

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

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-38662

**SUTRO BIOPHARMA, INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**47-0926186**

(I.R.S. Employer  
Identification No.)

**111 Oyster Point Blvd,  
South San Francisco, California**  
(Address of principal executive offices)

**94080**  
(Zip Code)

**Registrant's telephone number, including area code: (650) 881-6500**

**Not Applicable:**

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common stock, \$0.001 par value	STRO	The Nasdaq Stock Market LLC (Nasdaq Global Market)

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

As of November 8, 2023, the registrant had 60,953,204 shares of common stock, \$0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

**Sutro Biopharma, Inc.**  
**Condensed Balance Sheets**  
**(Unaudited)**  
(In thousands, except share and per share amounts)

	September 30, 2023	December 31, 2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 81,834	\$ 47,254
Marketable securities	239,274	255,090
Investment in equity securities	34,043	32,020
Accounts receivable	16,627	7,122
Prepaid expenses and other current assets	9,476	11,667
Total current assets	381,254	353,153
Property and equipment, net	22,344	24,621
Operating lease right-of-use assets	23,996	26,443
Other non-current assets	3,268	1,855
Restricted cash	872	872
Total assets	<u>\$ 431,734</u>	<u>\$ 406,944</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 5,525	\$ 4,797
Accrued compensation	11,369	13,142
Deferred revenue - current	23,983	16,759
Operating lease liability - current	6,174	4,585
Debt - current	7,137	12,500
Accrued expenses and other current liabilities	19,418	14,764
Total current liabilities	73,606	66,547
Deferred revenue - non-current	78,154	89,885
Operating lease liability - non-current	24,864	29,574
Debt - non-current	-	3,771
Deferred royalty obligation related to the sale of future royalties	142,763	-
Other non-current liabilities	-	119
Total liabilities	319,387	189,896
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value — 10,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 0 shares issued and outstanding as of September 30, 2023 and December 31, 2022	-	-
Common stock, \$0.001 par value — 300,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 60,900,704 and 57,499,541 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	61	58
Additional paid-in-capital	702,752	670,223
Accumulated other comprehensive income (loss)	7	(618 )
Accumulated deficit	(590,473 )	(452,615 )
Total stockholders' equity	112,347	217,048
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 431,734</u>	<u>\$ 406,944</u>

See accompanying notes to unaudited interim condensed financial statements.

**Sutro Biopharma, Inc.**  
**Condensed Statements of Operations**  
(Unaudited)  
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues	\$ 16,924	\$ 25,147	\$ 40,010	\$ 59,140
Operating expenses				
Research and development	45,669	31,714	126,660	94,036
General and administrative	15,269	14,643	45,780	44,825
Total operating expenses	60,938	46,357	172,440	138,861
Loss from operations	(44,014)	(21,210)	(132,430)	(79,721)
Interest income	4,550	1,014	9,952	1,327
Unrealized gain on equity securities	694	3,496	2,023	323
Non-cash interest expense related to the sale of future royalties	(5,936)	-	(6,378)	-
Interest and other income (expense), net	(2,739)	(2,788)	(8,640)	(4,039)
Loss before provision for income taxes	(47,445)	(19,488)	(135,473)	(82,110)
Provision for income taxes	1,839	-	2,385	2,500
Net loss	<u>\$ (49,284)</u>	<u>\$ (19,488)</u>	<u>\$ (137,858)</u>	<u>\$ (84,610)</u>
Net loss per share, basic and diluted	<u>\$ (0.81)</u>	<u>\$ (0.37)</u>	<u>\$ (2.30)</u>	<u>\$ (1.74)</u>
Weighted-average shares used in computing basic and diluted loss per share	<u>60,599,025</u>	<u>52,345,732</u>	<u>59,894,181</u>	<u>48,622,258</u>

*See accompanying notes to unaudited interim condensed financial statements.*

**Sutro Biopharma, Inc.**  
**Condensed Statements of Comprehensive Loss**  
(Unaudited)  
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	\$ (49,284 )	\$ (19,488 )	\$ (137,858 )	\$ (84,610 )
Other comprehensive (loss) income :				
Net unrealized (loss) income on available-for-sale securities	(9 )	20	625	(1,022 )
Comprehensive loss	<u>\$ (49,293 )</u>	<u>\$ (19,468 )</u>	<u>\$ (137,233 )</u>	<u>\$ (85,632 )</u>

*See accompanying notes to unaudited interim condensed financial statements.*

**Sutro Biopharma, Inc.**  
**Condensed Statements of Stockholders' Equity**  
**(Unaudited)**  
**(In thousands, except share amounts)**

	Common Stock		Additional Paid-In- Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balances at December 31, 2022</b>	57,499,541	\$ 58	\$ 670,223	\$ (618)	\$ (452,615)	\$ 217,048
Exercise of common stock options	53,060	—	314	—	—	314
Issuance of common stock under Employee Stock Purchase Plan	239,060	—	1,097	—	—	1,097
Vesting of restricted stock units	801,769	—	—	—	—	—
Stock transaction associated with taxes withheld on restricted stock units	(73,003)	—	(451)	—	—	(451)
Stock-based compensation expense	—	—	6,021	—	—	6,021
Issuance of common stock in connection with At-The-Market sale, net of issuance costs of \$308	1,641,374	2	10,921	—	—	10,923
Net unrealized income on available-for-sale securities	—	—	—	511	—	511
Net loss	—	—	—	—	(50,050)	(50,050)
<b>Balances at March 31, 2023</b>	60,161,801	\$ 60	\$ 688,125	\$ (107)	\$ (502,665)	\$ 185,413
Vesting of restricted stock units	94,500	—	—	—	—	—
Stock transaction associated with taxes withheld on restricted stock units	(1,296)	—	(6)	—	—	(6)
Stock-based compensation expense	—	—	6,661	—	—	6,661
Issuance of common stock in connection with At-The-Market sale, net of issuance costs of \$151	216,036	—	1,048	—	—	1,048
Net unrealized income on available-for-sale securities	—	—	—	123	—	123
Net loss	—	—	—	—	(38,524)	(38,524)
<b>Balances at June 30, 2023</b>	60,471,041	\$ 60	\$ 695,828	\$ 16	\$ (541,189)	\$ 154,715
Issuance of common stock under Employee Stock Purchase Plan	287,019	—	954	—	—	954
Vesting of restricted stock units	150,250	1	—	—	—	1
Stock transaction associated with taxes withheld on restricted stock units	(7,606)	—	(33)	—	—	(33)
Stock-based compensation expense	—	—	6,003	—	—	6,003
Net unrealized loss on available-for- sale securities	—	—	—	(9)	—	(9)
Net loss	—	—	—	—	(49,284)	(49,284)
<b>Balances at September 30, 2023</b>	<u>60,900,704</u>	<u>\$ 61</u>	<u>\$ 702,752</u>	<u>\$ 7</u>	<u>\$ (590,473)</u>	<u>\$ 112,347</u>

	Common Stock		Additional Paid-In- Capital	Accumulated Other Comprehensive (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balances at December 31, 2021</b>	46,327,131	\$ 46	\$ 586,243	\$ (314)	\$ (333,411)	\$ 252,564
Exercise of common stock options	32,497	—	180	—	—	180
Issuance of common stock under Employee Stock Purchase Plan	146,165	—	1,006	—	—	1,006
Vesting of restricted stock units	465,731	1	(1)	—	—	—
Stock transaction associated with taxes withheld on restricted stock units	(44,665)	—	(404)	—	—	(404)
Stock-based compensation expense	—	—	6,974	—	—	6,974
Net unrealized loss on available-for-sale securities	—	—	—	(838)	—	(838)
Net loss	—	—	—	—	(39,110)	(39,110)
<b>Balances at March 31, 2022</b>	46,926,859	\$ 47	\$ 593,998	\$ (1,152)	\$ (372,521)	\$ 220,372
Exercise of common stock options	298	—	2	—	—	2
Vesting of restricted stock units	31,375	—	—	—	—	—
Stock transaction associated with taxes withheld on restricted stock units	(1,296)	—	(9)	—	—	(9)
Stock-based compensation expense	—	—	6,696	—	—	6,696
Issuance of common stock in connection with At-The-Market sale, net of issuance costs of \$690	1,716,996	2	8,211	—	—	8,213
Net unrealized loss on available-for-sale securities	—	—	—	(204)	—	(204)
Net loss	—	—	—	—	(26,012)	(26,012)
<b>Balances at June 30, 2022</b>	48,674,232	\$ 49	\$ 608,898	\$ (1,356)	\$ (398,533)	\$ 209,058
Exercise of common stock options	16,659	—	85	—	—	85
Issuance of common stock under Employee Stock Purchase Plan	124,351	—	607	—	—	607
Vesting of restricted stock units	76,875	—	—	—	—	—
Stock transaction associated with taxes withheld on restricted stock units	(7,606)	—	(50)	—	—	(50)
Stock-based compensation expense	—	—	6,782	—	—	6,782
Issuance of common stock in connection with At-The-Market sale, net of issuance costs of \$902	5,746,849	6	32,706	—	—	32,712
Net unrealized gain on available-for- sale securities	—	—	—	20	—	20
Net loss	—	—	—	—	(19,488)	(19,488)
<b>Balances at September 30, 2022</b>	<u>54,631,360</u>	<u>\$ 55</u>	<u>\$ 649,028</u>	<u>\$ (1,336)</u>	<u>\$ (418,021)</u>	<u>\$ 229,726</u>

See accompanying notes to unaudited interim condensed financial statements.

**Sutro Biopharma, Inc.**  
**Condensed Statements of Cash Flows**  
(Unaudited)  
(In thousands)

	Nine Months Ended September 30,	
	2023	2022
<b>Operating activities</b>		
Net loss	\$ (137,858 )	\$ (84,610 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,085	4,162
(Accretion of discount) amortization of premium on marketable securities	(6,022 )	810
Stock-based compensation	18,685	20,452
Non-cash lease expenses	2,447	1,968
Realized gain on sale of equity securities	—	(30 )
Unrealized gain on equity securities	(2,023 )	(323 )
Non-cash interest expense on deferred royalty obligation	6,378	—
Other	414	144
Changes in operating assets and liabilities:		
Accounts receivable	(9,505 )	1,213
Prepaid expenses and other assets	778	(2,941 )
Accounts payable	755	(288 )
Accrued compensation	(1,773 )	(1,037 )
Accrued expenses and other liabilities	4,579	1,329
Deferred revenue	(4,507 )	85,156
Change in operating lease liability	(3,121 )	1,408
Net cash (used in) provided by operating activities	(125,688 )	27,413
<b>Investing activities</b>		
Purchases of marketable securities	(379,728 )	(114,498 )
Maturities of marketable securities	390,960	88,460
Sales of marketable securities	11,231	32,764
Proceed from sale of equity securities	—	625
Purchases of equipment and leasehold improvements	(2,874 )	(4,491 )
Net cash provided by investing activities	19,589	2,860
<b>Financing activities</b>		
Proceeds from sales of common stock, net of issuance costs	11,971	40,925
Payment of debt	(9,375 )	(6,250 )
Proceeds from the sale of future royalties, net of issuance costs	136,208	—
Proceeds from exercise of common stock options	314	267
Taxes paid related to net shares settlement of restricted stock units	(490 )	(463 )
Proceeds from employee stock purchase plan	2,051	1,613
Net cash provided by financing activities	140,679	36,092
Net increase in cash, cash equivalents and restricted cash	34,580	66,365
Cash, cash equivalents and restricted cash at beginning of period	48,126	31,286
Cash, cash equivalents and restricted cash at end of period	<u>\$ 82,706</u>	<u>\$ 97,651</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	<u>\$ 971</u>	<u>\$ 1,442</u>
<b>Supplemental disclosure of non-cash investing and financing information:</b>		
Purchases of equipment included in accounts payable and accrued expense	<u>\$ 327</u>	<u>\$ 1,775</u>
Financing component associated with program fees	<u>\$ 7,531</u>	<u>\$ 2,251</u>

*See accompanying notes to unaudited interim condensed financial statements.*

**Sutro Biopharma, Inc.**  
**Notes to Unaudited Interim Condensed Financial Statements**

## **1. Organization and Principal Activities**

### ***Description of Business***

Sutro Biopharma, Inc. (the "Company"), is a clinical-stage oncology company developing site-specific and novel-format antibody drug conjugates, or ADCs. The Company was incorporated on April 21, 2003 and is headquartered in South San Francisco, California.

