in investing activities for the three months ended March 31, 2020 was $0.3 million, which related primarily to purchases of lab equipment.

***Cash Flows from Financing Activities***

Cash provided by financing activities for the three months ended March 31, 2021 was $0.5 million, which primarily consisted of proceeds from exercise of common stock options.

Cash provided by financing activities for the three months ended March 31, 2020 was $109.8 million, which primarily consisted of net proceeds from the issuance of our Series D redeemable convertible preferred stock.

**Contractual Obligations and Commitments**

The following table summarizes our contractual obligations and commitments at March 31, 2021:

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| | Less than 1 Year | 1 - 3 Years | 3 - 5 Years | More than 5 Years | Total |
| | (in thousands) | | | | |
| Operating lease obligations[1] | $ (69) | $ 781 | $ 689 | $ — | $ 1,401 |
| Total | $ (69) | $ 781 | $ 689 | $ — | $ 1,401 |

(1) Consists of our office lease in Palo Alto, California that is estimated to expire in January 2022 and our office leases in Foster City, California that expire in March 2022 and April 2022. The amount in the Less than 1 Year column is net of lease incentives allocated to the Palo Alto office. The amounts included in the 1-3 Years and 3-5 Years columns include lease payments for the San Carlos office that are allocated to the Palo Alto office as a result of accounting for the leases as a combined lease. See footnote 5, "Leases" under Part I, Item 1 of this Quarterly Report on Form 10-Q.

The contractual obligations table above does not include lease payments allocated to the San Carlos office of approximately $25.1 million to be paid over the four years beginning with the rent commencement date of the lease. Lease payments for the San Carlos office will be finalized upon the rent commencement date of the lease, which we anticipate will occur by the end of 2021 or early 2022.

We have certain payment obligations under various license agreements. Under these agreements, we are required to make milestone payments upon successful completion and achievement of certain intellectual property, clinical, regulatory and sales milestones. The payment obligations under the license agreements are contingent upon future events such as our achievement of specified development, clinical, regulatory and commercial milestones, and we will be required to make development milestone payments and royalty payments in connection with the sale of products developed under these agreements. As the achievement and

timing of these future milestone payments are not probable or estimable, such amounts have not been included in our balance sheets as of March 31, 2021 or December 31, 2020, or in the contractual obligations table above. See Note 14, "Related Party Transactions," to our condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

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

**Legal Contingencies**

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

**Off-Balance Sheet Arrangements**

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

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

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

Except as disclosed in Note 2, "Basis of Presentation and Summary of Significant Accounting Policies" to our condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, there have been no significant changes in our critical accounting policies during the three months ended March 31, 2021, as compared with those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 29, 2021.

**Emerging Growth Company Status**

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years of audited financial statements in a registration statement for an initial public offering, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation and less extensive disclosure about our executive compensation arrangements. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. However, as described in Note 3 to our financial statements included elsewhere in this Quarterly Report on Form 10-Q, we early adopted certain accounting standards, as the JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies to the extent early adoption is permitted. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenues of $1.07 billion or more, (ii) December 31, 2025, (iii) the date on which we are deemed to be a "large

accelerated filer," under the rules of the SEC, which means the market value of equity securities that is held by non-affiliates exceeds $700.0 million as of the prior June 30th and (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

**Recently Adopted Accounting Pronouncements**

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

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

***Interest Rate Risk***

Our cash and cash equivalents as of March 31, 2021 and December 31, 2020 consisted of readily available checking and money market funds. As of March 31, 2021, we also invested in U.S. Treasury securities, U.S. government agency securities, corporate debt and commercial paper. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operations. We believe that our exposure to interest rate risks is not significant and that a hypothetical 10% movement in market interest rates would not have a significant impact on the total value of our portfolio or our interest income. In addition, we do not believe that our cash and cash equivalents have significant risk of default or illiquidity.

***Foreign Currency Risk***

We are exposed to market risk related to changes in foreign currency exchange rates, mainly relating to our contract with Lonza, our contract manufacturing organization in Switzerland. We have also entered into a limited number of contracts with other parties with payments denominated in foreign currencies. Payments under these contracts are made in foreign currencies and are subject to fluctuations in foreign currency rates. We do not currently have a formal program in place to hedge foreign currency risks. However, from time to time, we buy Swiss Francs, or CHF, which is the majority of our foreign currency exposure, at market and are holding CHF in our bank accounts. As of March 31, 2021 and December 31, 2020, we had approximately $26.4 million and $4.3 million held at one financial institution. As of March 31, 2021 and December 31, 2020, we had foreign currency denominated accounts payable and accrued expenses of $44.4 million and $41.2 million, respectively. To date, foreign currency transaction gains and losses have not been material to our 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 March 31, 2021 and our net loss for the three months ended March 31, 2021:

| Hypothetical Change in Currency Exchange Rates | Impact on Net Assets as of March 31, 2021 | Impact on Net Loss for the Three Months Ended March 31, 2021 |
|---|---|---|
| | (in thousands) | |
| 10% increase | $ (1,804) | $ (2,702) |
| 10% decrease | $ 1,804 | $ 2,702 |

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

***Effects of Inflation***

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

**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 Chief Executive Officer, or CEO, and our Chief Financial Officer, or CFO, our principal executive officer and principal financial officer, respectively, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of March 31, 2021. Based on this evaluation, our CEO and CFO have concluded that our disclosure controls and procedures as of March 31, 2021 were effective at a reasonable assurance level (i) to ensure information that we are required to disclose in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (ii) to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

***Changes in Internal Control over Financial Reporting***

There was no change in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, that occurred during the quarter ended March 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II—OTHER INFORMATION

**Item 1. Legal Proceedings.**

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

**Item 1A. Risk Factors.**

### RISK FACTORS

*Our business involves significant risks, some of which are described below. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the related notes. Many of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. 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 early stages of vaccine development and have a very limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

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

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

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

We are a preclinical-stage biotechnology vaccine company that was incorporated in November 2013. Investment in preclinical-stage companies and vaccine development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential vaccine candidate will not gain regulatory approval or become commercially viable. We do not have any products approved for sale and have not generated any revenue from product sales. As a result, we are not profitable and have incurred losses in each year since inception. Our net losses were $89.2 million and $50.3 million for the years ended December 31, 2020 and 2019, respectively, and $21.2 million and $27.1 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of $219.8 million.

We expect to continue to spend significant resources to fund research and development of, and seek regulatory approvals for, our vaccine candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, manufacturing, preclinical testing and clinical trial activities increase. As a result, our accumulated deficit will also increase significantly. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. However, we do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our vaccine candidates, which we expect will take a number of years. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Even if we eventually generate revenue, we may never be profitable and, if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

***We will require substantial additional funding to finance our operations, which may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.***

As of March 31, 2021, we had cash, cash equivalents and investments of $370.9 million. We believe our existing cash, cash equivalents and investments will fund our current operating plans through at least the next 12 months from the date of this Quarterly Report on Form 10-Q. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. We will need to raise additional capital before we can progress any of our vaccine candidates into a pivotal clinical trial. We expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements or any combination of these approaches. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide, including the trading price of common stock, resulting from the ongoing COVID-19 pandemic. Our future capital requirements will depend on many factors, including:

- the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical development and clinical trials;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the U.S. Food and Drug Administration, or FDA, and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies for our pneumococcal conjugate vaccine, or PCV, candidates, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the cost of building a sales force in anticipation of any product commercialization;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our vaccine candidates for which we receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the 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 of any patents or other intellectual property rights;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs of operating as a public company; and
- the impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

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

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

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

**Risks Related to Our Business and Industry**

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

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

Furthermore, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our vaccine candidates and understand these critical factors. Conjugate vaccine development is highly complex, and development of broad-valency PCVs is further complicated by the number of components, analytical assays and potential for adjustments, including but not limited to changes in raw materials, composition, formulation, manufacturing methods and dosing, which could result in drug substances and/or drug product that may vary between preclinical and clinical studies over time. Over the course of the development and manufacturing of VAX-24, we have encountered process-related matters that have required us to make adjustments to our processes. Recently, 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. Although Lonza has resumed manufacturing of VAX-24, 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, or that there will not be further delays due to additional process adjustments we are required to make or due to future scheduling conflicts at Lonza. Such process changes and manufacturing delays have caused a change in our IND timelines and future changes or delays could impact future timelines for VAX-24 or for our other product candidates.

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

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

We have no vaccine candidates that have entered clinical trials or products that are on the market, and all of our vaccine candidates are in early discovery and preclinical stages of development. Vaccine development generally takes many years. In particular, our most advanced vaccine candidate, VAX-24, showed positive results in a preclinical proof-of-concept study in 2017, and we expect to submit an investigational new drug, or IND, application to the FDA between January and June 2022 and initiate our Phase 1/2 clinical proof-of-concept study in adults thereafter. We expect to announce topline data from this study between late 2022 and early 2023. Our other vaccine candidates are in earlier stages of discovery and preclinical development and may never advance to clinical-stage development. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing our vaccine candidates, either alone or with third parties, and we cannot guarantee that we will ever obtain regulatory approval for any of our vaccine candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. Before obtaining regulatory approval for the commercial distribution of our vaccine candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of our vaccine candidates.

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

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

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

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

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

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

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

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

The clinical and commercial success of 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, or cGMP, and do so in a timely manner;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials, including field efficacy studies, or other studies beyond those planned to support the approval and commercialization of our vaccine candidates or any future vaccine candidates;
- acceptance of our proposed indications and primary surrogate endpoint assessments for our PCV candidates by the FDA and similar foreign regulatory authorities;
- any changes to the required threshold for the achievement of non-inferiority using established surrogate immune endpoints that our PCVs will need to meet in our clinical trials;
- our ability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of VAX-24 or any future vaccine candidates;
- the pace and prevalence of serotype replacement following the introduction of VAX-24 or VAX-XP or other vaccines targeting pneumococcal disease;
- any vaccine-vaccine interference studies that may be required, particularly with the standard of care pediatric vaccine regimen;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our vaccine candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA or comparable foreign regulatory authorities;
- achieving, maintaining and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to our lead vaccine candidates or any future vaccine candidates or approved products, if any;
- obtaining and maintaining an Advisory Committee on Immunization Practices, or ACIP, preferred recommendation or comparable foreign regulatory authority's recommendation of our vaccine candidates and the willingness of physicians, operators of clinics and patients to utilize or adopt any of our future vaccine candidates to prevent or treat age-associated diseases;

- our ability to successfully develop a commercial strategy and thereafter commercialize our vaccine candidates or any future vaccine candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;

- the convenience of our treatment or dosing regimen;

- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our vaccine candidates or any future vaccine candidates, if approved, including relative to alternative and competing treatments;

- patient demand for our vaccine candidates, if approved;

- our ability to establish and enforce intellectual property rights in and to our vaccine candidates or any future vaccine candidates;

- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims; and

- the impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

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

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

The vaccine market is intensely competitive and is dominated by a small number of multinational, globally established pharmaceutical corporations with significant resources; Pfizer, Merck, GlaxoSmithKline and Sanofi together control approximately 75% of the global vaccine market. We may also face competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. For example, Sanofi and SK Chemicals have partnered to develop a PCV, and Affinivax and Astellas have partnered to develop an affinity-bound pneumococcal vaccine.

Vaccine candidates that we successfully develop and commercialize may compete with existing vaccines and new vaccines that may become available in the future. Many of our competitors have substantially greater financial, lobbying, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior vaccines, including the potential that our competitors may develop chemical processes or utilize novel technologies for developing vaccines that may be superior to those we employ. In addition, many of these competitors have significantly greater experience than we have in undertaking preclinical studies and clinical trials of new products and in obtaining regulatory approvals, including for many vaccine franchises. Accordingly, our competitors may succeed in obtaining FDA approval or a preferred recommendation for their products. For example, Prevnar 13 obtained FDA approval for the prevention of invasive pneumococcal disease, or IPD, in infants based on non-inferior IgG antibody responses relative to Prevnar, using the surrogate immune endpoints established by the prior Prevnar field efficacy study. Pfizer is currently implementing a similar approach to development of its 20-valent PCV vaccine candidate, and may have a more efficient path to regulatory approval given Pfizer’s and the FDA’s previous experience with Prevnar 13.

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

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

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

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

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

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

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

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

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

- receiving Centers for Disease Control and Prevention, or CDC, and ACIP recommendations for use, as well as recommendations of comparable foreign regulatory and advisory bodies;
- prevalence and severity of the disease targets for which our vaccine candidates are approved;
- physicians, hospitals, third-party payors and patients considering our vaccine candidates as safe and effective;

- the potential and perceived advantages of our vaccine candidates over existing vaccines, including with respect to spectrum coverage or immunogenicity;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory and advisory bodies;
- limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory and advisory bodies;
- the timing of market introduction of our vaccine candidates as well as competitive products;
- the cost in relation to alternatives;
- the availability of coverage and adequate reimbursement and pricing by third-party payors, including government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors, including government authorities;
- relative convenience and ease of administration, including as compared to competitive vaccines and alternative treatments; and
- the effectiveness of our sales and marketing efforts.