The Company operates in one business segment, the development of biopharmaceutical products.

### ***At-The-Market Sales***

During the three and nine months ended September 30, 2023, the Company sold zero shares and 1,857,410 shares, respectively, of its common stock through its At-the-Market Facility ("ATM Facility") pursuant to its Open Market Sales Agreement<sup>SM</sup> dated April 2, 2021 with Jefferies LLC ("Jefferies"), as sales agent (the "Sales Agreement").

During the three and nine months ended September 30, 2023, the gross proceeds from these sales were approximately zero and \$12.4 million, respectively, before deducting fees of approximately zero and \$0.4 million, respectively, resulting in net proceeds of approximately zero and \$12.0 million, respectively, to the Company.

### ***Liquidity***

The Company has incurred significant losses and has negative cash flows from operations. As of September 30, 2023, the Company had an accumulated deficit of \$590.5 million. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development and other operational activities.

As of September 30, 2023, the Company had unrestricted cash, cash equivalents, and marketable securities of \$321.1 million and equity securities of \$34.0 million, consisting solely of common stock of Vaxcyte, which are available to fund future operations. The Company will need to raise additional capital to support the completion of its research and development activities and to support its operations.

The Company believes that its unrestricted cash, cash equivalents, marketable securities and equity securities as of September 30, 2023, will enable the Company to maintain its operations for a period of at least 12 months following the filing date of its condensed financial statements.

## **2. Summary of Significant Accounting Policies**

### ***Basis of Presentation and Use of Estimates***

The accompanying interim condensed financial statements of the Company are unaudited. These interim condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") and the applicable rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all the information and footnotes required by U.S. GAAP for complete financial statements. The December 31, 2022 condensed balance sheet was derived from the audited financial statements as of that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates on historical experience and market-specific or other relevant assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported on the Company's condensed Balance Sheets and the amounts of expenses and income reported for each of the periods presented are affected by estimates and assumptions, which are used for, but are not limited to, determining research and development periods under collaboration arrangements, stock-based compensation expense, valuation of marketable securities, impairment of long-lived assets, income taxes, deferred royalty obligation related to the sale of future royalties and related non-cash interest expense, and certain accrued liabilities. Actual results could differ from such estimates or assumptions.



The accompanying unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements and, in the opinion of management, reflect all adjustments of a normal recurring nature considered necessary to state fairly the Company's financial position, results of operations, comprehensive loss, and cash flows for the interim periods. The interim results for the three and nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023, or for any other future annual or interim period.

The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the Company's audited financial statements included in the Annual Report on Form 10-K pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, for the year ended December 31, 2022.

#### **Deferred Royalty Obligation related to the Sale of Future Royalties and Non-cash Interest Expense**

In June 2023, the Company entered into a purchase and sale agreement (the "Purchase Agreement") with Blackstone, pursuant to which the Company sold to Blackstone its 4% royalty, or revenue interest, in the potential future net sales of Vaxcyte products, including VAX-24 (the "Purchased Interest") under that certain Amended and Restated SutroVax Agreement, dated October 12, 2015, by and between the Company and Vaxcyte, as amended (the "2015 License Agreement"). In June 2023, Blackstone made an upfront payment of \$140.0 million to the Company and will also pay up to an additional \$250.0 million upon the achievement of various return thresholds as set forth in the Purchase Agreement. The net proceeds from the upfront payment received by the Company from the sale of future royalties from Vaxcyte are recorded as deferred royalty obligation related to the sale of future royalties on the Company's condensed Balance Sheets. As royalties are earned and remitted pursuant to the 2015 License Agreement, the balance of the deferred royalty obligation will be amortized over the estimated life of the royalty term arrangement, and non-cash interest expense related to the sale of future royalties is recorded using the effective interest method. To determine the amortization of our deferred royalty obligation, the Company is required to estimate the total amount of future royalties to be earned under the 2015 License Agreement. There are a number of factors that could materially affect the amount and timing of royalty payments earned, most of which are not within the Company's control. The Company will periodically assess the amount of royalty payments expected to be earned which are subject to the Purchase Agreement and, to the extent that the amount or timing of such earned royalties is materially different than the Company's original estimates, the Company will prospectively adjust the imputed interest rate and the related amortization of the deferred royalty obligation.

Issuance fees and costs directly related to the Purchase Agreement were offset against the initial carrying value of the deferred royalty obligation and were amortized using the effective interest method over the estimated life of the royalty term arrangement.

#### **Recent Accounting Pronouncements Not Yet Adopted**

There were no new accounting pronouncements issued since the Company's filing of the Annual Report on Form 10-K for the year ended December 31, 2022, which could have a significant effect on the Company's condensed financial statements.

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

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the Company's condensed Balance Sheets that sum to the total of the same amounts shown in the Company's condensed Statements of Cash Flows.

	September 30,	
	2023	2022
	(in thousands)	
Cash and cash equivalents	\$ 81,834	\$ 96,779
Restricted cash	872	872
Total cash, cash equivalents, and restricted cash shown in the condensed Statements of Cash Flows	<u>\$ 82,706</u>	<u>\$ 97,651</u>

#### **Investments in Equity Securities**

Vaxcyte common stock held by the Company is measured at fair value at each reporting period based on the closing price of Vaxcyte's common stock on the last trading day of each reporting period, with any realized or unrealized gains and losses recorded in the Company's condensed Statements of Operations.

## **Fair Value Measurements**

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date and establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The Company determined the fair value of financial assets and liabilities using the fair value hierarchy that describes three levels of inputs that may be used to measure fair value, as follows:

Level 1—Quoted prices in active markets for identical assets and liabilities;

Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices 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 assets or liabilities; and

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

The carrying amounts of accounts receivable, prepaid expenses, accounts payable, accrued liabilities and accrued compensation and benefits approximate fair value due to the short-term nature of these items.

The fair value of the Company's outstanding loan (See Note 6) is estimated using the net present value of the payments, discounted at an interest rate that is consistent with the market interest rate, which is a Level 2 input. The estimated fair value of the Company's outstanding loan approximates the carrying amount, as the loan bears a floating rate that approximates the market interest rate.

The carrying value of the deferred royalty obligation related to the sale of future royalties under the 2015 License Agreement with Vaxcyte approximates its fair value as of September 30, 2023, and is based on our current estimates of future royalties expected to be earned over the estimated life of the royalty term arrangement. See Note 9. Deferred Royalty Obligation Related to the Sale of Future Royalties for a description of the Level 3 inputs used to estimate the fair value of the liability.

## **Revenue Recognition**

When the Company enters into collaboration agreements, it assesses whether the arrangements fall within the scope of ASC 808, Collaborative Arrangements ("ASC 808") based on whether the arrangements involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of ASC 808, the Company assesses whether the payments between the Company and its collaboration partner fall within the scope of other accounting literature. If it concludes that payments from the collaboration partner to the Company represent consideration from a customer, such as license fees and contract research and development activities, the Company accounts for those payments within the scope of Accounting Standards Update (ASU) No. 2014-09 (Topic 606), Revenue from Contracts with Customers ("ASC 606").

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. However, if the Company concludes that its collaboration partner is not a customer for certain activities and associated payments, such as for certain collaborative research, development, manufacturing and commercial activities, the Company presents such payments as a reduction of research and development expense or general and administrative expense, based on where the Company presents the underlying expense.

The Company has no products approved for commercial sale and has not generated any revenue from commercial product sales. The total revenue to date has been generated principally from collaboration and license agreements and to a lesser extent, from manufacturing, supply and services, and materials the Company provides to its collaboration partners.

*Collaboration Revenue:* The Company derives revenue from collaboration arrangements, under which the Company may grant licenses to its collaboration partners to further develop and commercialize its proprietary product candidates. The Company may also perform research and development activities under the collaboration agreements. Consideration under these contracts generally includes a nonrefundable upfront payment, development, regulatory and commercial milestones and other contingent payments, and royalties based on net sales of approved products. Additionally, the collaborations may provide options for the customer to acquire from the Company materials and reagents, clinical product supply or additional research and development services under separate agreements.

The Company assesses which activities in the collaboration agreements are considered distinct performance obligations that should be accounted for separately. The Company develops assumptions that require judgement to determine whether the license to the Company's intellectual property is distinct from the research and development services or participation in activities under the collaboration agreements.

At the inception of each agreement, the Company determines the arrangement transaction price, which includes variable consideration, based on the assessment of the probability of achievement of future milestones and contingent payments and other potential consideration. The Company recognizes revenue over time by measuring its progress towards the complete satisfaction of the relevant performance obligation using an appropriate input or output method based on the nature of the service promised to the customer.

For arrangements that include multiple performance obligations, the Company allocates the transaction price to the identified performance obligations based on the standalone selling price, or SSP, of each distinct performance obligation. In instances where SSP is not directly observable, the Company develops assumptions that require judgment to determine the SSP for each performance obligation identified in the contract. These key assumptions may include full-time equivalent, or FTE, personnel effort, estimated costs, discount rates and probabilities of clinical development and regulatory success.

*Upfront Payments:* For collaboration arrangements that include a nonrefundable upfront payment, if the license fee and research and development services cannot be accounted for as separate performance obligations, the transaction price is deferred and recognized as revenue over the expected period of performance using a cost-based input methodology. The Company uses judgement to assess the pattern of delivery of the performance obligation. In addition, amounts paid in advance of services being rendered may result in an associated financing component to the upfront payment. Accordingly, the interest on such borrowing cost component will be recorded as interest expense and revenue, based on an appropriate borrowing rate applied to the value of services to be performed by the Company over the estimated service performance period.

*License Grants:* For collaboration arrangements that include a grant of a license to the Company's intellectual property, the Company considers whether the license grant is distinct from the other performance obligations included in the arrangement. For licenses that are distinct, the Company recognizes revenues from nonrefundable, upfront payments and other consideration allocated to the license when the license term has begun and the Company has provided all necessary information regarding the underlying intellectual property to the customer, which generally occurs at or near the inception of the arrangement.

*Milestone and Contingent Payments:* At the inception of the arrangement and at each reporting date thereafter, the Company assesses whether it should include any milestone and contingent payments or other forms of variable consideration in the transaction price using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty, the associated milestone value is included in the transaction price. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of each milestone and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Since milestone and contingent payments may become payable to the Company upon the initiation of a clinical study or filing for or receipt of regulatory approval, the Company reviews the relevant facts and circumstances to determine when the Company should update the transaction price, which may occur before the triggering event. When the Company updates the transaction price for milestone and contingent payments, the Company allocates the changes in the total transaction price to each performance obligation in the agreement on the same basis as the initial allocation. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment, which may result in recognizing revenue for previously satisfied performance obligations in such period. The Company's collaborators generally pay milestones and contingent payments subsequent to achievement of the triggering event.

*Research and Development Services:* For amounts allocated to the Company's research and development obligations in a collaboration arrangement, the Company recognizes revenue over time using a cost-based input methodology, representing the transfer of goods or services as activities are performed over the term of the agreement.

*Materials Supply:* The Company provides materials and reagents, clinical materials, and services to certain of its collaborators under separate agreements. The consideration for such services is generally based on FTE personnel effort

used to manufacture those materials, reimbursed at an agreed upon rate in addition to agreed-upon pricing for the provided materials. The amounts billed are recognized as revenue as the performance obligations are met by the Company.

Revenue subject to governmental withholding taxes is recognized on a gross basis with the withholding taxes recorded as a component of income tax expense.

### 3. Fair Value Measurements

The following table sets forth the fair value of the Company's financial assets measured on a recurring basis by level within the fair value hierarchy:

	Total	September 30, 2023		
		Level 1	Level 2	Level 3
(in thousands)				
<b>Assets:</b>				
Money market funds	\$ 54,078	\$ 54,078	\$ -	\$ -
Commercial paper	78,348	-	78,348	-
Corporate debt securities	54,494	-	54,494	-
Equity securities	34,043	34,043	-	-
Asset-backed securities	27,750	-	27,750	-
U.S. government securities	104,316	104,316	-	-
<b>Total</b>	<b>\$ 353,029</b>	<b>\$ 192,437</b>	<b>\$ 160,592</b>	<b>\$ -</b>

	Total	December 31, 2022		
		Level 1	Level 2	Level 3
(in thousands)				
<b>Assets:</b>				
Money market funds	\$ 36,486	\$ 36,486	\$ -	\$ -
Commercial paper	87,140	-	87,140	-
Corporate debt securities	36,429	-	36,429	-
Equity securities	32,020	32,020	-	-
Asset-backed securities	14,016	-	14,016	-
U.S. government securities	91,251	91,251	-	-
U.S. agency securities	16,607	-	16,607	-
Supranational debt securities	16,481	-	16,481	-
<b>Total</b>	<b>\$ 330,430</b>	<b>\$ 159,757</b>	<b>\$ 170,673</b>	<b>\$ -</b>

Where applicable, the Company uses quoted market prices in active markets for identical assets to determine fair value. This pricing methodology applies to Level 1 investments, which are comprised of money market funds, U.S. government securities and the shares of Vaxcyte common stock held by the Company.

If quoted prices in active markets for identical assets are not available, then the Company uses quoted prices for similar assets or inputs other than quoted prices that are observable, either directly or indirectly. These investments are included in Level 2 and consist of commercial paper, corporate debt securities, asset-backed securities, U.S. agency securities and supranational debt securities. These assets are valued using market prices when available, adjusting for accretion of the purchase price to face value at maturity.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The Company's 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.

In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3 within the valuation hierarchy. As of September 30, 2023, the deferred royalty obligation related to the sale of future Vaxcyte royalties was classified as Level 3 within the valuation hierarchy. As of December 31, 2022, the Company did not hold any securities that were classified as Level 3 within the valuation hierarchy.

### Investments in Equity Securities

As of September 30, 2023 and December 31, 2022, the Company held 667,780 shares of Vaxcyte common stock with an estimated fair value of \$34.0 million and \$32.0 million, respectively. The Company recognized an unrealized gain of \$0.7 million and \$3.5 million for the three months ended September 30, 2023 and 2022, respectively, and an unrealized gain of \$2.0 million and \$0.3 million for the nine months ended September 30, 2023 and 2022, respectively.

### 4. Cash Equivalents and Marketable Securities

Cash equivalents and marketable securities consisted of the following:

	Amortized Cost Basis	September 30, 2023		Fair Value
		Unrealized Gains	Unrealized Losses	
(in thousands)				
Money market funds	\$ 54,078	\$ -	\$ -	\$ 54,078
Commercial paper	78,348	-	-	78,348
Corporate debt securities	54,501	4	(11)	54,494
Asset-based securities	27,743	8	(1)	27,750
U.S. government securities	104,309	7	-	104,316
U.S. agency securities	-	-	-	-
Total	318,979	19	(12)	318,986
Less amounts classified as cash equivalents	(79,711)	(2)	1	(79,712)
Total marketable securities	<u>\$ 239,268</u>	<u>\$ 17</u>	<u>\$ (11)</u>	<u>\$ 239,274</u>

	Amortized Cost Basis	December 31, 2022		Fair Value
		Unrealized Gains	Unrealized Losses	
(in thousands)				
Money market funds	\$ 36,486	\$ -	\$ -	\$ 36,486
Commercial paper	87,140	-	-	87,140
Corporate debt securities	36,554	2	(127)	36,429
Asset-based securities	14,026	-	(10)	14,016
U.S. government securities	91,619	8	(376)	91,251
U.S. agency securities	16,646	-	(39)	16,607
Supranational debt securities	16,555	-	(74)	16,481
Total	299,026	10	(626)	298,410
Less amounts classified as cash equivalents	(43,318)	(2)	-	(43,320)
Total marketable securities	<u>\$ 255,708</u>	<u>\$ 8</u>	<u>\$ (626)</u>	<u>\$ 255,090</u>

There were \$56.9 million and \$139.5 million of investments in an unrealized loss position of \$11 thousand and \$0.6 million as of September 30, 2023 and December 31, 2022, respectively. During the three and nine months ended September 30, 2023 and 2022, the Company did not record any other-than-temporary impairment charges on its available-for-sale securities. Based on the Company's procedures under the expected credit loss model, including an assessment of unrealized losses on the portfolio after September 30, 2023 and 2022, the Company concluded that the unrealized losses for its marketable securities were not attributable to credit and therefore an allowance for credit losses for these securities has not been recorded as of September 30, 2023 and 2022. Also, based on the scheduled maturities of the investments, the Company was more likely than not to hold these investments for a period of time sufficient for a recovery of the Company's cost basis.

The Company recognized no material gains or losses on its cash equivalents and current and non-current marketable securities as of September 30, 2023 and December 31, 2022 and as a result, the Company did not reclassify any amounts out of accumulated other comprehensive income (loss) for the period then ended.

## 5. Collaboration and License Agreements and Supply Agreements

The Company has entered into collaboration and license agreements and supply agreements with various pharmaceutical and biotechnology companies. See "Note 5. Collaboration and License Agreements and Supply Agreements" to the Company's financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2022, or as further described below, for additional information on each of its collaboration agreements.

The Company's accounts receivable balances may contain billed and unbilled amounts from milestones and other contingent payments, as well as reimbursable costs from collaboration and license agreements and supply agreements. The Company performs a regular review of its customers' credit risk and payment histories, including payments made after the period end. Historically, the Company has not experienced credit loss from its accounts receivable and, therefore, has not recorded a reserve for estimated credit losses as of September 30, 2023 and December 31, 2022.

In accordance with the collaboration agreements, the Company recognized revenue as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Bristol Myers Squibb Company ("BMS")	\$ 189	4,343	\$ 5,591	8,774
Merck Sharp & Dohme Corporation ("Merck")	83	10,157	2,776	11,367
Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name "EMD Serono")	-	166	8	2,200
Astellas Pharma Inc. ("Astellas")	9,988	4,985	23,593	4,985
Tasly Biopharmaceuticals Co., Ltd. ("Tasly")	5,072	-	5,072	25,000
Vaxcyte	1,592	1,496	2,970	2,814
BioNova Pharmaceuticals, Ltd. ("BioNova")	-	4,000	-	4,000
Total revenue	<u>\$ 16,924</u>	<u>\$ 25,147</u>	<u>\$ 40,010</u>	<u>59,140</u>

The following table presents the changes in the Company's deferred revenue balance from collaboration agreements during the nine months ended September 30, 2023:

	Nine Months Ended September 30, 2023 (in thousands)	
Deferred revenue—December 31, 2022	\$	106,644
Additions to deferred revenue		11,018
Recognition of revenue in current period		(15,525)
Deferred revenue—September 30, 2023	<u>\$</u>	<u>102,137</u>

The Company's balance of deferred revenue contains upfront and contingent payments for obligations from our agreements which remain partially unsatisfied. The Company expects to recognize approximately \$24.0 million of the deferred revenue over the next twelve months.

### Collaboration with BMS

#### BMS Agreement and 2018 BMS Master Services Agreement

In September 2014, the Company signed a Collaboration and License Agreement (the "BMS Agreement") with BMS to discover and develop bispecific antibodies and/or antibody-drug conjugates ("ADCs"), focused primarily on the field of immuno-oncology, using the Company's proprietary integrated cell-free protein synthesis platform, XpressCF<sup>®</sup>. In August 2017, the Company entered into an amended and restated collaboration and license agreement with BMS to refocus the collaboration on four programs that were advancing through preclinical development, including an ADC program targeting B cell maturation antigen ("BCMA ADC" or "CC-99712").

In May 2019, the U.S. Food and Drug Administration cleared the investigational new drug ("IND") application for the BCMA ADC, which was discovered and manufactured by the Company and is the first collaboration program IND.

In March 2018, the Company entered into a Master Development and Clinical Manufacturing Services Agreement (the "2018 BMS Master Services Agreement") with BMS, wherein BMS requested the Company to provide development, manufacturing and supply chain management services, including clinical product supply.

In June 2023, the Company received a notice of termination from BMS indicating that it was stopping development of CC-99712 due to a portfolio prioritization decision. The termination of the BMS Agreement was effective as of October 7, 2023 (the "Termination Date"). Following the Termination Date, the Company has sole worldwide rights to CC-99712.

As of September 30, 2023, and December 31, 2022, there was no deferred revenue related to payments received by the Company under the BMS Agreement.

As of September 30, 2023, and December 31, 2022, there was zero and \$3.1 million, respectively, of deferred revenue under the 2018 BMS Master Services Agreement.

Revenues under the BMS Agreement and the 2018 BMS Master Services Agreement were as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Research and development services	\$ -	\$ 107	\$ 413	\$ 591
Materials supply	189	4,236	5,178	8,183
Total revenue	<u>\$ 189</u>	<u>\$ 4,343</u>	<u>\$ 5,591</u>	<u>\$ 8,774</u>

### **Collaboration with Merck**

#### **2018 Merck Agreement**

In July 2018, the Company entered into an agreement (the "2018 Merck Agreement") with Merck for access to the Company's technology and the identification and preclinical research and development of two target programs, with an option for Merck to engage the Company to continue these activities for a third program, upon the payment of an additional amount, focusing on cytokine derivatives for cancer and autoimmune disorders, with an initial transaction price of \$60.0 million. The option to expand activities to a third program expired in January 2021.

In March 2020, Merck exercised its option to extend the research term of the collaboration's first cytokine-derivative program by one year, which, pursuant to the terms of the 2018 Merck Agreement, triggered a payment of \$5.0 million.

In April 2021, the Company earned a \$15.0 million contingent payment for the initiation by Merck of the first IND-enabling toxicology study under the first cytokine-derivative program in the collaboration.

In September 2021, the Company entered into an amendment to the 2018 Merck Agreement (the "2021 Amendment") to extend the research term for the first program in the 2018 Merck Agreement. Under the terms of the 2021 Amendment, the Company received a payment of \$2.5 million with an additional \$7.5 million to be received upon the achievement of certain developmental milestones by Merck on a second molecule under the first cytokine-derivative program of the collaboration. Merck decided not to pursue further development of a second molecule under the first cytokine-derivative program of the collaboration and, therefore, allowed the option to extend the period for nomination of additional clinical candidates under the 2021 Amendment to expire in June 2022.