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

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

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

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

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

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

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

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

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

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

We rely on third-party contract manufacturers to manufacture preclinical and clinical trial product materials and supplies for our needs. There can be no assurance that our preclinical and clinical development product supplies will not be limited or interrupted or be of satisfactory quality or continue to be available on acceptable terms. Over the course of the development and manufacturing of VAX-24, we have encountered process-related matters that have required us to make adjustments to our processes. Recently, 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. Although Lonza has resumed manufacturing of VAX-24, 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, or that there will not be further delays due to additional process adjustments we are required to make or due to future scheduling conflicts at Lonza. Such process changes and manufacturing delays have caused a change in our IND timelines and future changes or delays could impact future timelines for VAX-24 or for our other product candidates. As a third-party manufacturer, we are also subject to Lonza's scheduling commitments for its other clients. Scheduling conflicts with Lonza's other clients have contributed to manufacturing delays in the past, and there is no guarantee that future scheduling conflicts or related capacity constraints will not affect our manufacturing campaigns and related timelines. In addition, certain aspects of our manufacturing process for our clinical trial product materials and supplies were adversely affected by the COVID-19 pandemic, and could be adversely affected by the ongoing COVID-19 pandemic, earthquakes and other natural or man-made disasters, equipment failures, labor shortages, power failures and numerous other factors in the future. Please see the risk factor titled "*Our business could be adversely affected by the effects of health epidemics, including the evolving effects of the COVID-19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations. The COVID-19 pandemic could materially affect our operations, including at our headquarters in the San Francisco Bay Area, as well as the business or operations of our contract manufacturers or other third parties with whom we conduct business.*"

The manufacturing process for a vaccine candidate is subject to FDA or comparable foreign regulatory authority review. Our suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of

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

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

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

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

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

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

Adverse effects or other undesirable or unacceptable side effects caused by our vaccine candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. We have not yet initiated any clinical trials of our vaccine candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In such an event, our clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our vaccine candidates. Such side effects could also affect trial recruitment or the ability of enrolled subjects to complete the clinical trial or result in potential product liability claims. A data safety monitoring board may also suspend or terminate a clinical trial at any time on various grounds, including a finding that the research volunteers are being exposed to an unacceptable health risk. Vaccine-related side effects could also affect recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, any vaccine to be approved in pediatric populations may need to undergo extensive vaccine-vaccine interference studies with the standard of care pediatric vaccine regimen. Further, to the extent field efficacy studies are required, prophylactic vaccines typically require

clinical testing in thousands to tens of thousands of healthy volunteers to define an approvable benefit-risk profile. The need to show a high degree of safety and tolerability when dosing healthy individuals could result in rare and even spurious safety findings, negatively impacting a program prior to or after commercial launch. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

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

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

We recently announced changes to our anticipated timing to submit an IND application to the FDA to initiate a clinical trial of VAX-24 due to delays of our drug substance manufacturing campaign at Lonza. Our timing of submitting the IND application for VAX-24 is dependent on further preclinical and manufacturing success, and if we experience additional drug substance manufacturing campaign or other delays, we may fail to meet our anticipated timelines. In addition, we cannot be sure that submission of an IND application or IND application amendment will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

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

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

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required institutional review board, or IRB, approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology that raise FDA concerns about risk to patients of the technology broadly; or if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;

- disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned clinical trials;
- delays in adding a sufficient number of trial sites and recruiting volunteers to participate in our clinical trials;
- failure by our CROs, other third parties or us, to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's good clinical practice, or GCP, requirements or applicable regulatory guidelines in other jurisdictions;
- transfer of manufacturing processes to any new CMO or our own manufacturing facilities or any other development or commercialization partner for the manufacture of vaccine candidates;
- delays in having subjects complete participation in a study or return for post-injection follow-up;
- subjects dropping out of a study;
- occurrence of side effects associated with our vaccine candidates that are viewed to outweigh their potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our vaccine candidates being greater than we anticipate;
- clinical studies of our vaccine candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs;
- delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary raw materials; and
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our vaccine candidates for use in clinical studies or the inability to do any of the foregoing.

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

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

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

- the eligibility and exclusion criteria defined in the protocol;
- the size of the population required for analysis of the trial's primary endpoints;
- the proximity of volunteers to study sites;
- the design of the trial;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain subject consents;
- the ability to monitor volunteers adequately during and after injection;
- the risk that volunteers enrolled in clinical trials will drop out of the trials before the injection of our vaccine candidates or trial completion; and
- the risks and disruptions caused by the COVID-19 pandemic related to patient and physician investigator recruitment and retention and study site initiation and clinical trial activities.

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

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

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

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

***We may seek breakthrough therapy designation or fast track designation by the FDA for one or more of our vaccine candidates, but we may not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our vaccine candidates will receive marketing approval.***

We may seek breakthrough therapy or fast track designation for some of our vaccine candidates. 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 if it believes that the designation is no longer supported. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

Whether to grant breakthrough therapy or fast track 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 if one or more of our vaccine candidates qualify for either of these designations, the FDA may later decide that the vaccine candidate no longer meets the conditions for qualification.

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

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

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

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

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

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

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping vaccine candidates abroad;
- import and export requirements and restrictions;
- differing and changing data protection and privacy regimes and requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;

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

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

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

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

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

As our discovery, development and commercialization plans and strategies develop, we have rapidly expanded our employee base and expect to continue to add managerial, operational, sales, research and development, marketing, financial and other personnel. Current and future growth imposes significant added responsibilities on members of management, including:

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

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

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

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

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

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

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

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

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

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

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

***If our security measures, or those maintained on our behalf by CROs, service providers or other third parties, are compromised now, or in the future, or the security, confidentiality, integrity or availability of our information technology, software, services, networks, communications or data is compromised, limited or fails, this could result in significant fines or other liability, interrupt our development programs, harm our reputation, or otherwise adversely affect our business.***

In the ordinary course of our business, we may collect, use, retain, safeguard, disclose, share, transfer or otherwise process proprietary, confidential and sensitive information, including personal data (including, key-coded data, health information and other special categories of personal data), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties (collectively, "Sensitive Information").

We may use third-party service providers and subprocessors to help us operate our business and engage in processing on our behalf. We may also share Sensitive Information with our partners or other third parties in connection with our business.

Despite the implementation of security measures, our internal computer systems and the systems of our CROs, contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Cyberattacks, malicious internet-based activity and online and offline fraud are prevalent and continue to increase. In addition to traditional computer "hackers"; threat actors; software bugs; malicious code (such as viruses and worms); employee error, theft or misuse; denial-of-service attacks (such as credential stuffing); advanced persistent threat intrusions; natural disasters; terrorism; war; telecommunication and electrical failures; and ransomware attacks, sophisticated nation-state and nation-state supported actors are threats to our information technology assets and data. 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. Additionally, the increased usage of computers operated on home networks due to the shelter-in-place or similar restrictions related to the COVID-19 pandemic may make our systems more susceptible to security breaches.

We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against security breaches and to mitigate, detect and remediate actual or potential vulnerabilities. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our vaccine candidates could be delayed.

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

We cannot be sure that our insurance coverage, if any, will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or other materially adverse impacts arising out of our processing activities, privacy and security practices, or security breaches we may experience. The successful assertion of one or more large claims against use that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large excess or deductible or co-insurance requirements), could result in substantial cost increase or prevent us from obtaining insurance on acceptable terms.

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

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

Our ability to manufacture our vaccine candidates could be disrupted if our operations or those of our suppliers are affected by a man-made or natural disaster or other business interruption, including the COVID-19 pandemic. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

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

Health epidemics in regions where we have concentrations of potential clinical trial sites or other business operations could adversely affect our business, including by causing significant disruption in the operations of our contract manufacturer and other third parties upon whom we rely. For example, the COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting employees, patients, communities and business operations, as well as the U.S. economy and financial markets. Our headquarters is located in the San Francisco Bay Area, and our contract manufacturer, Lonza, is located in Switzerland. In March 2020, the U.S. government imposed travel restrictions on travel between the United States, Europe and certain other countries. Further, the President of the United States declared the COVID-19 pandemic a national emergency, invoking powers under the Stafford Act, the legislation that directs federal emergency disaster response. Similarly, the State of California declared a state of emergency related to the spread of COVID-19, and county public health departments announced aggressive recommendations to reduce the spread of the disease. On March 16, 2020, the health officers of six San Francisco Bay Area counties, including San Mateo County where our headquarters are located, issued shelter-in-place orders, which (i) direct all individuals living in those counties to shelter at their places of residence (subject to limited exceptions), (ii) direct all businesses and governmental agencies to cease non-essential operations at physical locations in those counties, (iii) prohibit all non-essential gatherings of any number of individuals, and (iv) order cessation of all non-essential travel. The initial shelter-in-place orders took effect on March 17, 2020, were subsequently revised, and have now been superseded with the current reopening orders for California and the various San Francisco Bay Area counties. As a result, we have implemented work-from-home policies for all of our non-lab employees. The effects of these orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In connection with these measures, we may be subject to claims based upon, arising out of or related to COVID-19 and our actions and responses thereto, including any determinations that we may make to continue to operate or to re-open our facilities where permitted by applicable law. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, financial condition, results of operations and growth prospects.

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

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

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

Furthermore, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic could result in significant and prolonged disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

While we expect the COVID-19 pandemic to continue to adversely affect our business operations, the extent of the impact on our development and regulatory efforts and the future value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, and the effectiveness of actions taken globally to contain and treat COVID-19. In addition, to the extent the evolving effects of the COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this “Risk Factors” section.

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

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

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

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

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

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

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

In December 2017, the Tax Cuts and Jobs Act, or Tax Act, was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (ii) limitation of the tax deduction for interest expense to 30% of adjusted earnings (with certain exceptions, including for certain small businesses), (iii) limitation of the deduction for post-2017 net operating losses, or NOLs, to 80% of current-year taxable income and elimination of net operating loss carrybacks for post-2017 NOLs, (iv) immediate deductions for certain new investments instead of deductions for depreciation expense over time and (v) modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”).

In March 2020, the Coronavirus Aid, Relief, and Economic Security, or CARES, Act was signed into law. The CARES Act changed certain provisions of the Tax Act. Under the CARES Act, NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminated the limitation on the deduction of NOLs to 80% of current year taxable income for taxable years beginning before January 1, 2021, and increased the amount of interest expense that may be deducted to 50% of adjusted taxable income for taxable years beginning in 2019 or 2020. We continue to examine the impact the Tax Act may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business, financial condition, results of operations and prospects could be adversely affected. We urge our stockholders to consult with their legal and tax advisors with respect to the Tax Act and the tax consequences of investing in our common stock.

On June 29, 2020, California Assembly Bill 85 (AB 85) was signed into law, which suspends the use of net operating losses and limits the use of research tax credits for 2020, 2021 and 2022. There may be periods during which the use of NOLs is

suspended or otherwise limited, and limitation on the use of certain tax credits to offset California income and tax liabilities could accelerate or permanently increase state taxes owed. The Company continues to examine the impact this may have on our business.

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

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

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. As of December 31, 2020, we had federal and state NOL carryforwards of $186.5 million and $148.8 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, 2020, we also had federal and state research credit carryforwards of $0.8 million and $0.9 million, respectively. The federal research and development tax credit carryforwards expire beginning in 2039 unless previously utilized, and the state research and development tax credits can be carried forward indefinitely. In general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We have experienced ownership changes in the past. As a result of the ownership changes, we have determined that approximately $1.3 million of our federal research credits will expire unutilized, and such amounts are excluded from our research carryforwards as of December 31, 2020. We do not expect any ownership changes during the year ended December 31, 2020 to result in a limitation that would materially reduce the total amount of net operating loss carryforwards and credits that can be utilized. Subsequent ownership changes may affect the limitation in future years. As a result, if, and to the extent that we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations.

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

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

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

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

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

We will need to negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol and legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for vaccine candidates in clinical development. Regulatory

authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will require a large number of test subjects. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of subjects may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

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

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

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

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

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

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

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

- Our third-party suppliers and manufacturers might be unable to timely formulate and manufacture or supply raw materials for our vaccine candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any.

- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.

- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.

- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.

- Our third-party suppliers and manufacturers could breach or terminate their agreement with us.

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

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

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

**Risks Related to Government Regulation**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our vaccine candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

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

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

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

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

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

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

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

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

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

- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which also impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, including health plans, healthcare clearinghouses and certain healthcare providers and their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information for or on their behalf, as well as their covered subcontractors;

- the Federal Food Drug or Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding its payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;

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

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

- laws governing the privacy and security of certain protected information, such as the European Union's General Data Protection Regulation, or GDPR, and the California Consumer Privacy Act, or CCPA, which impose obligations and restrictions on the collection, use and disclosure of personal data (including health data) relating to individuals located in the EU and California, respectively.

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

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

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

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

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

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

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

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

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our vaccine candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our vaccine candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for administering the product. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from third-party payors and reduce the willingness of physicians to use our vaccine candidates. Certain ACA marketplace and other private payor plans are required to include coverage for certain preventative services, including vaccinations recommended by the ACIP without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members. Children through 18 years of age without other health insurance coverage may be eligible to receive such vaccinations free-of-charge through the CDC's Vaccines for Children program. For Medicare beneficiaries, vaccines may be covered under either the Part B program or Part D depending on several criteria, including the type of vaccine and the beneficiary's coverage eligibility. If our vaccine candidates, once approved, are covered only under the Part D program, physicians may be less willing to use our products because of the claims adjudication costs and time related to the claims adjudication process and collection of co-payments associated with the Part D program.