In December 2021, Merck did not extend the research term for the second research program of the collaboration, which research program reverted to the Company. The first research program of the collaboration is focused on one distinct cytokine derivative molecule for the treatment of cancer. The Company is eligible to receive aggregate contingent payments of up to approximately \$0.5 billion for the target program selected by Merck, assuming the development and sale of the therapeutic candidate and all possible indications identified under the collaboration. If one or more products from the target program is developed for non-oncology or a single indication, the Company will be eligible for reduced aggregate contingent payments. In addition, the Company is eligible to receive tiered royalties ranging from mid-single digit to low teen percentages on the worldwide sales of any commercial products that may result from the collaboration.

In July 2022, the first patient was dosed in a Phase 1 study of an investigational candidate resulting from the 2018 Merck Agreement for the development of a novel cytokine derivative therapeutic for the treatment of cancer. As a result of this achievement, the Company earned and received a \$10.0 million contingent payment from Merck during the year ended December 31, 2022.

As of both September 30, 2023 and December 31, 2022, there was no deferred revenue related to the 2018 Merck Agreement and 2021 Amendment.

### 2020 Merck Master Services Agreement

In August 2020, the Company entered into a Pre-Clinical and Clinical Supply Agreement (the “2020 Merck Master Services Agreement”) with Merck, wherein Merck requested the Company to provide development, manufacturing and supply chain management services, including clinical product supply, upon completion of the research programs under the 2018 Merck Agreement.

As of both September 30, 2023 and December 31, 2022, there was no deferred revenue under the 2020 Merck Master Services Agreement.

Revenues under the 2018 Merck Agreement and the 2020 Merck Master Services Agreement were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Ongoing performance related to unsatisfied performance obligations	\$ -	\$ -	\$ -	\$ 862
Contingent payment	-	10,000	-	10,000
Research and development services	20	136	224	402
Materials supply	63	21	2,552	103
Total revenue	<u>\$ 83</u>	<u>\$ 10,157</u>	<u>\$ 2,776</u>	<u>\$ 11,367</u>

### Collaboration with EMD Serono

#### MDA Agreement and 2019 EMD Serono Supply Agreement

The Company signed a Collaboration Agreement and a License Agreement with EMD Serono in May 2014 and September 2014, respectively, which were entered into in contemplation of each other and, therefore, treated as a single agreement for accounting purposes. The Collaboration Agreement was subsumed into the License Agreement (the “MDA Agreement”), which agreement is to develop ADCs for multiple cancer targets.

In April 2019, the Company entered into an ADC Product Preclinical and Phase I Clinical Supply Agreement (the “2019 EMD Serono Supply Agreement”) with EMD Serono, wherein EMD Serono requested the Company to provide development, manufacturing and supply chain management services, including clinical product supply.

In March 2023, EMD Serono disclosed its decision to close the Phase 1a trial of M1231 in patients with solid tumors and not initiate a previously planned expansion study. EMD Serono stated that the decision was based on strategic portfolio considerations.

As of both September 30, 2023 and December 31, 2022, there was no deferred revenue related to payments received by the Company under the MDA Agreement or the 2019 EMD Serono Supply Agreement.

Revenues under the EMD Serono agreements were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Research and development services	\$ -	\$ 78	\$ 6	\$ 494
Materials supply	-	88	2	1,706
Total revenue	<u>\$ -</u>	<u>\$ 166</u>	<u>\$ 8</u>	<u>\$ 2,200</u>

### Astellas License and Collaboration Agreement

In June 2022, the Company entered into a License and Collaboration Agreement (the “Astellas Agreement”) with Astellas for the development of immunostimulatory antibody-drug conjugates for up to three biological targets, to be identified by Astellas. The Company will conduct research and pre-clinical development of any compound (as designated by Astellas) in each of the three programs in accordance with the terms of a research plan between the Company and



Astellas. Astellas will have an exclusive worldwide license to develop and commercialize any such designated compound, subject to the Company's rights to participate in cost and profit sharing in the United States, as described below.

Pursuant to the Astellas Agreement, the Company received from Astellas a one-time, nonrefundable, non-creditable, upfront payment of \$90.0 million during the year ended December 31, 2022. Under ASC 808 and ASC 606, the Company determined that both parties are active participants in the activities and are exposed to significant risks and rewards dependent on the success of the development program, and identified four performance obligations under the Astellas Agreement as: (1) performance of services related to the first target program; (2) performance of services related to the second target program; (3) performance of services related to the third target program; and (4) the Company's estimated future services on the collaboration JSC. The transaction price of \$90.0 million was allocated among the performance obligations using the Company's best estimate of the standalone selling price, or SSP, for each of the associated performance obligations. Revenue allocated to the three target programs, which totaled \$89.1 million, is being recognized on a proportion of performance basis, using FTE cost as the basis of measurement, with such performance expected to occur over an estimated service period of four years for each target program. As it pertains to the JSC performance obligation, the revenue allocated to such performance obligation was \$0.9 million, and is being recognized on a proportion of performance basis using FTE cost as the basis of measurement, and such effort is expected to be incurred on a relatively consistent basis throughout the term of the Astellas Agreement.

Additionally, under ASC 606, the Company determined a financing component associated with the \$90.0 million upfront payment and has calculated \$32.3 million as of September 30, 2023, on the unearned revenue portion beyond one year from the effective date of the agreement, which amount is being recognized as interest expense and revenue over the estimated service period for the three target programs.

The Company is also eligible to receive up to \$422.5 million in development, regulatory and commercial milestones for each product candidate, and tiered royalties ranging from low double-digit to mid-teen percentages on worldwide sales of any commercial products that may result from the collaboration, subject to customary deductions under certain circumstances. The Company can also elect to convert any product candidate into a cost and profit-sharing arrangement, for the United States only. In the event the Company makes such election, it will share commercialization costs and profits relating to such product candidate equally with Astellas in the United States, and no royalties will be due from Astellas for net sales of such product candidates in the United States.

Revenues under the Astellas Agreement were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Ongoing performance related to unsatisfied performance obligations	\$ 5,612	\$ 1,925	\$ 11,423	\$ 1,925
Research and development services	1,920	809	4,639	809
Financing component on unearned revenue	2,456	2,251	7,531	2,251
Total revenue	<u>\$ 9,988</u>	<u>\$ 4,985</u>	<u>\$ 23,593</u>	<u>\$ 4,985</u>

As of September 30, 2023 and December 31, 2022, there was \$74.6 million and \$86.1 million of deferred revenue, respectively, related to the upfront payment received by the Company under the Astellas Agreement.

#### ***Tasly License Agreement***

In December 2021, the Company entered into a license agreement with Tasly to grant Tasly an exclusive license to develop and commercialize STRO-002, or luveltamab tazevibulin, or luvelta, in Greater China (the "Tasly License Agreement"). Tasly will pursue the clinical development, regulatory approval, and commercialization of luvelta in multiple indications, including ovarian cancer, non-small cell lung cancer, triple-negative breast cancer, and other indications in Greater China. The Company will retain development and commercial rights of luvelta globally outside of Greater China, including the United States.

Under the Tasly License Agreement, Tasly was obligated to make to the Company an initial nonrefundable upfront payment of \$40.0 million, with additional potential payments totaling up to \$345 million related to development, regulatory and commercialization contingent payments and milestones. The Company will provide luvelta to Tasly under appropriate clinical and commercial supply service agreements. Upon commercialization, the Company will receive tiered royalties,

ranging from low- to mid-teen percentages based on annual net sales of luvelta in Greater China for at least ten years following the first commercial sale of luvelta in Greater China.

The Company determined that the Tasly License Agreement falls within the scope of ASC 808, as both parties are active participants in the activities and are exposed to significant risks and rewards dependent on the success of the commercialization of indications for luvelta in Greater China. The Company concluded that the Tasly License Agreement contained the following units of account: i) licensed know-how and Sutro patents, license to trademark rights, and initial regulatory data and information necessary to prepare an IND; and ii) collaboration governance and information sharing activities, such as JSC participation and ongoing regulatory and pharmacovigilance support.

The promises related to the licensed know-how and Sutro patents, license to trademark rights, and initial regulatory data and information necessary to prepare an IND are considered to be interdependent and not distinct from each other, representing a combined output. The Company determined that these promises are capable of being distinct from the collaboration governance and information sharing activities discussed below and further determined that this unit of account is a vendor-customer relationship and accounted for it in accordance with ASC 606. All potential future milestones and other payments were considered constrained at the inception of the Tasly License Agreement since the Company could not conclude it was probable that a significant reversal in the amount of revenue recognized would not occur. Since there is only one performance obligation accounted for under ASC 606, no allocation of the transaction price was necessary.

The Company determined that the unit of account consisting of collaboration governance and information sharing activities, such as JSC participation and ongoing regulatory and pharmacovigilance support, do not represent a customer-vendor relationship between the Company and Tasly. These promises are considered to be interdependent and not distinct from each other, representing a combined output. However, the Company determined that these promises are capable of being distinct from the intellectual property and data license promises discussed above. As such, based on the nature of the agreement and collaborative activities, the Company determined that the costs associated with these governance and information sharing activities performed under the agreement will be included in research and development expenses in the Statements of Operations, with any reimbursement of costs by Tasly reflected as a reduction of such expenses. During the three and nine months ended September 30, 2023 and 2022, the Company recognized a reduction of \$16 thousand and zero, respectively, in research and development expenses under the Tasly License Agreement.

In April 2022, the Company entered into amendment No. 1 (the "Tasly Amendment") to the Tasly License Agreement with Tasly. Pursuant to the Tasly Amendment, the initial nonrefundable upfront payment due by Tasly was amended to \$25.0 million, and a \$15.0 million payment will become payable to the Company upon the achievement of certain regulatory milestones. The Tasly Amendment also added an additional regulatory milestone payment to the Tasly License Agreement, providing additional potential payments totaling up to \$350.0 million related to development, regulatory and commercialization milestones, beyond the payments described above, and made certain other ministerial edits.

During the year ended December 31, 2022, the Company recognized the \$25.0 million upfront payment as revenue after the payment, net of a withholding tax, was received by the Company from Tasly. The withholding tax of \$2.5 million was recorded as an income tax charge related to the upfront payment.

During the three months ended September 30, 2023, the Company recognized a \$5.0 million contingent payment as revenue, net of withholding tax, after Tasly received its first IND clearance by National Medical Products Administration, or NMPA, in Greater China. The withholding tax of \$0.5 million was recorded as an income tax charge related to the contingent payment.

During the three months ended September 30, 2023, the Company recognized a \$5.0 million contingent payment, received by the Company from Tasly related to the first patient dosed in the Company's REFRA<sup>®</sup>ME trial for luvelta, as deferred revenue, net of withholding tax of \$0.5 million. The REFRA<sup>®</sup>ME study consists of two parts, Part I being the dose-finding portion and Part II being the portion of the study that will focus on the selected dose from Part I, and is intended to generate data to enable the potential registration of luvelta. Although it currently intends to conduct the REFRA<sup>®</sup>ME study to completion, the Company has the sole discretion to terminate the REFRA<sup>®</sup>ME study at any time. As such, the Company has agreed with Tasly that, in the event the Company terminates the REFRA<sup>®</sup>ME study prior to dosing the first patient in Part II, the Company will refund Tasly the contingent payment received by the Company within 30 days of such study termination. Given the above, the contingent payment received by the Company was considered constrained for accounting purposes during the three months ended September 30, 2023, since the Company could not conclude it was probable that a significant reversal in the amount of revenue recognized would not occur. The withholding tax was recorded by the Company as a tax charge related to the received contingent payment.

Revenues under the Tasly License Agreement were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Upfront payment	\$ —	\$ —	\$ —	\$ 25,000
Contingent payments	5,000	—	5,000	—
Research and development services	72	—	72	—
Total revenue	<u>\$ 5,072</u>	<u>\$ —</u>	<u>\$ 5,072</u>	<u>\$ 25,000</u>

#### Agreements with Vaxcyte

##### Vaxcyte Supply Agreement

In May 2018, the Company entered into a Supply Agreement (the "Supply Agreement") with Vaxcyte, wherein Vaxcyte engaged the Company to provide research and development services and to supply extracts and custom reagents, as requested by Vaxcyte. The pricing is based on an agreed upon cost-plus arrangement.

During 2020, upon Vaxcyte's request and their agreement to reimburse the related costs, the Company entered into agreements with third-party contract manufacturing organizations, or CMOs, to conduct process transfers to allow for such CMOs to manufacture and supply extract and custom reagents for Vaxcyte. As part of the agreement with Vaxcyte, should the Company decide to purchase extract from the extract CMO, the Company would be required to reimburse Vaxcyte for a portion of all incurred process transfer costs. As of September 30, 2023 and December 31, 2022, there was \$6.1 million and \$4.8 million, respectively, in such accruals related to the Vaxcyte Supply Agreement.

For the three and nine months ended September 30, 2023, the agreed-upon reimbursements by Vaxcyte of the costs associated with such arrangements, principally for pass-through costs from the CMOs, were \$2.8 million and \$5.6 million, respectively, and were accounted for by the Company as a reduction to research and development expense based on the Company's conclusion that Vaxcyte was not a customer for such activities and associated payments.

For the three and nine months ended September 30, 2022, the agreed-upon reimbursements by Vaxcyte of the costs associated with such arrangements, principally for pass-through costs from the CMOs, were \$4.0 million and \$10.2 million, respectively.

Revenues under the Vaxcyte Supply Agreement were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Research and development services	\$ 636	\$ 651	\$ 1,707	\$ 1,794
Materials supply	956	845	1,263	1,020
Total revenue	<u>\$ 1,592</u>	<u>\$ 1,496</u>	<u>\$ 2,970</u>	<u>\$ 2,814</u>

##### Vaxcyte Agreement

In December 2022, the Company entered into a letter agreement (the "Vaxcyte Agreement") with Vaxcyte under which the Company granted to Vaxcyte (i) authorization to enter into an agreement with an independent alternate CMO to source cell-free extract solely for the products it licensed from the Company, allowing Vaxcyte to have direct oversight over financial and operational aspects of the relationship with the CMO ("CMO Relationship Rights"), and (ii) a right, but not an obligation, to obtain certain exclusive rights to internally manufacture and/or source extract from certain CMOs and the right to independently develop and make improvements to extract for use in connection with the exploitation of certain vaccine compositions (the "Option"). The Option is exercisable for five years following the effective date of the Vaxcyte Agreement (the "Option Period"), subject to potential acceleration in the event of a change of control of Vaxcyte.

Pursuant to the Vaxcyte Agreement, the Company received a one-time, nonrefundable, non-creditable, upfront payment of \$10.0 million in cash, and 167,780 shares of Vaxcyte common stock with a fair value of \$7.5 million in December 2022.

Additionally, pursuant to the Vaxcyte Agreement, the Company and Vaxcyte agreed to negotiate the terms and conditions of a form definitive agreement to be entered into in the event Vaxcyte exercises the Option (the "Form Definitive Agreement"). In September 2023, the Company and Vaxcyte mutually agreed upon the Form Definitive Agreement, and in October 2023, the Company received a \$5.0 million payment from Vaxcyte.

Effective immediately upon agreement to the Form Definitive Agreement, the Company and Vaxcyte entered into amendment No 3. (the "Amendment") to that certain license agreement between the Company and Vaxcyte, dated August 1, 2014, and amended and restated on October 12, 2015, and amended again on May 9, 2018 and May 29, 2018 (the "License Agreement"). The Amendment amended certain terms of the License Agreement including with respect to (i) royalty reduction provisions applicable in the event of expiration of relevant patent claims, which would result in lower royalties payable by Vaxcyte under certain circumstances, (ii) the ownership, prosecution, maintenance and enforcement of certain intellectual property rights licensed or arising under the License Agreement, and (iii) the timing and form for financial reporting of royalty payment calculations.

In the event Vaxcyte elects to exercise the Option, Vaxcyte will pay the Company \$75.0 million in cash in two installments, and upon the occurrence of certain regulatory milestones, certain additional payments totaling up to \$60.0 million. In the event that Vaxcyte undergoes a change of control, and subsequently exercises the Option, a substantial majority of the milestone payments will be accelerated.

The Company evaluated the terms of the Vaxcyte Agreement and concluded that the Vaxcyte Agreement is considered a new standalone contract and distinct from the previously existing agreements with Vaxcyte. Under ASC 606, the Company determined that Vaxcyte is a customer for this arrangement and identified the promised goods and services under the Vaxcyte Agreement as: (1) the Option; (2) the Form Definitive Agreement; (3) CMO Relationship Rights; and (4) Joint steering committee participation. The Company concluded that the promises within the contract are interrelated and interdependent of one another. As such, these are not considered distinct but are combined as a single performance obligation. This single performance obligation is considered a material right as it provides Vaxcyte with the right to acquire additional goods at a price it would not have received without having entered into the Vaxcyte Agreement. Revenue for the single performance obligation was deferred and will be eligible to begin to be recognized at the earlier of when the Option is exercised or expires.

As of September 30, 2023 and December 31, 2022, there was \$22.5 million and \$17.5 million, respectively, of deferred revenue, related to the payment receivable upon agreement to the Form Definitive Agreement, and the upfront cash and stock payments received by the Company under the Vaxcyte Agreement.

Refer to Note 9 below for information relating to the Purchase Agreement between the Company and Blackstone, pursuant to which the Company sold to Blackstone its 4% royalty, or revenue interest, in potential future net sales of Vaxcyte products, including VAX-24.

## 6. Loan and Security Agreement

The Company entered into a Loan and Security Agreement with Oxford Finance LLC (“Oxford”) and Silicon Valley Bank (“SVB”) in February 2020 (the “LSA”). See “Note 7. Loan and Security Agreement” to the Company’s Financial Statements included in the Annual Report on Form 10-K for the year ended December 31, 2022, or as further described below, for additional information.

In June 2022, the Company entered into an amendment to the LSA with Oxford and SVB (the “LSA Amendment”). The LSA Amendment added a financial covenant that requires the Company to maintain a minimum unrestricted cash balance of \$10.0 million. The Company was in compliance with the financial covenant under the LSA Amendment as of September 30, 2023.

The Loan and Security Agreement previously included a covenant requiring the Company to keep substantially all of its cash and investments with SVB, the substantial majority of which was held in a custodial account with another institution, for which SVB Asset Management was the advisor. In March and April 2023, the Loan and Security Agreement was amended to allow the Company to hold cash and investments at multiple financial institutions.

In June 2023, the Company entered into an amendment to the LSA with Oxford and SVB (the “5th LSA Amendment”). Under the 5th LSA Amendment, effective July 1, 2023, the loan bears interest at the floating per annum rate of interest equal to the greater of (i) 8.07% and (ii) the sum of (a) a specific published 1-month secured overnight financing rate (SOFR) reported on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 0.10%, plus (c) 6.40%. There was an immaterial impact of the 5th LSA Amendment on the financial statements of the Company.

As of September 30, 2023 and December 31, 2022, the Company has classified \$7.1 million and \$12.5 million, respectively, of the outstanding debt balance as a current liability, and zero and \$3.8 million, respectively, as a non-current liability, which reflects the scheduled repayment terms under the February 2020 LSA.

As of both September 30, 2023 and December 31, 2022, accrued interest expense was \$0.1 million.

During the three and nine months ended September 30, 2023, the Company recorded interest expense related to loans outstanding of \$0.3 million and \$1.1 million, respectively, with average interest rates of 11.76% and 11.38%, respectively, which includes interest related to the accretion of debt discount of \$0.1 million and \$0.3 million, respectively.

During the three and nine months ended September 30, 2022, the Company recorded interest expense related to loans outstanding of \$0.6 million and \$1.8 million, respectively, with average interest rates of 8.63% and 8.26%, respectively, which includes interest related to the accretion of debt discount of \$0.1 million and \$0.4 million, respectively.

## 7. Commitments and Contingencies

### Leases

The Company leases certain office, laboratory and manufacturing facilities in South San Francisco, California and San Carlos, California. These leases require monthly lease payments that may be subject to annual increases throughout the lease term. Certain of these leases also include renewal options at the election of the Company to renew or extend the lease for an additional 5 years. These renewal options have not been considered in the determination of the right-of-use assets and lease liabilities associated with these leases as the Company has determined it is not reasonably certain it will exercise such options.

The Company recognizes rent expense for these operating leases on a straight-line basis over the lease period. The components of lease costs, which the Company includes in operating expenses in the Company’s condensed Statements of Operations, were as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Operating lease cost	\$ 1,979	\$ 1,539	\$ 5,055	\$ 4,615
Short-term lease cost	59	19	102	60
Variable lease cost	580	325	1,431	1,179
Total lease costs	<u>\$ 2,618</u>	<u>\$ 1,883</u>	<u>\$ 6,588</u>	<u>\$ 5,854</u>

During the three and nine months ended September 30, 2023, the Company recorded operating lease expense of \$2.0 million and \$5.1 million, respectively. As of September 30, 2023, the Company paid \$5.7 million of operating lease payments related to the lease liabilities, which the Company includes in net cash used in operating activities in the Company's condensed Statements of Cash Flows.

During the three and nine months ended September 30, 2022, the Company recorded operating lease expense of \$1.5 million and \$4.6 million, respectively. As of September 30, 2022, the Company paid \$1.2 million of operating lease payments related to the lease liabilities, which the Company includes in net cash used in operating activities in the condensed Statements of Cash Flows.

As of September 30, 2023 and December 31, 2022, the weighted-average remaining lease term was 4.0 years and 4.8 years, respectively, and the weighted-average discount rate used to determine the operating lease liability was 10.8% for both periods.

As of September 30, 2023, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Year Ending December 31,	Amount (in thousands)
Remaining in 2023	\$ 2,266
2024	9,219
2025	9,533
2026	8,994
2027	8,289
Total lease payments	38,301
Less: imputed interest	(7,263 )
Operating lease liabilities	31,038
Less: current portion	(6,174 )
Total lease liabilities, non-current	<u>\$ 24,864</u>

#### **Indemnification & Other**

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to vendors, lessors, business partners, board members, officers, and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements, services to be provided by the Company, negligence or willful misconduct of the Company, violations of law by the Company, or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with directors and certain officers and employees that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers, or employees. No demands have been made upon the Company to provide indemnification under such agreements, and thus, there are no claims that the Company is aware of that could have a material effect on the Company's condensed Balance Sheets, condensed Statements of Operations, or condensed Statements of Cash Flows. The Company currently has directors' and officers' liability insurance.

In addition, the Company enters into agreements in the normal course of business, including with contract research organizations for clinical trials, contract manufacturing organizations for certain manufacturing services, and vendors for preclinical studies and other services and products for operating purposes, which are generally cancelable upon written notice.