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

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

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

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

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

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer’s Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer’s Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a requirement that certain ACA marketplace and other private payor plans include coverage for preventative services, including vaccinations recommended by the ACIP without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and

- establishment of a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, judicial and Congressional challenges to the ACA. For example, the Tax Act included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." The 2020 federal spending package eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. Although the U.S. Supreme Court has yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 unless additional Congressional action is taken. COVID-19 pandemic relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which ended the use of the statutory formula for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, the full impact of the introduction of the Medicare quality payment program on overall physician reimbursement remains unclear. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Further, in the United States there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug and biological product pricing, reduce the cost of prescription drugs and biological products under government payor programs and review the relationship between pricing and manufacturer patient programs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against

implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs, biological products and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

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

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

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

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

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

Separately, in response to the global COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on July 10, 2020, the FDA announced its intention to restart routine pre-announced surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

We are subject to or affected by numerous evolving federal, state and foreign laws and regulations, as well as policies, contracts and other obligations governing the collection, use, disclosure, retention, and security of personal data. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This landscape may create uncertainty in our business, result in liability or impose additional costs on us. These laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on

implementation and compliance practices are often updated or otherwise revised. The cost of compliance with these laws and regulations is high and is likely to increase in the future. Our failure or perceived failure to comply with these laws and regulations could result in negative publicity, diversion of management time and effort, an inability to process personal data or to operate in certain jurisdictions, restrictions on our operations and legal action against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

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

We are also subject to a growing body of privacy, data security and data protection laws outside of the United States. For example, the EU has adopted the GDPR, which went into effect in May 2018 and introduced strict requirements for processing personal data. Among other obligations under the GDPR, we are required to give more detailed disclosures about how we collect, use and share personal data; contractually commit to data protection measures in our contracts with clients; maintain adequate data security measures; notify regulators and affected individuals of certain personal data breaches; meet extensive privacy governance and documentation requirements; and honor individuals' expanded data protection rights, including their rights to access, correct and delete their personal data. The processing of sensitive personal data, such as health data information, may impose heightened compliance burdens under the GDPR and is a subject of active interest among regulators. Companies that violate the GDPR can face private litigation, regulatory enforcement action, prohibitions on data processing and fines of up to the greater of 20 million Euros or 4% of their worldwide annual revenue.

European data protection laws, including the GDPR, generally restrict the transfer of personal data from Europe, including the European Economic Area, United Kingdom and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. Historically, to comply with these restrictions, we have generally relied on the Standard Contractual Clauses for personal data transfers approved by the European Commission. However, a July 2020 decision of the EU's highest court called into question whether the Standard Contractual Clauses can lawfully be used for transfers of personal data from the EU to the United States and most other non-EU countries. Authorities in Switzerland may similarly question the viability of the Standard Contractual Clauses as a mechanism for the lawful transfer of personal data from those countries to the United States or other countries. Further, the UK's decision to leave the EU, often referred to as Brexit, and ongoing developments in the UK have created uncertainty regarding data protection regulation in the UK. Following December 31, 2020, and the expiry of transitional arrangements between the UK and EU, the data protection obligations of the GDPR continue to apply to UK-related Processing of personal data in substantially unvaried form under the so-called 'UK GDPR'. However, going forward, there is increasing risk for divergence in application, interpretation and enforcement of the data protection laws as between the UK and EEA. Furthermore, the relationship between the UK and the EEA in relation to certain aspects of data protection law remains uncertain. For example, it is unclear whether transfers of personal data from the EEA to the UK will be permitted to take place on the basis of a future adequacy decision of the European Commission, or whether a 'transfer mechanism' such as the Standard Contractual Clauses will be required. If we are unable to lawfully transfer personal data from Europe via the Standard Contractual clauses or an alternative mechanism, we will face increased exposure to regulatory actions, substantial fines, and injunctions against processing personal information from Europe, and we may be required to increase our data processing capabilities in Europe at significant expense. Inability to import personal information from Europe may also restrict our clinical trials activities in Europe and limit our ability to collaborate with contract research organizations, service providers, contractors and other companies subject to European data protection laws. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of operating our business.

Domestic privacy and data security laws beyond HIPAA and other healthcare privacy laws are also changing rapidly and becoming more complex. For example, California recently enacted the CCPA, which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt-out of certain personal information sharing, and receive detailed information about how their personal information is used, among others. The CCPA also requires covered businesses to provide detailed privacy notices to California residents and respond to requests from California residents to exercise their rights under the CCPA to access, delete and opt-out of certain sharing of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although there are limited exemptions for clinical trial data, the CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the U.S. In

addition, it is anticipated that the CCPA will be expanded on January 1, 2023, when the California Privacy Rights Act of 2020, or CPRA, becomes operative. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new law. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws could impact our business activities depending on how it is interpreted.

**Risks Related to Our Intellectual Property**

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

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

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

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

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

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

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

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

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

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering VAX-24 or any future vaccine candidate, or the XpressCF platform, our competitors might be able to enter the market, which would have an adverse effect on our business.

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

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

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

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

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

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

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

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

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

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

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

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

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

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

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

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

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

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

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

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

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

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

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

**Risks Related to Ownership of Our Common Stock**

***The price of our stock may be volatile, and the value of our common stock may decline.***

The market price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In particular, the COVID-19 pandemic has further heightened the volatility of the stock market for biopharmaceutical companies. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- the commencement, enrollment or results of our planned or future preclinical studies or clinical trials of our vaccine candidates and those of our competitors;
- regulatory or legal developments in the United States and abroad;
- the success of competitive vaccines or technologies;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the level of expenses related to our vaccine candidates or preclinical and clinical development programs;
- the results of our efforts to develop additional vaccine candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations or reports by securities analysts;
- the level of expenses and capital investment related to manufacturing our vaccine candidates;
- our inability to obtain or delays in obtaining adequate supply for any approved vaccine candidate;

- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies perceived to be similar to us;
- changes in the structure of healthcare payment systems, including coverage and adequate reimbursement for any approved vaccine;
- general economic, political and market conditions and overall fluctuations in the financial markets in the United States and abroad; and
- investors' general perception of us and our business.

In addition, the stock market in general, and the Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. You may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

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

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

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

Our executive officers, directors and 5% stockholders beneficially own approximately 70.1% of our common stock as of March 31, 2021. Accordingly, these stockholders have the ability to influence us through this ownership position and significantly affect the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to significantly affect the outcome of elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

***We are an emerging growth company as defined in the Jumpstart Our Business Startups Act, or JOBS Act, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements applicable to public companies that are not "emerging growth companies" including:

- the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- the "say on pay" provisions (requiring a non-binding stockholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding stockholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer; and

- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and instead provide a reduced level of disclosure concerning executive compensation.

Because our independent registered public accounting firm is not required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected may be increased. Likewise, our election not to provide certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, may make it more difficult for investors and securities analysts to evaluate our company.

We may take advantage of these reporting exemptions until we are no longer an "emerging growth company," which in certain circumstances could be for up to five years. We will cease to be an "emerging growth company" upon the earliest of: (i) December 31, 2025; (ii) the last day of the first fiscal year in which our annual gross revenue is $1.07 billion or more; (iii) the date on which we have, during the previous rolling three-year period, issued more than $1 billion in non-convertible debt securities; and (iv) the date on which we are deemed to be a "large accelerated filer" as defined in the Exchange Act.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

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

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd–Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC, or Nasdaq, and other applicable securities rules and regulations. Despite reforms made possible by the JOBS Act, as a public company we will incur significant legal, accounting and other expenses that we did not incur as a private company, which we expect to further increase after we are no longer an emerging growth company.

We are also subject to more stringent state law requirements. For example, on September 30, 2018, California Governor Jerry Brown signed into law Senator Bill 826, or SB 826, which generally requires public companies with principal executive offices in California to have a minimum number of females on the company's board of directors. As of December 31, 2019, each public company with principal executive offices in California is required to have at least one female on its board of directors. By December 31, 2021, each public company will be required to have at least two females on its board of directors if the company has at least five directors, and at least three females on its board of directors if the company has at least six directors. SB 826 does not provide a transition period for newly listed companies.

Additionally, on September 30, 2020, California Governor Gavin Newsom signed into law Assembly Bill 979, or AB 979, which generally requires public companies with principal executive offices in California to include specified numbers of directors from "underrepresented communities." A director from an "underrepresented community" means a director who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, Alaska Native, gay, lesbian, bisexual, or transgender. By December 31, 2021, each public company with principal executive offices in California is required to have at least one director from an underrepresented community. By December 31, 2022, a public company with more than four but fewer than nine directors will be required to have a minimum of two directors from underrepresented communities, and a public company with nine or more directors will need to have a minimum of three directors from underrepresented communities. Similar to SB 826, AB 979 does not provide a transition period for newly listed companies.

If we fail to comply with either SB 826 or AB 979, we could be fined by the California Secretary of State, with a $100,000 fine for the first violation and a $300,000 fine for each subsequent violation of either law, and our reputation may be 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.***

As of March 31, 2021, we had 51,338,801 shares of common stock outstanding. Substantially all of such shares are eligible for sale in the public market. In addition, upon issuance, shares of common stock subject to outstanding options under our stock option plans will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Moreover, holders of up to an aggregate of 28,610,337 shares of our common stock have the right to require us to register these shares under the Securities Act of 1933, as amended, or the Securities Act, pursuant to an investors' rights agreement. Sales of a substantial number of shares of our common stock in the public market, or the public's perception that such sales could occur, could have an adverse effect on the market price of our common stock. In addition, for the three months ended March 31, 2021, the average daily trading volume for our common stock on the Nasdaq Global Select Market was 428,992 shares. As a result of the low trading volume of our common stock, the trading of relatively small quantities of shares by our stockholders could disproportionately influence the market price of our common stock in either direction. The price for our shares could, for example, decline significantly in the event that a large number of shares of our common stock are sold on the market without commensurate demand, as compared to an issuer with a higher trading volume that could better absorb those sales without an adverse impact on its stock price.

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

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

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 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, or DGCL, which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

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

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

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

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

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

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

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

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

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

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act 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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or vaccine candidates, or grant licenses on terms unfavorable to us.

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

The global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including most recently as a result of the COVID-19 pandemic. 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, 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.

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

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

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

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

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by management related to the internal control over financial reporting in our Form 10-K for the year ending December 31, 2021 and, when we are no longer an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the Sarbanes-Oxley Act, the requirements of being a reporting company under the Exchange Act and any complex accounting rules in the future, we may need to upgrade our information technology systems, implement additional financial and management controls, reporting systems and procedures, and hire additional accounting and finance staff. We are currently in the process of hiring additional accounting and finance staff as we grow our business. If we are unable to hire the additional accounting and finance staff necessary to comply with these requirements, we may need to retain additional outside consultants. If we or, if required, our auditors, are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

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

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

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

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by

collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

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

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

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

Not applicable.

(b) **Use of Proceeds**

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

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. There has been no material change in the planned use of proceeds from our IPO from those disclosed in the final prospectus for our IPO dated as of June 11, 2020 and filed with the SEC pursuant to Rule 424(b)(4) on June 15, 2020.

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

Not applicable.

**Item 3. Defaults Upon Senior Securities.**

Not applicable.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

| Exhibit Number | Description | Incorporated by Reference | | | |
|---|---|---|---|---|---|
| | | Schedule Form | File Number | Exhibit | Filing Date |
| 3.1 | Amended and Restated Certificate of Incorporation of Vaxcyte, Inc., as amended | 8-K | 001-39323 | 3.1 | June 16, 2020 |
| 3.2 | Amended and Restated Bylaws of Vaxcyte, Inc. | 8-K | 001-39323 | 3.2 | June 16, 2020 |
| 10.1+* | Development and Manufacturing Services Agreement by and between the Registrant and Lonza Ltd, dated October 21, 2016, as amended. | | | | |
| 10.2 | Lease Agreement by and between the Company and ARE-San Francisco No. 63, LLC, dated as of January 21, 2021 | 8-K | 001-39323 | 10.1 | January 21, 2021 |
| 31.1* | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | |
| 31.2* | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | |
| 32.1† | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | |
| 32.2† | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | |
| 101.INS | Inline XBRL Instance Document: the instance document does not appear in the interactive Data File because its XBRL tags are embedded within the Inline XBRL document | | | | |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document | | | | |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document | | | | |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document | | | | |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document | | | | |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document | | | | |
| 104 | Inline XBRL for the cover page of the Quarterly Report on Form 10-Q included in the Exhibit 101 Inline XBRL Document Set. | | | | |

* Filed herewith.

\+ Certain portions of this agreement have been omitted because the omitted portions are both not material and would likely cause competitive harm if publicly disclosed.

† The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

**SIGNATURES**

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

Vaxcyte, Inc.

Date: May 11, 2021 By: /s/ Grant E. Pickering

**Grant E. Pickering**
**Chief Executive Officer**

Date: May 11, 2021 By: /s/ Andrew Guggenhime

**Andrew Guggenhime**
**President and Chief Financial Officer**

**Exhibit 10.1**

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.**

# Development and Manufacturing Services Agreement

(the "Agreement")

by and between

**Lonza Ltd**
Münchensteinerstrasse 38
CH-4002 Basel
Switzerland

- hereinafter "**Lonza**" -

and

**SutroVax Inc.**
400 E Jamie Ct #205
South San Francisco, CA 94080
United States

- hereinafter "**Customer**" -

Effective as of October 21, 2016 (the "Effective Date")

**Table of Contents**

**Appendix B**

**Appendix C**

**Recitals**

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

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

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

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

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

**1 Definitions and Interpretation**

| | |
|---|---|
| "Affiliate" | means any company, partnership or other entity which directly or indirectly Controls, is Controlled by or is under common Control with the relevant Party. "Control" means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of the relevant Party. |
| "Agreement" | means this agreement incorporating all Appendices, as amended from time to time by written agreement of the Parties. |
| "Applicable Laws" | means all relevant U.S. and European Union federal, state and local laws, statutes, rules, and regulations which are applicable to a Party's activities hereunder, including, without limitation, the applicable regulations and guidelines of any Governmental Authority and all applicable cGMP together with amendments thereto. |
| "Approval" | means the first marketing approval by the FDA or EMA of Product from the Facility for commercial supply. |
| "Background Intellectual Property" | means any Intellectual Property either (i) owned or controlled by a Party prior to the Effective Date or (ii) developed or acquired by a Party independently from the performance of the Services hereunder during the Term of this Agreement, and, in the case of Lonza, without use or reliance on Customer Materials or Customer Information, and, in the case of the Customer, without use or reliance on Lonza materials or Lonza Information. |
| "Batch" | means the Product derived from a single run of the Manufacturing Process at a scale to be mutually agreed by the Parties. |
| "Batch Price" | means the Price of each Batch. |

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| “Campaign” | means a series of no less than [***] cGMP Batches manufactured consecutively. |
| “Cancellation Fee” | has the meaning given in Clause 6.5. |
| “Capital Equipment” | means those certain pieces of equipment described in the Project Plan: (i) that are specific to the production of the Product and (ii) that are purchased by Customer or for which Customer reimburses Lonza, including, without limitation, the related documentation regarding the design, validation, operation, calibration and maintenance of such equipment. |
| “Certificate of Analysis” | means a document prepared by Lonza listing tests performed by Lonza or approved External Laboratories, the Specifications and test results. |
| “cGMP” | means those laws and regulations applicable in the U.S. and Europe, relating to the manufacture of medicinal products for human use, including, without limitation, current good manufacturing practices as specified in the ICH guidelines, including without limitation, ICH Q7A “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients”, US Federal Food Drug and Cosmetic Act at 21CFR (Chapters 210, 211, 600 and 610) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC. For the avoidance of doubt, Lonza’s operational quality standards are defined in internal cGMP policy documents. |
| “cGMP Batches” | means any Batches which are required under the Project Plan to be manufactured in accordance with cGMP. |
| “Change” | means any change to the Services or pricing incorporated into a written amendment to the Agreement in accordance with clause 16.2 or effected in accordance with the Quality Agreement. |
| “Commencement Date” | means the date of commencement of manufacturing activities for a Batch hereunder. |
| “Confidential Information” | means Customer Information and/or Lonza Information, as the context requires. |
| “Customer Information” | means all technical and other information which at the time of disclosure by Customer was not known to Lonza or in the public domain relating to the Manufacturing Process and the Product, from time to time supplied by the Customer to Lonza, including any materials supplied by Customer to Lonza in accordance with the Project Plan. |
| “Customer Materials” | means any Raw Materials, components of Product, or other materials of any nature provided by Customer. |
| “EMA” | means the European Medicines Agency or any successor agency thereto. |

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| “Engineering Batches” | means a Batch that is intended to demonstrate the transfer of the Manufacturing Process to the Facility. |
| “External Laboratories” | means any Third Party instructed by Lonza, with Customer’s prior consent, which is to conduct activities required to complete the Services. |
| “Facility” | means Lonza’s manufacturing facilities in Visp, Switzerland, or such other Lonza facility as may be agreed upon by the Parties. |
| “FDA” | means the United States Food and Drug Administration, or any successor agency thereto. |
| “Governmental Authority” | means any Regulatory Authority and any national, multi-national, regional, state or local regulatory agency, department, bureau, or other governmental entity in the U.S., Switzerland or the European Union. |
| “Intellectual Property” | means (i) inventions (whether or not patentable), patents, trade secrets, copyrights, trademarks, trade names and domain names, rights in designs, rights in computer software, database rights, rights in confidential information (including know-how) and any other intellectual property rights, in each case whether registered or unregistered, (ii) all applications (or rights to apply) for, and renewals or extensions of, any of the rights described in the foregoing clause (i) and (iii) and all rights and applications that are similar or equivalent to the rights and application described in the foregoing clauses (i) and (ii), which exist now, or which come to exist in the future, in any part of the world. |
| “Lonza Information” | means all information that is proprietary to Lonza or any Affiliate of Lonza and that is maintained in confidence by Lonza or any Affiliate of Lonza and that is disclosed by Lonza or any Affiliate of Lonza to Customer under or in connection with this Agreement, including without limitation, any and all Lonza know-how and trade secrets. |
| “Manufacturing Process” | means the production process provided by Customer for the manufacture of Product, as such process may be improved or modified from time to time by agreement of the Parties in writing. |
| “Master Batch Record” | means the document, proposed by Lonza and approved by Customer, which defines the manufacturing methods, test methods and other procedures, directions and controls associated with the manufacture and testing of Product. |
| “New Customer Intellectual Property” | has the meaning given in Clause 10.2. |
| “New General Application Intellectual Property” | has the meaning given in Clause 10.3. |
| “Party” | means each of Lonza and Customer and, together, the “Parties”. |

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|---|---|
| “Price” | means the price for the Services and Products as set out in Appendix A. |
| “Process Validation Batch” | means a Batch that is produced with the intent to show reproducibility of the Manufacturing Process and is required to complete process validation studies. |
| “Product” or “Products” | means the proprietary molecule identified by Customer as CRM12 (Lonza code: SUO-001) and Polysaccharide + CRM12 Conjugates (Lonza code: SUO-002), to be manufactured using the Manufacturing Process by Lonza for Customer as specified in the Project Plans. |
| “Project Plan” or “Project Plans” | means the plans describing the Services to be performed by Lonza under this Agreement, including any update and amendment of the Project Plan to which the Parties may agree from time to time. The initial Project Plans are attached hereto as Appendix A. |
| “Quality Agreement” | means the quality agreement, attached hereto as Appendix B, setting out the responsibilities of the Parties in relation to quality as required for compliance with cGMP. |
| “Raw Materials” | means all ingredients, solvents, consumables and other components of the Product required to perform the Manufacturing Process or Services set forth in the bill of materials detailing the same (including Resins but excluding any consumables or wearables). |
| “Raw Materials Fee” | means the procurement and handling fee of [***] of the acquisition cost of Raw Materials (save for polysaccharides for conjugation that are provided by Sutrovax) by Lonza that is charged to the Customer in addition to the cost of such Raw Materials. Resins are charged at a fee of [***] as set forth in Clause 8.3. |
| “Regulatory Authority” | means the FDA, EMA and any other similar regulatory authorities as may be agreed upon in writing by the Parties. |
| “Release” | has the meaning given in Clause 7.1. |
| “Resin” | means the chromatographic media and/or UF membranes intended to refine or purify the Product, as specified in the Master Batch Record. |
| “Services” | means all or any part of the services to be performed by Lonza under this Agreement (including, without limitation, process and analytical method transfer, process development, process optimization, validation, clinical and commercial manufacturing, as well as quality control and quality assurance activities), particulars of which are set out in a Project Plan. |
| “Specifications” | means the analytical tests and acceptance criteria of the Product as specified in Appendix C, which may be amended from time to time in accordance with this Agreement. |
| “Term” | has the meaning given in Clause 14.1. |
| “Third Party” | means any party other than Customer, Lonza and their respective Affiliates. |

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

**2 Performance of Services**

2.1 Performance of Services. Subject to Clause 2.3, Lonza shall itself and through its Affiliates, diligently carry out the Services as provided in the Project Plan and use commercially reasonable efforts to perform the Services without any material defect and according to the estimated timelines as set forth in the Project Plan. Lonza shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform the Services in accordance with this Agreement. Lonza may subcontract or delegate any of its rights or obligations under this Agreement to perform the Services; provided, that any External Laboratories shall be subject to the same obligations and other provisions contained in this Agreement or any applicable Project Plan, including obligations of confidentiality at least as stringent, and as protective of Customer, as those obligations of confidence and non-use imposed upon Lonza and provided that such External Laboratories shall be subject to obligations to act diligently. Lonza shall not be responsible for analytical lab services performed by External Laboratories.

2.2 Technology Transfer. The Parties expressly agree that they shall work together to transfer the Manufacturing Process to the Facility, including implementing the technology transfer plan set forth in Project Plan. Customer shall fully support such technology transfer as reasonably requested by Lonza.

2.3 Engineering Batches. Lonza shall manufacture Engineering Batches in accordance with the Project Plan. Customer shall have the- right to make whatever further use of the non-cGMP Engineering Batches as it shall determine, provided that Customer pays for such Batches, such use is not for human use and does not violate any Applicable Laws. Lonza makes no warranty that Engineering Batches will meet cGMP or the Specifications. If Lonza determines that an Engineering Batch does meet cGMP and the Specifications, it will release such Engineering Batch as a cGMP Batch. Regardless of whether any Engineering Batch meets cGMP or the Specifications, Customer shall pay to Lonza the Price for such Engineering Batch that were executed in accordance with mutually agreed plans and meet a mutually agreed specification for bioburden, plus the Raw Materials Fee associated with such Engineering Batches. If the Engineering Batch was not performed in accordance with mutually agreed plans or does not meet the agreed bioburden specification, then Lonza shall bear the costs of replacing the Batch, the Raw Materials and Customer Materials for any replacement Engineering Batch. For each CRM12 batch, the Raw Materials liability may be up to a maximum amount of [***]. For each bioconjugate batch, the Raw Materials liability (i) during storage of each bioconjugate batch is limited to [***], (ii) for manufacturing of each bioconjugate batch is limited to [***] and (iii) per manufacturing campaign is limited to [***].

2.4 cGMP Batches. Lonza will, in accordance with the terms of this Agreement and Quality Agreement, manufacture at the Facility and Release to Customer, cGMP Batches that comply with the Manufacturing Process, cGMP and the Specifications, together with a Certificate of Analysis; provided, however, that cGMP manufacture shall not commence until at least [***] has been manufactured in compliance with cGMP and Specifications. Lonza will bear the risk of replacing any Raw Materials or Customer Materials that were consumed in any cGMP Batch that does not meet the Specifications and is not released to Customer, and after [***], Lonza will bear the risk of replacing any Batch that does not meet the Specifications. For each CRM12 batch, the Raw

Materials liability may be up to a maximum amount of [***]. (i) during storage of each bioconjugate batch is limited to [***], (ii) for manufacturing of each bioconjugate batch is limited to [***] and (iii) per manufacturing campaign is limited to [***]. Prior to commencement of cGMP manufacturing, Lonza shall review the process assumptions. In the event that there is a material difference in the process assumptions as compared with the process results demonstrated during the manufacture of Engineering Batches, the Parties shall meet to discuss in good faith a revision to the Batch Price to reflect such difference.

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

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

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

2.6 Supply of Customer Information and Customer Materials. Customer shall supply to Lonza all Customer Information and Customer Materials and other information or materials that may be reasonably required by Lonza to perform the Services. Lonza shall not be responsible for any delays arising out of Customer's failure to provide such Customer Information, Customer Materials, or other information or materials reasonably required to perform the Services to Lonza, and [***]. Lonza hereby undertakes not to use the Customer Materials or Customer Information (or any part thereof) for any purpose other than the performance of the Services under this Agreement. With respect to any Customer Materials, title shall remain with the Customer and shall not transfer to Lonza.

2.7 Raw Materials. Lonza shall procure all required Raw Materials as well as consumables other than those Raw Materials that are Customer Materials. Customer shall be responsible for payment for all consumables and Raw Materials ordered or irrevocably committed to be procured by Lonza hereunder. Upon cancellation of any Batch or termination of the Agreement, all unused Raw Materials shall be paid for by Customer within [***] days of invoice and at Customer's option will either be (a) held by Lonza for future use for the production of Product, (b) delivered to Customer, or (c) disposed of by Lonza.

**3 Project Management / Steering Committee**

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

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

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

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

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

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

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

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

**4 Quality**

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

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

**5 Insurance**

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

**6 Forecasting, Ordering and Cancellation**

6.1 Forecasting. No later than the[***] day of each [***], Customer shall supply Lonza with a written forecast showing Customer's good faith estimated [***] requirements for Batches for the following [***] month period (the "Forecast"). No later than [***] following Lonza's receipt of a Forecast, Lonza shall provide written notice to Customer of [***] and shall provide Customer with an estimated production schedule showing the estimated Commencement Date and delivery date of each Batch. The forecast and [***] given in this Section 6.1 shall not be binding on Customer or Lonza.

6.2 Purchase Orders. Customer shall place purchase orders binding on Customer for the number of Batches it wishes to order at least [***] months (or earlier as may be [***]) prior to the Commencement Date for such Batches in accordance with Lonza's most recent response to the Forecast. Each binding purchase order shall be signed by Customer and shall authorize Lonza to manufacture such Batches of the Product as are set forth therein. Lonza shall not be obligated to commence manufacture of any Batch unless and until such written purchase order is accepted in writing by Lonza. Any delivery date set forth in Lonza's written confirmation of a purchase order shall be an estimated delivery date only. All ordered Batches shall be scheduled in a single Campaign in each calendar year unless otherwise agreed by Lonza. Any additional or inconsistent terms or conditions of any Customer purchase order, acknowledgement or similar standardized form given or received pursuant to this Agreement shall have no effect and such terms and conditions are hereby rejected.