#### **8. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consist of the following:

	September 30, 2023	December 31, 2022
	(in thousands)	
Vaxcyte-related accrual under Vaxcyte Supply Agreement	\$ 6,144	\$ 4,830
CMO-related accrual	7,428	3,900
Clinical trials-related accrual	2,804	2,954
Other	3,042	3,080
Total accrued expenses and other current liabilities	<u>\$ 19,418</u>	<u>\$ 14,764</u>

## 9. Deferred Royalty Obligation related to the Sale of Future Royalties

In June 2023, the Company entered into the Purchase Agreement with Blackstone, pursuant to which the Company sold to Blackstone its 4% royalty, or revenue interest, in the potential future net sales of Vaxcyte products, including the Purchased Interest under the 2015 License Agreement. The Company retains the right to discover and develop vaccines for the treatment or prophylaxis of any disease that is not caused by an infectious pathogen, including cancer.

In June 2023, Blackstone made an upfront payment of \$140.0 million to the Company and will also pay up to an additional \$250.0 million upon the achievement of various return thresholds as set forth in the Purchase Agreement.

Under the Purchase Agreement, and in connection with its sale of the Purchased Interest, the Company has agreed to certain covenants with respect to the exercise of its rights under the 2015 License Agreement, including with respect to the Company's right to amend, assign and terminate the 2015 License Agreement. The Purchase Agreement contains other customary terms and conditions, including representations and warranties, covenants, and indemnification obligations in favor of each party.

The Company recorded the \$140.0 million upfront payment from Blackstone as a deferred royalty obligation related to the sale of future royalties on the Company's condensed Balance Sheets. Due to the Company's ongoing manufacturing obligations under the 2015 License Agreement, the Company accounted for the proceeds as imputed debt and, therefore, will recognize future non-cash royalty revenues. Non-cash interest expense will be recognized over the estimated life of the royalty term arrangement using the effective interest method based on the imputed interest rate derived from estimated amounts and timing of future royalty payments to be received from Vaxcyte. As part of the sale, the Company incurred approximately \$3.8 million in transaction costs, which are being amortized over the estimated life of the royalty term arrangement using the effective interest method. As future royalties are earned from Vaxcyte by Blackstone, the balance of the deferred royalty obligation will be amortized over the estimated life of the royalty term arrangement.

There are a number of factors that could materially affect the fair value of the deferred royalty obligation. Such factors include, but are not limited to, the amount and timing of potential future royalty payments to be earned and received by Blackstone from Vaxcyte under the 2015 License Agreement, changing standards of care, the introduction of competing products, manufacturing or other delays, intellectual property matters, adverse events that result in governmental health authority imposed restrictions on the use of the vaccine products, and other events or circumstances that could result in reduced royalty payments from Vaxcyte to Blackstone, which are not within our control, and all of which would result in a reduction of non-cash royalty revenues and the non-cash interest expense over the estimated life of the royalty term arrangement. The Company will periodically assess the estimated royalty payments to be earned by Blackstone from Vaxcyte and, to the extent that the amount or timing of such payments is materially different than our original estimates, the Company will prospectively adjust the imputed interest rate and the related amortization of the deferred royalty obligation. As of September 30, 2023, our effective interest rate used to amortize the liability is 17.0%.

During the three and nine months ended September 30, 2023, the Company recognized approximately \$5.9 million and \$6.4 million, respectively, of non-cash interest expense on the deferred royalty obligation, which amount will increase such balance. As of September 30, 2023, Blackstone has not received any royalty payment from Vaxcyte and, therefore, the deferred royalty obligation has not begun to be amortized.

The following table shows the activity of the deferred royalty obligation since transaction inception through September 30, 2023:

	<b>September 30, 2023</b>
	<b>(in thousands)</b>
Proceeds from the sale of future Vaxcyte royalties	\$ 140,000
Issuance costs	(3,792 )
Non-cash interest expense associated with the sale of future Vaxcyte royalties	6,378
Amortization of issuance costs	177
Deferred royalty obligation related to the sale of future Vaxcyte royalties, net	<u>\$ 142,763</u>

## 10. Stockholders' Equity

### Common Stock

Holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company.

The Company has reserved common stock, on an if-converted basis, for issuance as follows:

	September 30, 2023	December 31, 2022
Common stock options issued and outstanding	7,920,561	7,310,611
Common stock awards issued and outstanding	5,213,248	3,958,478
Remaining shares reserved for issuance under 2018 Equity Incentive Plan and 2021 Equity Inducement Plan	1,903,250	1,541,706
Shares reserved for issuance under 2018 Employee Stock Purchase Plan	914,911	865,995
Warrants to purchase common stock	127,616	127,616
Total	<u>16,079,586</u>	<u>13,804,406</u>

### Preferred Stock

As of September 30, 2023 and December 31, 2022, the Company had 10,000,000 shares of preferred stock authorized with a par value of \$0.001 per share. No shares of preferred stock were outstanding as of September 30, 2023 and December 31, 2022.

## 11. Equity Incentive Plans, Equity Inducement Plans, Employee Stock Purchase Plan and Stock-Based Compensation

### 2004 Equity Incentive Plan, 2018 Equity Incentive Plan, 2021 Equity Inducement Plan, and Amended and Restated 2021 Equity Inducement Plan

In September 2018, the Company adopted the 2018 Equity Incentive Plan ("2018 Plan"), which became effective on September 25, 2018. As a result, the Company will not grant any additional awards under the 2004 Equity Incentive Plan ("2004 Plan"). The terms of the 2004 Plan and applicable award agreements will continue to govern any outstanding awards thereunder. In addition to the shares of common stock reserved for future issuance under the 2004 Plan that were added to the 2018 Plan upon its effective date, the Company initially reserved 2,300,000 shares of common stock for issuance under the 2018 Plan. In addition, the number of shares of common stock reserved for issuance under the 2018 Plan will automatically increase on the first day of January for a period of up to ten years, commencing on January 1, 2019, in an amount equal to 5% of the total number of shares of the Company's capital stock outstanding on the last day of the preceding year (rounded to the nearest whole share), or a lesser number of shares determined by the Company's board of directors. As a result, common stock reserved for issuance under the 2018 Plan was increased by 2,874,977 shares on January 1, 2023.

In August 2021, the Company adopted the 2021 Equity Inducement Plan ("2021 Plan"), which became effective on August 4, 2021. Upon its effective date, the Company initially reserved 750,000 shares of common stock for issuance pursuant to non-qualified stock options and restricted stock units ("RSUs") under the 2021 Plan. In accordance with Rule 5635(c)(4) of the Nasdaq listing rules, equity awards under the 2021 Plan may only be made to an employee if he or she is granted such equity awards in connection with his or her commencement of employment with the Company and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. In addition, awards under the 2021 Plan may only be made to employees who have not previously been an employee or member of the Board (or any parent or subsidiary of the Company) or following a bona fide period of non-employment of the employee by the Company (or a parent or subsidiary of the Company). At all times, the Company will reserve and keep available a sufficient number of shares as will be required to satisfy the requirements of all outstanding awards granted under the 2021 Plan.

In August 2022, the Company amended and restated the 2021 Plan (the "Amended and Restated 2021 Plan") and reserved an additional 750,000 shares of common stock available for issuance under the Amended and Restated 2021 Plan to be granted by the Company to certain employees as a material inducement to their acceptance of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).



Additionally, in February 2023, the Company amended and restated the 2021 Plan and reserved an additional 500,000 shares of common stock available for issuance under the Amended and Restated 2021 Plan to be granted by the Company to certain employees as a material inducement to their acceptance of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4). The total number of shares reserved for issuance pursuant to the Amended and Restated 2021 Plan is 2,000,000 shares.

As of September 30, 2023, the Company had a total of 1,903,250 shares available for grant under the 2018 Plan and the 2021 Plan.

The following table summarizes option activity under the Company's 2004 Plan, 2018 Plan and 2021 Plan:

	Shares		Weighted-Average Exercise Price
Stock options outstanding at December 31, 2022	7,310,611	\$	12.68
Granted	1,562,500		5.43
Exercised	(53,060 )		5.92
Canceled and forfeited	(899,490 )		12.69
Stock options outstanding at September 30, 2023	<u>7,920,561</u>		11.30
Stock options exercisable at September 30, 2023	<u>5,484,791</u>	\$	12.56

#### **Restricted Stock Units**

During the nine months ended September 30, 2023, the Company granted 2,629,225 shares of restricted common stock units ("RSUs") to certain employees. These RSUs vest annually, and generally, will become fully vested over four years.

A summary of the status and activity of non-vested RSUs during the nine months ended September 30, 2023 is as follows:

	Number of shares		Weighted Average Grant-Date Fair Value
Non-vested December 31, 2022	3,958,478	\$	11.70
Granted	2,629,225		5.58
Vested and released	(1,046,519 )		12.51
Canceled and forfeited	(327,936 )		10.24
Non-vested September 30, 2023	<u>5,213,248</u>	\$	8.55

#### **2018 Employee Stock Purchase Plan**

In September 2018, the Company adopted the 2018 Employee Stock Purchase Plan ("ESPP"), which became effective on September 26, 2018, in order to enable eligible employees to purchase shares of the Company's common stock. The Company initially reserved 230,000 shares of common stock for sale under the ESPP. The aggregate number of shares reserved for sale under the ESPP will automatically increase on the first day of January for a period of up to ten years, commencing on January 1, 2019, in an amount equal to 1% of the total number of shares of the Company's capital stock outstanding on the last day of the preceding year (rounded to the nearest whole share), or a lesser number of shares determined by the Company's board of directors. As a result, common stock reserved for issuance under the ESPP was increased by 574,995 shares on January 1, 2023. The aggregate number of shares issued over the term of the Company's ESPP, subject to stock-splits, recapitalizations or similar events, may not exceed 2,300,000 shares of the Company's common stock.

As of September 30, 2023, 1,270,335 shares had been purchased and 914,911 shares were available for future issuance under the ESPP.

## Stock-Based Compensation Expense

The Company believes that the fair value of the stock options, RSUs and ESPP shares is more reliably measurable than the fair value of services received.

Total stock-based compensation expense recognized was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Research and development expense:	\$ 2,877	\$ 2,630	\$ 8,825	\$ 7,514
General and administrative expense:	3,126	4,152	9,860	12,938
Total	<u>\$ 6,003</u>	<u>\$ 6,782</u>	<u>\$ 18,685</u>	<u>\$ 20,452</u>

As of September 30, 2023, unrecognized stock-based compensation expense related to the unvested stock options and RSUs granted was \$12.9 million and \$34.7 million, respectively. The remaining unrecognized compensation cost related to the unvested stock options and RSUs is expected to be recognized over a weighted-average period of 2.1 years and 2.4 years, respectively. As of September 30, 2023, there was \$0.6 million of unrecognized stock-based compensation expense related to the ESPP.

As of September 30, 2022, unrecognized stock-based compensation expense related to the unvested stock options and RSUs granted was \$18.7 million and \$39.6 million, respectively. The remaining unrecognized compensation cost related to the unvested stock options and RSUs is expected to be recognized over a weighted-average period of 2.4 years and 2.9 years, respectively. As of September 30, 2022, there was \$0.5 million of unrecognized stock-based compensation expense related to the ESPP.

## 12. Provision for Income Taxes

For the three and nine months ended September 30, 2023, the Company recognized an income tax expense of \$1.8 million and \$2.4 million, respectively, resulting in an effective tax rate of (1.2)%.

The income tax charge for the three and nine months ended September 30, 2023, was primarily due to unfavorable book-tax differences related to capitalizing and amortizing research and development expenditures under Internal Revenue Code, or IRC, Section 174, the upfront payment from the sale of future royalties, foreign income tax, and IRC Section 382 limitations imposed on the utilization of the Company's historical tax attributes as a result of cumulative ownership changes that the Company more likely than not experienced in prior years. The effective tax rates for the three and nine months ended September, 2023 vary from the U.S. federal statutory tax rate of 21% primarily due to the Company's inability to recognize the benefit from its net deferred tax assets, which are offset by a valuation allowance. The Company has established a full valuation allowance against its net deferred tax assets due to the uncertainty surrounding the realization of such assets. All losses to date have been incurred domestically.