6.3 Rescheduling. Lonza shall have the right to reschedule a Commencement Date of any Batch or Campaign upon reasonable prior written notice to Customer, provided that the rescheduled Commencement Date is no earlier or no later than [***] from the Commencement Date originally estimated at the time of Lonza's acceptance of the binding purchase order, and further provided that Customer is able to provide the necessary Customer Materials. If the Customer requests to change the Commencement Date, Lonza will make all reasonable attempts to accommodate the request; provided, however, in the event that this change would impact other projects scheduled for occupancy in the designated suite or suites, manufacture of the Customer's Batch or Campaign may be delayed until an adequate time period is available in the Facility schedule. Any such change requested by Customer may result in a rescheduling fee. Any delay requested by Customer of more than [***] shall be considered a cancellation pursuant to Section 6.5.

6.4 Cancellation of a Binding Purchase Order for Polysaccharide + CRM12 Conjugates. Customer may cancel a binding purchase order for Polysaccharide + CRM12 Conjugates upon written notice to Lonza, subject to the payment of a cancellation fee as calculated below (the "Cancellation Fee"):

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

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

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

6.4.4 In the event Customer provides written notice of cancellation more [***] prior to the Commencement Date of a subject Batch, then [***].

6.4.5 Notwithstanding the provisions of this Clause 6.4, Lonza will use commercially reasonable efforts to reschedule its Facility to mitigate any losses from a cancellation, and if Lonza is able to reallocate any reserved capacity for the performance of services for any third party during the applicable period, then Customer's obligation to pay the amounts under Sections 6.4.1, 6.4.2 or 6.4.3, shall be reduced pro-rata based on the use of such capacity for such third party during the applicable period.

6.5 Cancellation of a Binding Purchase Order for CRM 12. Customer may cancel a binding purchase order for CRM 12 upon written notice to Lonza, subject to the payment of a cancellation fee as calculated below (the "Cancellation Fee'):

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

6.5.2 In the event Customer provides written notice of cancellation more than [***] prior to the Commencement Date of a subject Batch, then [***].

Notwithstanding the provisions of this Clause 6.4, Lonza will use commercially reasonable efforts to reschedule its Facility to mitigate any losses from a cancellation, and if Lonza is able to reallocate any reserved capacity for the performance of services for any third party during the applicable period, then Customer's obligation to pay the amounts under Sections 6.4.1, 6.4.2 or 6.4.3, shall be reduced pro-rata based on the use of such capacity for such third party during the applicable period

6.6 Payment of Cancellation Fee. Any Cancellation Fee shall be payable within [***] following the written notice of cancellation associated with the cancelled Batch. Any Cancellation Fee shall include all costs associated with the cancelled Batch, including any Raw Materials.

6.7 Replacement Project. Notwithstanding the foregoing, Lonza will use commercially reasonable efforts to secure a new project [***] for the cGMP manufacturing space, [***], and then, in such case, the Cancellation Fee for each Batch cancelled that is replaced by a Batch of the new project shall be reduced by an amount equal to [***] of the production fees associated with such replacement Batch.

6.8 Preferred Partnership. Customer and Lonza recognize the mutual strategic value of forging a long-term business relationship (hereinafter a "Preferred Partnership"). Reflecting this Preferred Partnership, Customer agrees [***] from the Effective Date of this Agreement to contract exclusively with Lonza for the manufacture of any and all [***] provided that Lonza can manufacture said product a) [***], b) [***], and c) [***].

**7 Delivery and Acceptance**

7.1 Delivery. All Product shall be delivered [***] (as defined by Incoterms® 2010). Lonza shall deliver to Customer the Certificate of Analysis and such other documentation as is reasonably required to meet all applicable regulatory requirements of the Governmental Authorities not later than the date of delivery of Batches (the "Release"). With respect to any Customer Materials, title and risk of loss shall remain with the Customer and shall not transfer to Lonza. With respect to Product, title and risk of loss shall remain with Lonza until Release, and shall transfer to Customer upon Release in accordance with this provision.

7.2 Storage. Customer shall arrange for shipment and take delivery of such Batch from the Facility, at Customer's expense, within [***] after Release or pay applicable storage costs. Lonza shall provide storage on a bill and hold basis for such Batch(es) at no charge for up to [***]; provided that any additional storage beyond [***] will be subject to availability and, if available, will be charged to Customer and will be subject to a separate agreement. In addition to Section 8.2, Customer shall be responsible for all value added tax (VAT) and any other applicable taxes, levies, import, duties and fees of whatever nature imposed as a result of any storage. Notwithstanding anything to the contrary contained in this Agreement, in no event shall Lonza be required to store any Batch for more than [***] after Release. Within [***] following a written request from Lonza, Customer shall provide Lonza with a letter in form satisfactory to Lonza confirming the bill and hold status of each stored Batch.

7.3 Acceptance/Rejection of Product.

7.3.1 Promptly following Release of Batches, Customer shall inspect such Batches and shall have the right to test such Batches to determine compliance with the Specifications. Customer shall notify Lonza in writing of any rejection of a Batch based on any claim that it fails to meet Specifications within [***] of Release, after which time all unrejected Batches shall be deemed accepted.

7.3.2 In the event that Lonza believes that a Batch has been incorrectly rejected, Lonza may require that Customer provide to it Batch samples for testing. Lonza may retain and test the samples of such Batch. In the event of a discrepancy between Customer's and Lonza's test results such that Lonza's test results fall within relevant Specifications, or there exists a dispute between the Parties over the extent to which such failure is attributable to a given Party, the Parties shall cause an independent laboratory promptly to review records, test data and perform comparative tests and/or analyses on samples of the Product that allegedly fails to conform to Specifications. Such independent laboratory shall be mutually agreed upon by the Parties. The independent laboratory's results shall be in writing and shall be final and binding save for manifest error. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules.

7.3.3 Lonza shall replace any Batch that failed to conform with the Specifications (a "Failed Batch"), in the event that it is determined (by the Parties or the independent laboratory) that such failure was [***] ("Lonza Responsibility"). If any replacement cGMP Batch provided as replacement for a Failed Batch also fails to conform to the Specifications, then the Steering Committee shall decide in its sole discretion, [***]. Such replacement shall be made as promptly as practicable, in light of available manufacturing capacity, after the confirmation of Lonza Responsibility, and in any case as soon as reasonably possible after confirmation of Lonza Responsibility. Where possible, such replacement Batch shall be manufactured with the next scheduled cGMP Batch or Campaign. [***] acknowledges and agrees that [***] with respect to a Failed Batch that is a Lonza Responsibility [***], and in furtherance thereof, [***]. Lonza shall not be responsible for the cost of Raw Materials or Customer Materials consumed in any Failed Batch except to the extent set forth in this Clause 7.3.3.

## 8 Price and Payment

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

8.2 Unless otherwise indicated in writing by Lonza, all Prices and charges are exclusive of value added tax (VAT) and of any other applicable taxes, levies, import, duties and fees of whatever nature imposed by or under the authority of any government or public authority and all such charges applicable to the Services (other than taxes on Lonza's income) shall be paid by Customer. When sending payment to Lonza, the Customer shall quote the relevant invoice number in its remittance advice.

8.3 Lonza shall issue invoices to Customer for [***] of the Price for Products or Services upon commencement thereof and [***] upon Release of applicable Batches or completion of applicable Services, unless otherwise stated in the Project Plan. Charges for Raw Materials and the Raw Materials Fee for each Batch shall be invoiced upon the Release of each Batch. Charges for Resins shall be invoiced by Lonza upon placement of purchase orders for such Resins by Lonza at cost plus a fee of [***]. All invoices are strictly net and payment must be made within [***] of date of invoice. Payment shall be made without deduction, deferment, set-off, lien or counterclaim.

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

8.5 Price adjustments.

8.5.1 Not more than once per calendar year, Lonza may adjust the Price in accordance with the [***] for the previous calendar year. The new Price reflecting such Batch Price adjustment shall be effective for any Batch for which the Commencement Date is on or after the date of Lonza's notice to Customer of the Price adjustment.

8.5.2 In addition to the above, the Price may be changed by Lonza, upon reasonable prior written notice to Customer (providing reasonable detail in support thereof), to reflect (i) an increase in variable costs (such as energy or Raw Materials) by more than [***] (based on the initial Price or any previously amended Price), or for a process adjustment or assumption changes, and (ii) any material change in an environmental, safety or regulatory standard that substantially impacts Lonza's cost and ability to perform the Services.

**9 Capital Equipment**

9.1 Any Capital Equipment required for the performance of the Services shall be acquired on terms to be agreed by the Parties prior to commencement of the relevant Services.

**10 Intellectual Property**

10.1 Except as expressly otherwise provided herein, neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Background Intellectual Property of the other Party.

10.2 Subject to Clause 10.3, Customer shall own all right, title, and interest in and to any and all Intellectual Property that Lonza and/or its Affiliates, the External Laboratories or other contractors or agents of Lonza develops, conceives, invents, first reduces to practice or makes, solely or jointly with Customer or others, in the performance of the Services, to the extent such Intellectual Property is a direct derivative of or improvement to the Product, Customer Materials, Customer Information and/or Customer Background Intellectual Property (collectively, the "New Customer Intellectual Property"). For avoidance of doubt, "New Customer Intellectual Property" shall include any material, processes or other items that solely embody, or that solely are claimed or covered by, any of the foregoing Intellectual Property, but excluding any New General Application Intellectual Property.

10.3 Notwithstanding Clause 10.2, and subject to the license granted in Clause 10.5, Lonza shall own all right, title and interest in Intellectual Property that Lonza and/or its Affiliates, the External Laboratories or other contractors or agents of Lonza, solely or jointly with Customer, develops, conceives, invents, or first reduces to practice or makes in the course of performance of the Services to the extent such Intellectual Property (i) [***], or (ii) [***] ("New General Application Intellectual Property"). For avoidance of doubt, "New General Application Intellectual Property" shall include any material, processes or other items that embody, or that are claimed or covered by, any of the foregoing Intellectual Property.

10.4 Lonza hereby assigns to Customer all of its right, title and interest in any New Customer Intellectual Property. Lonza shall execute, and shall require its personnel as well as its Affiliates, External Laboratories or other contractors or agents and their personnel involved in the performance of the Services to execute, any documents reasonably required to confirm Customer's ownership of the New Customer Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New Customer Intellectual Property.

10.5 Subject to the terms and conditions set forth herein (including the payment of the Price as required above), Lonza hereby grants to Customer a non-exclusive, world-wide, fully paid-up, irrevocable, transferable license, including the right to grant sublicenses, under the New General Application Intellectual Property, to research, develop, make, have made, use, sell and import the Product manufactured under this Agreement.

10.6 Customer hereby grants Lonza the non-exclusive right to use the Customer Information, Customer Background Intellectual Property and New Customer Intellectual Property during the Term solely for the purpose of fulfilling its obligations under this Agreement; provided, however, that no license is granted to any Customer Background Intellectual Property that is owned or controlled by Sutro Biopharma, Inc.

10.7 Customer will have the right to transfer the Manufacturing Process to itself and/or to any Third Party; provided, however, to the extent such technology transfer includes Lonza Confidential Information, or Lonza Background Intellectual Property, such technology transfer shall be subject to [***], and a reasonable royalty and/or licensing fee and terms to be agreed upon by the Parties. [***]. If [***] the Manufacturing Process includes the use of any such additional royalty-bearing Lonza Confidential Information or Lonza Background Intellectual Property, then Customer will pay to Lonza an agreed royalty and/or other agreed payments for the use of Lonza Confidential Information or Lonza Background Intellectual Property. Lonza shall provide reasonably necessary documents to complete such technology transfer, including transfer of New General Application Intellectual Property, if applicable, and, subject to the terms and conditions of this Clause 10.7, Lonza Confidential Information or Lonza Background Intellectual Property, [***] and Customer shall reimburse Lonza for any costs [***] and expenses, provided that the total cost of such assistance (excluding any costs paid to Lonza for the use of Lonza's Confidential Information or Lonza Background Intellectual Property) will not exceed [***].

**11 Warranties**

11.1 Lonza warrants that:

11.1.1 the Services shall be performed in a professional and workmanlike manner and in accordance with all Applicable Laws;

11.1.2 Lonza will not knowingly include in the Manufacturing Process any elements that infringe any such intellectual or industrial property rights vested in any Third Party;

11.1.3 except with respect to any development services and Engineering Batches, the manufacture of Product shall be performed in accordance with cGMP and will meet the Specifications at the date of delivery;

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

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

11.1.6 Lonza has never been debarred under the Generic Drug Enforcement Act of 1992, 21 U.S.C. Sec. 335a (a) or (b) (the "Act"). In the event that during the term of this Agreement, Lonza (i) becomes debarred, suspended, excluded, sanctioned, or otherwise declared ineligible under the Act; Lonza agrees to promptly notify Customer. Lonza also agrees that in the event that it becomes debarred, suspended, excluded, sanctioned, or otherwise declared ineligible under the Act, it shall promptly cease all activities relating to this Agreement;

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

11.2 Customer warrants that:

11.2.1 as of the date of this Agreement to the best of the Customer's knowledge and belief, the Customer has all the rights necessary to permit Lonza to perform the Services without infringing the Intellectual Property rights of any Third Party and the performance of the Services shall not infringe any Third Party Intellectual Property rights;

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

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

11.3 DISCLAIMER: THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, AND ALL OTHER WARRANTIES, BOTH EXPRESS AND IMPLIED, ARE EXPRESSLY DISCLAIMED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

11.4 Debarment.

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

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

**12 Indemnification and Liability**

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

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

12.3 Indemnification Procedure. If the Party to be indemnified intends to claim indemnification under this Clause 12, it shall promptly notify the indemnifying Party in writing of such claim. The indemnitor shall have the right to control the defense and/or settlement thereof; provided, however, that (i) the indemnitor must obtain the prior written consent of the indemnitee (not to be unreasonably withheld) before entering into any settlement of such third party claim, and (ii) any indemnitee shall have the right to retain its own counsel at its own expense. The indemnitee, its employees and agents, shall reasonably cooperate with the indemnitor in the investigation of any liability covered by this Clause 12. The failure to deliver prompt written notice to the indemnitor of any claim, to the extent prejudicial to its ability to defend such claim, shall relieve the indemnitor of any obligation to the indemnitee under this Clause 12.

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

12.5 LIMITATION OF LIABILITY. LONZA'S LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED, IN THE AGGREGATE, [***], EXCEPT TO THE EXTENT RESULTING FROM LONZA'S FRAUD, GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT.

**13 Confidentiality**

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

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

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

13.3.1 at the time of disclosure was publicly available; or

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

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

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

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

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

13.5 Each Party will restrict the disclosure of Confidential Information to such officers, employees, professional advisers, finance-providers, consultants and representatives of itself and its Affiliates who have been informed of the confidential nature of the Confidential Information and who have a need to know such Confidential Information for the purpose of this Agreement or an applicable financing or acquisition. Both Parties may disclose Confidential Information of the other Party and its Affiliates to potential and actual acquirers provided such disclosure is limited to the terms of this Agreement. Customer also may disclose to its potential and actual: (i) acquirers and (ii) bona fide collaborators in the research, development and commercialization of the Products, the work product provided to Customer by Lonza as a consequence of the provision of the Services. Prior to disclosure to such persons, the Receiving Party shall inform the Disclosing Party and it shall bind its and its Affiliates' officers, employees, consultants and representatives to confidentiality and non-use obligations no less stringent than those set forth herein. The Receiving Party shall notify the Disclosing Party as promptly as practicable of any unauthorized use or disclosure of the Confidential Information.

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

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

**14 Term and Termination**

14.1 Term. This Agreement shall commence on the Effective Date and shall end on the fifth (5th) anniversary of the Effective Date unless terminated earlier as provided herein or extended by mutual written consent of the Parties (the "Term"). Notwithstanding the foregoing, each Project Plan may have separate term and termination provisions so long as the term of any Project Plan does not extend beyond the Term.

14.2 Termination. This Agreement may be terminated as follows:

14.2.1 by either Party for any reason upon [***] prior written notice; provided that Lonza may not provide such notice until after [***]. In such an event all cancellation terms in this Agreement shall apply (except, in the case of termination by Lonza pursuant to Clause 14.2.1, the Cancellation Fees shalt not apply), and the Customer shall make payments for work commenced and performed under any purchase order(s) by Lonza prior to the termination notice date;

14.2.2 by either Party if the other Party breaches a material provision of this Agreement or a Project Plan and fails to cure such breach to the reasonable satisfaction of the non-breaching Party within [***] following written notification of such breach from the non-breaching party to the breaching party; provided, however, that such [***] period shall be extended as agreed by the Parties if the identified breach is incapable of cure within [***] and if the breaching Party provides a plan and timeline to cure the breach, promptly commences efforts to cure the breach and diligently prosecutes such cure [***];

14.2.3 by either Party, immediately, if the other Party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, or files or has filed against it, a petition in bankruptcy or has a receiver appointed for a substantial part of its assets; or

14.2.4 by either Party pursuant to Clause 15.

14.3 Consequences of Termination. In the event of termination hereunder, Lonza shall be compensated for (i) Services rendered up to the date of termination, including in respect of any Product in-process; (ii) all costs incurred through the date of termination, including Raw Materials costs and Raw Materials Fees for Raw Materials used or purchased for use in connection with the Project Plan; (iii) all unreimbursed Capital Equipment and related decommissioning charges incurred pursuant to Clause 9; (iv) all amounts due under Clause 6.4, without proration of the final calendar year and (v) any applicable Cancellation Fees. In the case of termination by Lonza for Customer's material breach, Cancellation Fees shall be calculated as of the date of written notice of termination.

14.4 Survival. The rights and obligations of each Party which by their nature survive the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement, including Clauses 5, 10-13 and 16 (to the extent relevant).

**15 Force Majeure**

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

15.2 "Force Majeure" shall be deemed to include any reason or cause beyond Lonza's reasonable control affecting the performance by Lonza of its obligations under the Agreement, including, but not limited to, any cause arising from or attributable to acts of God, strike, labor troubles, restrictive governmental orders or decrees, riots, insurrection, war, terrorist acts, or the inability of Lonza to obtain any required raw material, energy source, equipment, labor or transportation, at prices and on terms deemed by Lonza to be reasonably practicable, from Lonza's usual sources of supply.

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

**16 Miscellaneous**

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

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

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

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

16.5 Governing Law/Jurisdiction. This Agreement is governed in all respects by the laws of [***], without regard to its conflicts of laws principles. The Parties agree to submit to the jurisdiction of the state and federal courts [***].

16.6 Entire Agreement. This Agreement contains the entire agreement between the Parties as to the subject matter hereof and supersedes all prior and contemporaneous agreements with respect to the subject matter hereof. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same document. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by .pdf shall constitute an original signature for purposes of this Agreement.

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

**LONZA LTD**

By: */s/ Bart A. M. van Aarnhem*

Name Bart A. M. van Aarnhem
Title Senior Legal Counsel
Date 26 October 2016

By: _____

Name
Title
Date

**SutroVax Inc.**

By: */s/ Grant E. Pickering*

Name Grant E. Pickering
Title President & CEO
Date October 21, 2016

*APPENDIX A*

**Project Plan A—1**

**[Attached]**

**[***]**

**Project Plan A – 2**

**[Attached]**

{16 pages omitted}

[***]

*APPENDIX B*
**Quality Agreement**

**[Attached]**

{37 pages omitted}

**[***]**

*APPENDIX C*

**Specifications**

**{9 pages omitted}**

**[***]**

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.**

# FIRST AMENDMENT TO DEVELOPMENT AND MANUFACTURING SUPPLY AGREEMENT

This First Amendment ("**First Amendment**"), which comes into effect on January 1, 2017 (the "**First Amendment Effective Date**"), is made by and between Lonza Ltd ("**Lonza**") and SutroVax Inc ("**SutroVax**"). This First Amendment is to be incorporated as part of the Development and Manufacturing Agreement, dated October 21, 2016, between Lonza and SutroVax (the "**Original Agreement**"). Lonza and Sutrovax, hereafter referred to as a "**Party**" and collectively as the "**Parties.**"

Whereas:

1. Lonza and SutroVax entered into the **Original Agreement**, which the Parties now desire to amend;

2. Sutrovax wishes to extend the Original Agreement in order to add the conjugation to the protein development and manufacturing;

Parties hereby agree that the following amendments are made pursuant to the Original Agreement:

1. Project Plan A-2 (Polysaccharide + CRM12 Conjugates, Lonza code SUO-002), version 4, dated 04 January 2017 shall be added to Appendix A of the Original Agreement, in addition to the pre-existing Project Plan A-1 (Technology Transfer and cGMP Manufacturing of CRM12, Lonza code SUO-001). Project Plan A-2 is attached to this First Amendment as **Annex 1**.

2. All capitalized terms used herein shall have the meaning set forth in the Original Agreement.

3. All other terms and conditions of the Original Agreement shall remain in full force and effect. In the event of any conflict between the terms and conditions of this First Amendment and the Original Agreement, the terms and conditions set forth in the Original Agreement shall control.

4. No modification of or amendment to this First Amendment, nor any waiver of any rights under this First Amendment, will be effective unless in writing signed by the duly authorized representatives of both Parties, and the waiver of any breach or default will not constitute a waiver of any other right hereunder or any subsequent breach or default.

IN WITNESS WHEREOF, SutroVax and Lonza hereby enter into this First Amendment, effective as of the First Amendment Effective Date.

**[Signatures on following page]**

**SUTROVAX INC**

| | |
|---|---|
| By: | */s/ Grant E. Pickering* |
| Name: | Grant E. Pickering |
| Title: | President & CEO |
| By: | |
| Name: | |
| Title: | |

**LONZA LTD**

| | |
|---|---|
| By: | */s/ Bart A M. van Aarnhem* |
| Name: | Bart A M. van Aarnhem |
| Title: | Senior Legal Counsel |
| By: | */s/ Cordula Altekrüger* |
| Name: | Cordula Altekrüger |
| Title: | Senior Legal Counsel |

**Annex 1**

**Project Plan A-2**

**to**

**Development and Manufacturing Agreement**

{24 pages omitted}

[***]

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.**

# SECOND AMENDMENT TO DEVELOPMENT AND MANUFACTURING SUPPLY AGREEMENT

This Second Amendment ("**Second Amendment**"), which comes into effect on July 1, 2017 (the "**Second Amendment Effective Date**"), is made by and between Lonza Ltd ("**Lonza**") and SutroVax Inc ("**SutroVax**"). This Second Amendment is to be incorporated as part of the Development and Manufacturing Agreement, dated October 21, 2016, between Lonza and SutroVax (the "**Original Agreement**"). Lonza and SutroVax, hereafter referred to as a "**Party**" and collectively as the "**Parties.**"

Whereas:

- Lonza and SutroVax entered into the **Original Agreement**, which the Parties now desire to amend;

- SutroVax wishes to extend the Original Agreement in order to add generation of RCB/PCB for 24 *S. pneumoniae* strains.

Parties hereby agree that the following amendments are made pursuant to the Original Agreement:

Project Plan A-3 (Generation of RCB/PCB of 24 *S. pneumoniae* strains, Lonza code SUO-005), version 2, dated 19 June 2017 shall be added to Appendix A of the Original Agreement, in addition to the pre-existing Project Plan A-1 (Technology Transfer and cGMP Manufacturing of CRM12, Lonza code SUO-001) and Project Plan A-2 (Polysaccharide + CRM12 Conjugates, Lonza code SUO-002); Project Plan A-3 is attached to this Second Amendment as **Annex 1**.

1. All capitalized terms used herein shall have the meaning set forth in the Original Agreement.

2. All other terms and conditions of the Original Agreement shall remain in full force and effect. In the event of any conflict between the terms and conditions of this Second Amendment and the Original Agreement, the terms and conditions set forth in the Original Agreement shall control.

3. No modification of or amendment to this Second Amendment, nor any waiver of any rights under this Second Amendment, will be effective unless in writing signed by the duly authorized representatives of both Parties, and the waiver of any breach or default will not constitute a waiver of any other right hereunder or any subsequent breach or default.

IN WITNESS WHEREOF, SutroVax and Lonza hereby enter into this Second Amendment, effective as of the Second Amendment Effective Date.

**[Signatures on following page]**

| **SUTROVAX INC** | | **LONZA LTD** | |
|---|---|---|---|
| By: | */s/ Grant E. Pickering* | By: | */s/ Marina Eiting* |
| Name: | Grant E. Pickering | Name: | Marina Eiting |
| Title: | President & CEO | Title: | PM |
| By: | | By: | */s/ Andreas Brunner* |
| Name: | | Name: | Andreas Brunner |
| Title: | | Title: | Director |

**Annex 1**

**Project Plan A-3**

**to**

**Development and Manufacturing Agreement**

{11 pages omitted}

[***]

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.**

# THIRD AMENDMENT TO DEVELOPMENT AND MANUFACTURING SUPPLY AGREEMENT

This Third Amendment ("**Third Amendment**"), which comes into effect on September 26, 2017 (the "**Third Amendment Effective Date**"), is made by and between Lonza Ltd ("**Lonza**") and SutroVax Inc ("**SutroVax**"). This Third Amendment is to be incorporated as part of the Development and Manufacturing Agreement, dated October 21, 2016, between Lonza and SutroVax (the "**Original Agreement**"). Lonza and SutroVax, hereafter referred to as a "**Party**" and collectively as the "**Parties**."

Where

1. Lonza and SutroVax entered into the **Original Agreement**, which the Parties now desire to amend;

2. SutroVax wishes to extend the Original Agreement in order to add the production of 25 Polysaccharides to the pneumococcal conjugate vaccine project.

Parties hereby agree that the following amendments are made pursuant to the Original Agreement:

1. All capitalized terms used herein shall have the meaning set forth in the Original Agreement

2. Project Plan A-4 (cGMP Supply of 25 Polysaccharides for a Multi-Valent Pneumococcal Vaccine, Lonza code SUO-005), version 5, dated September 15, 2017 shall be added to Appendix A of the Original Agreement, in addition to the pre-existing Project Plan A-1 (Technology Transfer and cGMP Manufacturing of CRM12, Lonza code SUO-001), Project Plan A-2 (Polysaccharide + CRM12 Conjugates, Lonza code SUO-002), version 4, dated 22 December 2016, and Project Plan A-3 (Generation of RCB/PCB of 24 *S. pneumonia* strains, Lonza code SUO-005), version 2, dated 19 June 2017. Project Plan A-4 is attached to this Third Amendment as **Annex 1**.