The Company recorded a foreign income tax charge of zero and \$2.5 million during the three and nine months ended September 30, 2022, respectively, due to a withholding tax in China on its license revenue from Tasly.

## 13. Net Loss Per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands, except share and per share amounts)			
Numerator:				
Net loss	\$ (49,284)	\$ (19,488)	\$ (137,858)	\$ (84,610)
Denominator:				
Shares used in computing net loss per share	60,599,025	52,345,732	59,894,181	48,622,258
Net loss per share, basic and diluted	<u>\$ (0.81)</u>	<u>\$ (0.37)</u>	<u>\$ (2.30)</u>	<u>\$ (1.74)</u>

The following common stock equivalents were excluded from the computation of diluted net loss per share for the period ended September 30, 2023 and 2022, because including them would have been antidilutive:

	<b>As of September 30,</b>	
	<b>2023</b>	<b>2022</b>
Common stock options issued and outstanding	7,920,561	7,473,527
Restricted stock units issued and outstanding	5,213,248	3,893,070
Warrants to purchase common stock	127,616	127,616
Shares to be issued under employee stock purchase plan	38,772	23,346
<b>Total</b>	<b>13,300,197</b>	<b>11,517,559</b>

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

*You should read the following discussion of our financial condition and results of operations in conjunction with our condensed financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2022. In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties, such as statements of our plans, objectives, expectations, intentions and belief. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A below. All statements contained in this Quarterly Report on Form 10-Q other than statements of historical fact, including statements related to our expectations regarding our future results of operations and financial position, business strategy, market size for our product candidates, potential future milestone and royalty payments, the value of our holdings of Vaxcyte common stock, potential growth opportunities, nonclinical and clinical development activities, efficacy and safety profile of our product candidates, our ability to maintain and recognize the benefits of certain designations received by product candidates, our ability to successfully leverage Fast Track Designation, the timing and results of nonclinical studies and clinical trials, collaboration with third parties, the expected impact of pandemics or contagious diseases, such as the COVID-19 pandemic, on our operations, and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, are forward-looking statements. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "predict," "target," "intend," "could," "would," "should," "project," "plan," "expect," and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.*

*These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q and, while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete; and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.*

### Overview

We are a clinical-stage oncology company developing site-specific and novel-format antibody drug conjugates, or ADCs, enabled by our proprietary integrated cell-free protein synthesis platform, XpressCF<sup>®</sup>, and our site-specific conjugation platform, XpressCF+<sup>®</sup>. We aim to design and develop therapeutics using the most relevant and potent modalities, including ADCs, bispecific ADCs, immunostimulatory ADCs, or iADCs, dual conjugate ADCs, or ADC<sup>2</sup>s, and cytokine derivatives. Our molecules are directed primarily against clinically validated targets where the current standard of care is suboptimal. We believe that our platform allows us to accelerate the discovery and development of potential first-in-class and/or best-in-class molecules by enabling the rapid and systematic evaluation of protein structure-activity relationships to create optimized homogeneous product candidates. Our mission is to transform the lives of patients by creating medicines with improved therapeutic profiles for areas of unmet need.

Once identified, production of protein drug candidates can be rapidly and predictably scaled in our current Good Manufacturing Practices, or cGMP, compliant manufacturing facility. We have the ability to manufacture our proprietary cell-free extract that supports our production of proteins on a large scale using a semi-continuous fermentation process. Our most advanced product candidate is STRO-002, or luveltamab tazevibulin, or luvelta, an ADC directed against folate receptor-alpha, or FolR $\alpha$ , for patients with FolR $\alpha$ -expressing cancers, including ovarian cancer.

Luvelta was designed and optimized for an improved therapeutic index by placing a precise number of linker-warheads at four specific locations within the antibody using our proprietary XpressCF+<sup>®</sup> platform. Our first Phase 1 trial for luvelta is an open-label study evaluating luvelta as a monotherapy for patients with ovarian and endometrial cancers. This trial is being conducted in two-parts, dose escalation and dose expansion. The primary objectives of the clinical trial are to determine the safety and tolerability profile, to define the recommended Phase 2 dose level and interval and to evaluate preliminary anti-tumor activity. Our secondary objectives are to characterize the human pharmacokinetics and additional safety, tolerability, and efficacy measures.

In 2019, we began enrolling patients in a Phase 1 trial of luvelta that focused on ovarian and endometrial cancers. The dose escalation portion of the luvelta Phase 1 trial has been completed and the dose expansion portion of the trial to assess the efficacy, safety, and tolerability of luvelta is ongoing. In January 2023, we reported preliminary final results from the dose-expansion cohort in platinum-resistant ovarian cancer and updated results in June 2023. The data from the dose-escalation and dose expansion cohorts suggested that luvelta exhibited a manageable safety profile together with promising preliminary efficacy data in the tested patient population. We also initiated an exploratory cohort C to assess the safety of treatment with luvelta at 5.2 mg/kg in combination with prophylactic pegfilgrastim and presented preliminary data from ten patients from this cohort in January 2023. Early results from these initial 10 patients in cohort C, when

compared to patients who were not given prophylactic pegfilgrastim in the dose-expansion cohort at a starting dose of 5.2 mg/kg (n=21) demonstrated substantial reductions in Grade 3+ neutropenia and instances of dose delays.

We announced preliminary data from our Phase 1 dose-expansion study of luvelta for the treatment of endometrial cancer in October 2023, which demonstrated a similar encouraging preliminary efficacy and safety profile to that observed in connection with our study of luvelta in connection with platinum-resistant ovarian cancer. Initial data were presented on 16 patients with at least one post baseline scan of 17 total patients enrolled. In patients with endometrial cancer having a tumor proportion score, or TPS, of greater than 25% FOLR $\alpha$  expression (n=7), confirmed partial response, or PR, was seen in 29% (2/7) and the Disease Control Rate, or DCR, was 86% (6/7). In patients with endometrial cancer having TPS  $\geq$ 1% FOLR $\alpha$  expression (n=16), confirmed PR was seen in 19% (3/16) and the DCR was 69% (11/16). Consistent with previous reported luvelta safety results, the most common adverse event was neutropenia and no new safety signals were observed.

We plan to announce updated data from cohort C and from the study of the combination of luvelta with bevacizumab for the treatment of ovarian cancer in the second half of 2023. In August 2021, luvelta was granted Fast Track Designation by the U.S. Food and Drug Administration, or FDA, for the treatment of patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior lines of systemic therapy. We are currently in discussions with the FDA and EMA to refine our proposed trial design for a registration-directed trial of luvelta. In June 2023, we announced that sites are open for enrollment in our registration-directed Phase 2/3 trial of luvelta, referred to as REFRA $\alpha$ ME, for patients with platinum-resistant ovarian cancer. The first patient was enrolled in Part I of the REFRA $\alpha$ ME study in July 2023.

In addition, we have been offering compassionate use of luvelta to treat pediatric patients with relapsed/refractory CBF/GLIS AML, commonly known as RAM phenotype AML. Compassionate use data showed anti-leukemic activity of luvelta in pediatric patients with relapsed/refractory CBF/GLIS AML and was presented at the 64th American Society of Hematology Annual Meeting and Exposition (ASH 2022). The data showed that luvelta was well tolerated as a monotherapy agent and in combination with standard cancer therapies. Luvelta was granted Orphan Drug Designation by the FDA in December 2022 in this pediatric patient population.

Our next most advanced product candidate is STRO-001, an optimally designed ADC directed against the cancer target CD74, for multiple myeloma and NHL. STRO-001 was designed and optimized for maximal therapeutic index by placing linker-warheads at specific locations within the antibody using our proprietary XpressCF+<sup>®</sup> platform. The Phase 1 trial for STRO-001 is an open-label study evaluating STRO-001 as a monotherapy for patients with multiple myeloma and NHL. The trial is being conducted in two parts: dose escalation and dose expansion. The primary objectives of the trial are to determine the safety and tolerability profile of STRO-001, to determine the recommended Phase 2 dose level and interval and to evaluate preliminary anti-tumor activity. Our secondary objectives are to characterize the human pharmacokinetics of STRO-001 and additional safety, tolerability, and efficacy measures.

We have completed enrollment for STRO-001 dose escalation in a Phase 1 trial for multiple myeloma and NHL. STRO-001 has been generally well-tolerated and no ocular toxicity signals have been observed, with no patients receiving prophylactic corticosteroid eye drops. We have completed dose escalation in the STRO-001 Phase 1 trial following identification of the maximum tolerated dose. In October 2021, we granted BioNova, an option to exclusively license the right to develop and commercialize STRO-001 in Greater China, or the BioNova Option Agreement. In February 2023, BioNova announced that the first patient had been dosed in the Phase 1 clinical trial of STRO-001. We plan to leverage the clinical data produced by BioNova in Greater China to make future prioritization decisions regarding further clinical development.

We also have two preclinical product candidates for which IND-enabling activities are underway. The first, STRO-003, is a single homogeneous ADC directed against an anti-Receptor tyrosine kinase-like orphan receptor 1, or ROR1, which we intend to develop for the treatment of solid tumors. We presented expanded preclinical data for STRO-003 at the American Association for Cancer Research (AACR) Annual Meeting in April 2023, which demonstrated potent anti-tumor activity and immune-modulating properties, suggesting that STRO-003 may have the potential to augment checkpoint blockade therapy. Preparations are underway for IND enabling studies for STRO-003, which we expect will be completed in 2024. We expect to begin Phase 1 safety studies of STRO-003 in 2024. The second preclinical product candidate, STRO-004, is an ADC directed against Tissue Factor, or TF, which is also intended for the treatment of solid tumors.

Enabled through our proprietary XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms, we have entered into multi-target, product-focused collaborations with leading pharmaceutical and biotechnology companies in the field of oncology, including an immunostimulatory antibody-drug conjugates collaboration with Astellas, a cytokine derivatives collaboration with Merck; BioNova; and Tasly. Our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms have also supported Vaxcyte, focused on discovery and development of vaccines for the treatment and prophylaxis of infectious disease. In the first quarter of 2022, Vaxcyte announced that it had initiated a Phase 1/2 clinical proof-of-concept study of its lead product candidate, VAX-24, its 24-valent pneumococcal conjugate vaccine candidate, under investigation for the prevention of invasive pneumococcal

disease in adults. In April 2023, Vaxcyte announced positive clinical data from this trial. Also in 2022, we entered into an agreement with Vaxcyte, granting it an option to access expanded rights to develop and manufacture cell-free extract for use in development and manufacture of its vaccine products, among certain other rights. In October 2023, Vaxcyte announced FDA clearance of its investigational new drug application for VAX-31, a 31-valent pneumococcal conjugate vaccine candidate for the prevention of invasive pneumococcal disease in adults. Further, in June 2023, we entered into a purchase and sale agreement (the "Purchase Agreement") with Blackstone, in which Blackstone acquired the right to receive our 4% revenue interest in Vaxcyte's future products, including VAX-24 and other products developed by Vaxcyte under its license with us. In August 2023, Tasly received its first IND clearance by NMPA in Greater China for luvelta. Additionally, we have sole worldwide rights to develop CC-99712 following the termination of our collaboration with BMS.