3. The Parties hereby agree that the current definition of "Background Intellectual Property" shall be deleted in its entire and shall be replaced by the following:

| | |
|---|---|
| "Background Intellectual Property" | *means any Intellectual Property either (i) owned, licensed or controlled by a Party prior to the Effective Date or (ii) developed or acquired by a Party independently from the performance of the Services hereunder during the Term of this Agreement, and, in the case of Lonza, without the use or reliance on Customer Materials or Customer Information, and, in the case of the Customer, without use or reliance on Lonza materials or Lonza information.* |

4. The Parties hereby agree that the current definition of "Product" shall be deleted in its entire and shall be replaced by the following:

| | |
|---|---|
| "*Product*" | *means the proprietary molecules identified by Customer in the applicable Project Plan, including: (a) CRM12 (Lonza code: SUO-001); (b) Polysaccharide + CRM12 Conjugates (Lonza code: SUO-002); (c) RCB/PCB of 24 S. pneumoniae strains (Lonza code SUO-005); and (d) 25 Polysaccharides (Lonza code SUO-006).* |

5. The Parties hereby agree that the current definition of "Raw Material Fee" shall be deleted in its entire and shall be replaced by the following:

| | |
|---|---|
| "*Raw Material Fee*" | *means the procurement and handling fee of [***] of the acquisition cost of Raw Materials by Lonza that is charged to the Customer in addition to the cost of such Raw Materials. Resins are charged at a fee of [***] as set forth in Clause 8.3.* |

6. The Parties hereby agree that the current clause 6.5 shall be deleted in its entire and shall be replaced by the following clause:

*"6.5 Cancellation of a Binding Purchase Order for CRM12 and/or for the manufacturing of polysaccharides Batches. Customer may cancel a binding purchase order for CRM12 and/or for the manufacturing of polysaccharides Betches upon written notice to Lonza, subject to the payment of a cancellation fee as calculated below (the "Cancellation Fee"):*

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

*6.5.2 In the event Customer provides written notice of cancellation more than [***] prior to the Commencement Date of a subject Batch, then [***]; and*

*6.5.3 Notwithstanding the above, the Parties hereby agree that [***] shall apply with respect to [***], unless Customer [***], in which case [***].*

7. The Parties hereby agree that the current clause 7.2 shall be deleted in its entire and shall be replaced by the following clause:

"*7.2 Storage. CRM12 and polysaccharide Batches (required intermediates for the production of Conjugate Drug Substances) will be stored at no charge for up to [***] after Release of Conjugate Drug Substances; provided that any additional storage beyond [***] will be subject to availability and, if available, will be charged to Customer and will be subject to a separate agreement. Except for CRM12 and polysaccharide Batches, Customer shall arrange far shipment and take delivery of such Batch from the Facility, at Customer's expense, within [***] days after Release or pay applicable storage costs, unless otherwise agreed to by the Parties. Lonza shall provide storage on a bill and hold basis for such Batch(es) at no charge for up to [***]; provided that any additional storage beyond [***]) days will be subject to availability and, if available, will be charged to Customer and will be subiect to a separate agreement. In addition to Section 8.2, Customer shall be responsible for all value added tax (VAT) and any other applicable taxes, levies, import, duties and fees of whatever nature imposed as a result of any storage. Unless otherwise agreed to by the Parties, in no event shall Lonza be required to store any Batch for more than [***] calendar days after Release. Within [***] days following a written request from Lonza, Customer shall provide Lonza with a letter in form satisfactory to Lonza confirming the bill and hold status of each stored Batch.*"

8. The Parties hereby agree that the current clause 8.3 shall be deleted in its entire and shall be replaced by the following clause:

"*8.3 Lonza shall issue invoices to Customer for [***] of the Price for Products or Services upon commencement thereof (the "Initiation Payment") and [***] upon Release of applicable Batches or completion of applicable Services (the "Completion Payment"), unless otherwise stated in the Project Plan. Charges for Raw Materials and the Raw Materials Fee for each Batch shall be invoiced upon the Release of each Batch. Charges for Resins shall be invoiced by Lonza upon placement of purchase orders for such Resins by Lonza at cost plus a fee of [***]. Charges for consumables and wearables, as well as charges for Services provided by External Laboratories, shall be invoiced upon the Release of the applicable Batch at cost plus a fee of [***]. Notwithstanding the above, Parties agree that in the event that Lonza does not complete stages of the IND enabling work (i.e. the stages necessary for Customer to submit the IND application, including in any event the Release of at least one (1) GMP Drug Product Batch plus one (1) month of GMP Drug Product stability testing before 31 December 2019), Lonza shall for any stage that commences after 31 December 2019 or has not been completed by 31 December 2019, invoice the Initiation Payment for Products or Services upon commencement thereof. The Completion Payment for Products or Services shall be invoiced by Lonza either (i) [***] or (ii) on [***]. All invoices are strictly net and payment must be made within [***] days of date of invoice. Payment shall be made without deduction, deferment, set-off, lien or counterclaim, except as set forth in the Agreement or any Amendments. The provisions of this Clause 8.3, including the rate of markup charges set forth herein and in the definition of Raw Materials Fees, shall apply prospectively to all Services under the Agreement, including those Services to be performed after the Amendment Three Effective Date under Work Plan A-1, Work Plan A-2, Work Plan A-3 and Work Plan A-4.*"

9. The Parties hereby agree that the current clause 10.3 shall be deleted in its entire and shall be replaced by the following clause:

"*10.3 Nowithstanding Clause 10.2, and subject to the license granted in Clause 10.5, Lonza shall own all right, title and interest in Intellectual Property that Lonza and/or its Affiliates, the External Laboratories or other contractors or agents of Lonza, solely or jointly with Custorner, develops, conceives, invents, or first reduces to practice or makes in the course of performance of the Services to the extent such Intellectual Property (i) is generally applicable to the development or manufacture of chemieal or biological products or product components, and could reasanably have been made without the use of the Customer Materials, Customer Information, or Customer Baekground Intellectual Property or (ii) is an improvement of or direct derivative of, any Lonza Background Intellectual Praperty ("New General Application Intellectual Property"). For avoidance of doubt, "New General Application Intellectual Property" shall include any material, processes or other items that embody, or that are claimed or covered by, any of theforegoing Intellectual Property.*"

10. The Parties hereby agree that the current clause 10.5 shall be deleted in its entire and shall be replaced by the following clause:

"*10.5 Subject to the terms and conditions set forth herein (including the payment of the Price as required above), Lonza hereby grants to Customer a non-exclusive, world-wide, 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.*"

11. The Parties hereby agree that the current clause 10.7 shall be deleted in its entire and shall be replaced by the following clause:

"*10.7 Customer will have the right to transfer the Manufacturing Process to itself, its Affiliates and/or any third Party, provided, however, to the extent such technology transfer includes Lonza Confidential Information, or Lonza Background Intellectual Property, such technology transfer to any Third Party shall be subject to [***], and a reasonable royalty and/or licensing fee and terms to be agreed upon by the Parties. Lonza will not include in the Manufacturing Process any Lonza Confidential Information or Lonza Background Intellectual Property that would require Customer to pay any additional payment and/or royalty to Lonza in order to transfer the Manufacturing Process to itself, its Affiliates and/or any Third Party without first obtaining Customer's prior written consent and advising Customer as to the royalty structure and any other payment that would apply for the use of such additional technologies. If Customer has provided such consent and the Manufacturing Process includes the use of any such additional payment-bearing or royalty-bearing Lonza Confidential Information or Lonza Background Intellectual Property, then Customer will pay to Lonza an agreed royalty and/or other agreed payments for the use of Lonza Confidential Information or Lonza Background Intellectual Property. Lonza shall provide reasonably necessary documents to complete such technology transfer, including transfer of New General Application Intellectual Property, if applicable, and subject to the terms and conditions of this Clause 10.7, Lonza Confidential Information or Lonza Background Intellectual Property, if incorporated into the Manufacturing Process with Customer's consent, and Customer shall reimburse Lonza for any costs (based on a full-time employee rate for such support) and expenses, provided that the total cost of such assistance (excluding any costs paid to Lonza for the use of Lonza's Confidential Information or Lonza Background Intellectual Property) will not exceed [***].*"

12. The Parties hereby agree that the current clause 14.2.1 shall be deleted in its entire and shall be replaced by the following clause:

"*14.2.1 by either Party for any reason upon [***] prior written notice; provided that Lonza may not provide such notice until [***]. In such an event all cancellation terms in this Agreement shall apply (except, in the case of termination by Lonza pursuant to Clause 14.2.1, the Cancellation Fees shall not apply), and the Customer shall make payments for work commenced and performed under any purchase order(s) by Lonza prior to the termination notice date.*"

13. All other terms and conditions of the Original Agreement shall remain in full force and effect. In the event of any conflict between the terms and conditions of this Third Amendment and the Original Agreement, the terms and conditions set forth in the Original Agreement shall control.

14. No modification of or amendment to this Third Amendment, nor any waiver of any rights under this Third Amendment, will be effective unless in writing signed by the duly authorized representatives of both Parties, and the waiver of any breach or default will not constitute a waiver of any other right hereunder or any subsequent breach or default.

[Signatures on following page]

IN WITNESS WHEREOF, SutroVax and Lonza hereby enter into this Third Amendment, effective as of the Third Amendment Effective Date.

| **SUTROVAX INC.** | | **LONZA LTD** | |
|---|---|---|---|
| By: | /s/ Grant E. Pickering | By: | /s/ Bart A. M. van Aarnhem |
| Name: | Grant E. Pickering | Name: | Bart A. M. van Aarnhem |
| Title: | President & CEO | Title: | Senior Legal Counsel |

| | | | |
|---|---|---|---|
| By: | | By: | /s/Lee Newton |
| Name: | Name: | Lee Newton | |
| Title: | Title: | Director, Commercial Development | |

**Annex 1**

**Project Plan A-4**

**to**

**Development and Manufacturing Agreement**

{23 pages omitted}

[***]

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.**

**ALL REFERENCES TO THE "FIFTH AMENDMENT" CONTAINED HEREIN SHOULD BE READ AS THE "FOURTH AMENDMENT."**

# FIFTH AMENDMENT TO DEVELOPMENT AND MANUFACTURING SUPPLY AGREEMENT

This Fifth Amendment ("**Fifth Amendment**"), which comes into effect retrospectively as per 10 June, 2018 (the "**Fifth Amendment Effective Date**"), is made by and between Lonza Ltd ("**Lonza**") and SutroVax Inc ("**SutroVax**"). This Fifth Amendment is to be incorporated as part of the Development and Manufacturing Agreement, dated October 21, 2016, between Lonza and SutroVax, as amended from time to time (the "**Original Agreement**"). Lonza and SutroVax, hereafter referred to as a "**Party**" and collectively as the "**Parties**."

Whereas

1. Lonza and SutroVax signed the Original Agreement in October 2016;

2. The Parties now wish to change the production of CRM12 from the [***] facility into the [***] facility;

3. The current Project Plan A-1 therefore needs to be adjusted and/or partly replaced by a new Project Plan A-1.1, which shall be attached to this Fifth Amendment as Annex 1.

Parties hereby agree that the following amendments are made pursuant to the Original Agreement:

1. All capitalized terms used herein shall have the meaning set forth in the Original Agreement.

2. The proposal (Technology Transfer and cGMP Manufacturing of CRM12, Lonza code SUO-001), version 4.0, dated 21 October 2016 (the "**Proposal [***]**") attached to the Original Agreement under Appendix A as Project Plan A-1, will be amended as follows:

   The stages 2-C, 2-D, 2-E and 2-F of the Proposal [***] will be replaced by the stages 2-C, 2-D, 2-E and 2-F as further set out in the proposal (cGMP Manufacturing of CRM12 in [***] facility, Lonza code SUO-001), version 1 dated 22nd June 2018 ("**Proposal [***]**"). This Proposal [***] shall be attached to the Original Agreement under Appendix A as Project Plan A-1.1, in addition to the existing Project Plans. For the avoidance of doubt, the remaining of Proposal [***] does not change and shall remain in full force and effect.

3. In addition to the above, the Parties hereby agree that the following new sub-clause 6.5.3 shall be added to the existing clause 6.5:

   6.5.3. The initial campaign in the [***] covering [***] Batches, of which the first Batch will always be an Engineering Batch, is currently scheduled for [***] (the "**CRM12 Campaign**"). As part of the transition from Proposal [***] to Proposal [***], Customer shall be entitled to cancel [***], that are part of the CRM12 Campaign up to [***] prior to the commencement of such CRM12 Campaign, without paying any cancellation fees to Lonza for such cancelled Batches. In such event, Lonza will deduct an amount of CHF [***] per cancelled Batch from the Price stated in the Purchase Order for the CRM12 Campaign. The remaining, un-cancelled Batches of the CRM12 Campaign shall be manufactured in accordance with Clause 2.3 and Clause 2.4 of the Original Agreement. For the sake of clarity, the Raw Materials purchased by Lonza for manufacturing the full

CRM12 Campaign shall remain payable by Customer and shall not be (pro-rata) refunded in the event of (partly) cancellation of this Purchase Order.

For illustrative purposes:

(i) in the event that Customer cancels the Purchase Order for the CRM12 shall pay an amount equal to the Price stated in Campaign in full, Customer that Purchase Order (i.e. [***] Batches and raw materials) CHF [***]; and

(ii) minus an amount of in the event that Customer cancels one of the Batches of the Purchase Order for the CRM12 Campaign, Customer shall pay an amount equal to the Price stated in that Purchase Order minus an amount of CHF [***].

4. All other terms and conditions of the Original Agreement shall remain in full force and effect. In the event of any conflict between the terms and conditions of this Fifth Amendment and the Original Agreement, the terms and conditions set forth in the Original Agreement shall control unless Parties specifically deviated from such terms via this Fifth Amendment.

5. No modification of or amendment to this Fifth Amendment, nor any waiver of any rights under this Fifth Amendment, will be effective unless in writing signed by the duly authorized representatives of both Parties, and the waiver of any breach or default will not constitute a waiver of any other right hereunder or any subsequent breach or default.

IN WITNESS WHEREOF, SutroVax and Lonza hereby enter into this Fifth Amendment, effective as of the Fifth Amendment Effective Date.

SUTROVAX INC

By: /s/ Grant E. Pickering
Name: Grant E. Pickering
Title: President & CEO

LONZA LTD

By: /s/ Axel Evlev
Name: Axel Evlev
Title: Commercial Development

**Annex 1 – to Fifth Amendment**

Project Plan A-1.1

{7 pages omitted}

[***]

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.**

**ALL REFERENCES TO THE "SIXTH AMENDMENT" CONTAINED HEREIN SHOULD BE READ AS THE "FIFTH AMENDMENT."**

# SIXTH AMENDMENT TO DEVELOPMENT AND MANUFACTURING SUPPLYAGREEMENT

This Sixth Amendment ("**Sixth Amendment**"), which comes into effect on March 16, 2020 (the "**Sixth Amendment Effective Date**"), is made by and between Lonza Ltd ("**Lonza**") and SutroVax Inc ("**SutroVax**"). This Sixth Amendment is to be incorporatedas part of the Development and Manufacturing Agreement, dated October 21, 2016, between Lonza and SutroVax (the "**Original Agreement**"). Lonza and SutroVax, hereafter referred to as a "**Party**" and collectively as the "**Parties**."

Whereas:

1. Lonza and SutroVax entered into the **Original Agreement**, as amended, whichthe Parties now desire to amend;

2. The Parties wish to modify the payment terms as agreed in the OriginalAgreement, as amended.

Now, therefore, the Parties hereby agree that the following amendments are made to theOriginal Agreement:

1. All capitalized terms used herein shall have the meaning set forth in the OriginalAgreement

2. The Parties hereby agree that the current clause 8.3 shall be deleted in its entire and shallbe replaced by the following clause:

> "8.3 Lonza shall issue invoices to Customer for [***] of the Price for Products or Services upon commencement thereof (the "Initiation Payment") and [***] upon Release of applicable Batches or completion of applicable Services (the "Completion Payment"), unless otherwise stated in the Project Plan. Charges for Raw Materials and the Raw Materials Fee for each Batch shall be invoiced upon the Release of each Batch. Charges for Resins shall be invoiced by Lonza upon placement of purchase orders for such Resins by Lonza at cost plus a fee of [***]. Charges for consumables and wearables, as well as charges for Services provided by External Laboratories, shall be invoiced upon the Release of the applicable Batch at cost plus a fee of [***]. Notwithstanding the above, Parties agree that in the event that Lonza does not complete stages of the IND enabling work, i.e. the stages necessary for Customer to submit the IND application, including in any event the Release of at least one (1) GMP Drug Product Batch plus one (1) month of GMP Drug Product stability testing before 31 December 2019 (the "IND-

Enabling Activities"), Lonza shall for any stage that commences after 31 December 2019 or has not been completed by 31 December 2019, invoice the Initiation Payment for Products or Services upon commencement thereof. The Completion Payment for Products or Services shall be invoiced by Lonza upon release of such Products or completion of such Services, provided, however, that Customer shall not be required to effect any payment before either (i) within thirty (30) days following completion of all IND-Enabling Activities or (ii) 30 April 2021, whichever event occurs first. All invoices are strictly net and payment must be made [***]. Payment shall be made without deduction, deferment, set-off, lien or counterclaim, except as set forth in the Agreement or any Amendments. The provisions of this Clause 8.3, including the rate of markup charges set forth herein and in the definition of Raw Materials Fees, shall apply prospectively to all Services under the Agreement, including those Services to be performed after the Amendment Three Effective Date under Work Plan A-1, Work Plan A-2, Work Plan A-3 and Work Plan A-4."

3. All other terms and conditions of the Original Agreement, as amended, shall remain in full force and effect. In the event of any conflict between the terms and conditions of thisThird Amendment and the Original Agreement, the terms and conditions set forth in the Original Agreement shall control.

4. No modification of or amendment to this Sixth Amendment, nor any waiver of any rightsunder this Sixth Amendment, will be effective unless in writing signed by the duly authorized representatives of both Parties, and the waiver of any breach or default will not constitute a waiver of any other right hereunder or any subsequent breach or default.

**[Signatures on following page]**

IN WITNESS WHEREOF, SutroVax and Lonza hereby enter into this Sixth Amendment,effective as of the Sixth Amendment Effective Date.

**SUTROVAX INC**

By: /s/ Grant Pickering

Name: Grant Pickering

Title: President & CEO

**LONZA LTD**

By: /s/ Michael Stanek

Name Michael Stanek

Title: General Counsel

/s/ Bart van Aarnhem

Bart van Aarnhem

Associate General Counsel

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.**

**ALL REFERENCES TO THE "SEVENTH AMENDMENT" CONTAINED HEREIN SHOULD BE READ AS THE "SIXTH AMENDMENT."**

# SEVENTH AMENDMENT TO DEVELOPMENT AND MANUFACTURING SUPPLY AGREEMENT

This Seventh Amendment ("**Seventh Amendment**"), which comes into effect as per April 1, 2021 (the "**Seventh Amendment Effective Date**"), is made by and between Lonza Ltd ("**Lonza**") and Vaxcyte, Inc., having its principal place of business at 353 Hatch Drive, Foster City, CA 94404, USA ("**Vaxcyte**" or "**Customer**"). This Seventh Amendment is to be incorporated as part of the Development and Manufacturing Agreement, dated October 21, 2016, between Lonza and Vaxcyte (at that time known as SutroVax, Inc.), as amended from time to time (the "**Original Agreement**"). Lonza and Vaxcyte, hereafter referred to as a "**Party**" and collectively as the "**Parties**."

**Whereas**

(A) Lonza and Vaxcyte have entered into the Original Agreement, as amended;

(B) Vaxcyte now wishes to engage Lonza for the process development and manufacturing of [***], a [***] for the 24-valent vaccine against pneumococcal infections, to serve [***] to be manufactured in a larger scale at Lonza's [***] facility;

(C) The Parties wish to enter into this Seventh Amendment in order to (i) modify the payment terms as agreed in the Original Agreement, (ii) to ensure a slot reservation for Customer in Lonza's [***] facility and (iii) expeditiously negotiate in good faith an amendment to the Original Agreement regarding the [***] of the [***] by Lonza in [***] facility (the "**Technology Transfer Amendment**").

**Now, therefore,** the Parties hereby agree that the following amendments are made to the Original Agreement:

1. All capitalized terms used herein shall have the meaning set forth in the Original Agreement.

2. The Parties hereby agree that the current clause 8.3 shall be deleted in its entirety and shall be replaced by the following clause:

*"8.3Lonza shall issue invoices to Customer for [***] of the Price for Products or Services upon commencement thereof (the "Initiation Payment") and [***] upon Release of applicable Batches or completion of applicable Services (the "Completion Payment"), unless otherwise stated in the Project Plan. Charges for Raw Materials and the Raw Materials Fee for each Batch shall be invoiced upon the Release of each Batch. Charges for Resins shall be invoiced by Lonza upon placement of purchase orders for such Resins by Lonza at cost plus a fee of [***]. Charges for consumables and wearables, as well as charges for Services provided by External Laboratories, shall be invoiced upon the Release of the applicable Batch at cost plus a fee of [***].*

*Notwithstanding the above, Parties agree that in the event that Lonza does not complete stages of the IND enabling work, i.e. the stages necessary for Customer to submit the IND application, including in any event the Release of at least one (1) GMP Drug Product Batch plus one (1) month of GMP Drug Product stability testing before 31 December 2019 (the "IND-Enabling Activities"), Lonza shall for any stage that commences after 31 December 2019 or has not been completed by 31 December 2019, invoice the Initiation Payment for Products or Services upon commencement thereof. The Completion Payment for Products or Services shall be invoiced by Lonza upon release of such Products or completion of such Services, provided, however, that Customer shall not be required to effect any payment before either (i) within thirty (30) days following completion of all IND-Enabling Activities or (ii) 30 April 2021, whichever event occurs first. If all IND-Enabling Activities are not complete by 30 April 2021, Customer will pay an amount equal to 50% of the current Completion Payment totals. The rest of the 50% Completion Payment to be paid at the completion of all IND-Enabling Activities or 31, December 2021, whichever event occurs first. All invoices are strictly net and payment must be made [***]. Payment shall be made without deduction, deferment, set-off, lien or counterclaim, except as set forth in the Agreement or any Amendments. The provisions of this Clause 8.3, including the rate of markup charges set forth herein and in the definition of Raw Materials Fees, shall apply prospectively to all Services under the Agreement, including those Services to be performed after the Amendment Three Effective Date under Work Plan A-1, Work Plan A-2, Work Plan A-3 and Work Plan A-4.*"

3. Upon execution of this Seventh Amendment, Customer agrees that it commits to a firm capacity reservation for Lonza's manufacturing capacity as follows: Customer and Lonza agree that upon signature of this Seventh Amendment Lonza will issue an invoice to Customer for the reservation of capacity in the amount of [***] (the "Reservation Fee"). The payment terms as per the Original Agreement apply ([***]). The Reservation Fee will serve as a [***] reservation, by Lonza, of sufficient capacity within Lonza`s [***] facility in [***], personnel and resources to start the [***] for the [***] on behalf of Customer in [***] and commencement of manufacturing the first campaign of the [***] in the [***] facility in [***], subject to execution of the Technology Transfer Amendment within the timeframe set forth in clause 3.c) below and a successful technology transfer. Upon signature of the Technology Transfer Amendment, the Reservation Fee [***]. In the event, however, the Parties do not reach an agreement regarding the Technology Transfer Amendment before the term mentioned in clause 3.c) below, despite good faith negotiations, Lonza shall [***]. Moreover, in such case, Lonza may release such capacity and allocate it to other customers without liability to Customer.

4. With respect to the negotiations and specific terms and conditions of the Technology Transfer Amendment, the Parties wish to record the following intentions:

   a) Upon execution of this Seventh Amendment, the Parties shall enter into good faith negotiations regarding the Technology Transfer Amendment.

   b) The Parties intend that the Technology Transfer Amendment will include, all additional terms and activities or suitable to manufacturing the Product in Lonza's [***] facility.

   c) The Parties intend to execute the Technology Transfer Amendment as soon as practicable, but in any event not later than [***]. In the event that the Parties are unable to sign the Technology Transfer Amendment by such date, despite good faith efforts by both Parties, a [***] extension for proper cause can be granted at the request of either Party.

5. The Parties agree that any activities performed by Lonza while negotiations for the Technology Transfer Amendment are in process shall be performed in accordance with the Original Agreement as currently in force.

6. All other terms and conditions of the Original Agreement shall remain in full force and effect. In the event of any conflict between the terms and conditions of this Seventh Amendment and the Original Agreement, the terms and conditions set forth in the Original Agreement shall control, unless Parties specifically deviated from such terms via this Seventh Amendment.

7. No modification of or amendment to this Seventh Amendment, nor any waiver of any rights under this Seventh Amendment, will be effective unless in writing signed by the duly authorized representatives of both Parties, and the waiver of any breach or default will not constitute a waiver of any other right hereunder or any subsequent breach or default.

8. This Seventh Amendment shall be governed by the law, and be subject to the jurisdiction of the courts of the state specified in Section 16.5 of the Original Agreement.

**[Signatures on following page]**

IN WITNESS WHEREOF, Customer and Lonza hereby enter into this Seventh Amendment, effective as of the Seventh Amendment Effective Date.

**VAXCYTE. INC.**

By: /s/ Grant Pickering

Name: Grant Pickering

Title: CEO

**LONZA LTD**

By: /s/ Marina Eiting

Name Marina Eiting

Title: Senior Program Manager

/s/ Michael Stanek

Michael Stanek

General Counsel

**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)) 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) 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

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

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

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

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

Date: May 11, 2021

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)) 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) 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

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

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

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

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

Date: May 11, 2021

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**

In connection with the Quarterly Report of Vaxcyte, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. §Section 1350, as adopted pursuant to §Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: May 11, 2021

By: /s/ Grant E. Pickering

**Grant E. Pickering**
**Chief Executive Officer**

**Exhibit 32.2**

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

In connection with the Quarterly Report of Vaxcyte, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. §Section 1350, as adopted pursuant to §Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: May 11, 2021

By: /s/ Andrew Guggenhime

**Andrew Guggenhime**
**President and Chief Financial Officer**