Since the commencement of our operations, we have devoted substantially all of our resources to performing research and development and manufacturing activities in support of our own product development efforts and those of our collaborators, raising capital to support and expand such activities and providing general and administrative support for these operations. We have funded our operations to date primarily from upfront, milestone and other payments under our collaboration agreements with BMS, Merck, Astellas, EMD Serono, Vaxcyte, BioNova, and Tasly, the issuance and sale of redeemable convertible preferred stock, our initial public offering, or IPO, follow-on public offerings of common stock, sales of our common stock through our ATM Facility, debt financing, and the royalty monetization agreement with Blackstone.

We do not have any products approved for commercial sale and have not generated any revenue from commercial product sales. We had a loss from operations of \$132.4 million and a net loss of \$137.9 million for the nine months ended September 30, 2023, which net loss included the non-operating, unrealized gain of \$2.0 million related to our holdings of Vaxcyte common stock. We had a loss from operations of \$79.7 million and net loss of \$84.6 million, which net loss included the non-operating, unrealized gain of \$0.3 million related to our holdings of Vaxcyte common stock, for the nine months ended September 30, 2022. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We cannot assure you that we will have net income or that we will generate positive cash flow from operating activities in the future. As of September 30, 2023, we had an accumulated deficit of \$590.5 million. 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 product candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, access, marketing, manufacturing and distribution. Our operating expenses would significantly increase due to continued activities to develop, and seek regulatory approvals for, our product candidates, engage in other research and development activities, expand our pipeline of product candidates, continue to develop our manufacturing facility and capabilities, maintain and expand our intellectual property portfolio, seek regulatory and marketing approval for any product candidates that we may develop, acquire or in-license other assets or technologies, ultimately establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval, and operate as a public company. Current capital market conditions provide a challenging financing environment. In this context, we are evaluating our programs and spending as we fully develop our 2024 goals and financial plan. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials, our expenditures on other research and development activities and the timing of achievement and receipt of upfront, milestones and other collaboration agreement payments.

## **Financial Operations Overview**

### **Revenue**

We do not have any products approved for commercial sale and have not generated any revenue from commercial product sales. Our total revenue to date has been generated principally from our collaboration and license agreements with BMS, Merck, Astellas, EMD Serono, Vaxcyte, BioNova and Tasly, and to a lesser extent, from manufacturing, supply and services and materials we provide to the above collaborators.

We derive revenue from collaboration arrangements, under which we may grant licenses to our collaboration partners to further develop and commercialize our proprietary product candidates. We may also perform research and development activities under the collaboration agreements. Consideration under these contracts generally includes a nonrefundable upfront payment, development, regulatory and commercial milestones and other contingent payments, and royalties based on net sales of approved products. Additionally, the collaborations may provide options for the customer to acquire from us materials and reagents, clinical product supply or additional research and development services under separate agreements. We assess which activities in the collaboration agreements are considered distinct performance obligations that should be accounted for separately. We develop assumptions that require judgement to determine whether the license to our intellectual property is distinct from the research and development services or participation in activities under the collaboration agreements.

At the inception of each agreement, we determine the arrangement transaction price, which includes variable consideration, based on the assessment of the probability of achievement of future milestones and contingent payments and other potential consideration. We recognize revenue over time by measuring our progress towards the complete satisfaction of the relevant performance obligation using an appropriate input or output method based on the nature of the service promised to the customer.

For arrangements that include multiple performance obligations, we allocate the transaction price to the identified performance obligations based on the standalone selling price, or SSP, of each distinct performance obligation. In instances where SSP is not directly observable, we develop assumptions that require judgment to determine the SSP for each performance obligation identified in the contract. These key assumptions may include full-time equivalent, or FTE, personnel effort, estimated costs, discount rates and probabilities of clinical development and regulatory success.

### 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 those of our collaborators, and include salaries, employee benefits, stock-based compensation, laboratory supplies, outsourced research and development expenses, professional services, and allocated facilities-related costs. We expense both internal and external research and development costs as they are incurred. Nonrefundable advance payments for services that will be used or rendered for future research and development activities are recorded as prepaid expenses and recognized as expenses as the related services are performed.

We expect our research and development expenses would increase in the future due to activities to advance our product candidates into and through preclinical studies and clinical trials, pursue regulatory approval of our product candidates, expand our pipeline of product candidates, and continue to develop our manufacturing facility and capabilities. 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 product candidates may be affected by a variety of factors including: the safety and efficacy of our product candidates, early clinical data, investment in our clinical programs, the ability of collaborators to successfully develop our licensed product candidates, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our product 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 when and to what extent we will generate revenue from the commercialization and sale of our product candidates.

The following table summarizes our research and development expenses incurred during the indicated periods. The internal costs include personnel, facility costs and research and scientific related activities associated with our pipeline. The external program costs reflect external costs attributable to our clinical development candidates and preclinical candidates selected for further development. Such expenses include third-party costs for preclinical and clinical studies and research, development and manufacturing services, and other consulting costs.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
<b>Internal costs:</b>				
Research and drug discovery	\$ 8,391	\$ 8,924	\$ 25,825	\$ 25,378
Process and product development	5,047	3,857	15,264	11,302
Manufacturing	10,074	9,132	32,804	27,101
Clinical development	3,083	2,452	9,101	6,492
Total internal costs	26,595	24,365	82,994	70,273
<b>External Program Costs:</b>				
Research and drug discovery	1,522	1,003	2,366	2,574
Process and product development	759	69	2,189	337
Manufacturing	11,033	3,149	21,353	11,857
Clinical development	5,760	3,128	17,758	8,995
Total external program costs	19,074	7,349	43,666	23,763
<b>Total research and development expenses</b>	<b>\$ 45,669</b>	<b>\$ 31,714</b>	<b>\$ 126,660</b>	<b>\$ 94,036</b>

## **General and Administrative**

Our general and administrative expenses consist primarily of personnel costs, expenses for outside professional services, including legal, human resources, audit, accounting and tax services and allocated facilities-related costs. Personnel costs include salaries, employee benefits and stock-based compensation. We expect to incur expenses operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and listing standards applicable to companies listed on the Nasdaq Global Market, additional insurance expenses, investor relations activities and other administrative and professional services. The size of our administrative function and our general and administrative expenses to support the anticipated growth of our business would increase as we continue to advance our product candidates into and through the clinic.

## **Interest Income**

Interest income consists primarily of interest earned on our invested funds.

## **Unrealized Gain (Loss) on Equity Securities**

Unrealized gain (loss) on equity securities consists of the remeasurement of our investment in Vaxcyte common stock.

## **Non-cash interest expense related to the sale of future royalties**

Non-cash interest expense related to the sale of future Vaxcyte royalties represents the imputed interest expense on our deferred royalty obligation related to the sale of future Vaxcyte royalties pursuant to the Purchase Agreement, using the effective interest method. As further described in the interim condensed financial statements Note 9. Deferred Royalty Obligation Related to the Sale of Future Royalties, in June 2023, we entered into the Purchase Agreement with Blackstone, pursuant to which we sold to Blackstone our 4% royalty, or revenue interest, in the potential future net sales of Vaxcyte products, including VAX-24.

Non-cash interest expense will be recognized over the estimated life of the royalty term arrangement using the effective interest method based on the imputed interest rate derived from estimated amounts and timing of future royalty payments to be earned and received by Blackstone from Vaxcyte under the 2015 License Agreement.

## **Interest and Other Income (Expense), Net**

Interest expense includes interest incurred on our debt and amortization of debt issuance costs, including accretion of the final payment. Additionally, we identified a financing component under the Astellas Agreement and recorded interest expense associated with the upfront payment. Other income (expense) includes realized gain (loss) on the equity securities.

## **Income Taxes**

We recorded an income tax charge of \$1.8 million and \$2.4 million during the three and nine months ended September 30, 2023, respectively. The income tax charge was primarily due to unfavorable book-tax differences related to capitalizing and amortizing research and development expenditures under Internal Revenue Code, or IRC, Section 174, the upfront payment from the sale of future royalties, foreign income tax, and IRC Section 382 limitations imposed on the utilization of our historical tax attributes as a result of cumulative ownership changes that we more likely than not experienced in prior years.

We recorded a foreign income tax charge of zero and \$2.5 million during the three and nine months ended September 30, 2022, respectively, due to a withholding tax in China on an upfront license fee payment received from Tasly.

All other income tax charges and benefits for the three and nine months ended September 30, 2023, and 2022, have been immaterial, primarily due to the net loss in each period. Our deferred tax assets continue to be fully offset by a valuation allowance.



Comparison of the Three Months Ended September 30, 2023 and 2022

	Three Months Ended September 30,			Change (%)
	2023	2022 (in thousands)	Change	
Revenues	\$ 16,924	\$ 25,147	\$ (8,223)	(33)%
Operating expenses				
Research and development	45,669	31,714	13,955	44%
General and administrative	15,269	14,643	626	4%
Total operating expenses	60,938	46,357	14,581	31%
Loss from operations	(44,014)	(21,210)	(22,804)	108%
Interest income	4,550	1,014	3,536	349%
Unrealized gain on equity securities	694	3,496	(2,802)	(80)%
Non-cash interest expense related to the sale of future royalties	(5,936)	-	(5,936)	*
Interest and other income (expense), net	(2,739)	(2,788)	49	(2)%
Loss before provision for income taxes	(47,445)	(19,488)	(27,957)	143%
Provision for income taxes	1,839	-	1,839	*
Net loss	\$ (49,284)	\$ (19,488)	\$ (29,796)	153%

\*Percentage not meaningful

**Revenue**

We have recognized revenue as follows during the indicated periods:

	Three Months Ended September 30,			Change (%)
	2023	2022 (in thousands)	Change	
Bristol Myers Squibb Company ("BMS")	\$ 189	\$ 4,343	\$ (4,154)	(96)%
Merck Sharp & Dohme Corporation ("Merck")	83	10,157	(10,074)	(99)%
Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name "EMD Serono")	-	166	(166)	(100)%
Astellas Pharma Inc. ("Astellas")	9,988	4,985	5,003	100%
Tasly Biopharmaceuticals Co., Ltd. ("Tasly")	5,072	-	5,072	*
Vaxcyte	1,592	1,496	96	6%
BioNova Pharmaceuticals, Ltd. ("BioNova")	-	4,000	(4,000)	(100)%
Total revenue	\$ 16,924	\$ 25,147	\$ (8,223)	(33)%

\*Percentage not meaningful

Total revenue decreased by \$8.2 million during the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. This was primarily due to an earned \$10.0 million contingent payment from Merck in 2022, an earned \$4.0 million licensing option payment from BioNova in 2022, and a \$4.1 million and a \$0.2 million decrease in BMS and EMD Serono revenue, respectively, due to their decisions to end clinical development of CC-99712 and M1231, respectively, in 2023. These decreases were partially offset by a contingent payment of \$5.0 million earned from Tasly in 2023, a \$5.0 million increase from Astellas, of which \$3.7 million was from the ongoing performance related to partially unsatisfied performance obligations, \$1.1 million was from research and development services, and \$0.2 million was from the financing component related to the Astellas Agreement, and a \$0.1 million increase in Vaxcyte revenue.

**Research and Development Expense**

Research and development expense increased by \$13.9 million, or 44%, during the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. The overall increase was due primarily to increases of \$9.7 million in consulting and outside services mainly due to increased CMO-related activities, \$2.3 million in personnel-related expenses due to higher headcount, \$2.1 million in clinical development expenses, and \$1.2 million in facilities-related expenses, partially offset by decreases of \$0.8 million in preclinical research expenses and \$0.6 million in laboratory supplies.

**General and Administrative Expense**

General and administrative expense increased by \$0.6 million, or 4%, during the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. The overall increase was due primarily to increases of \$1.0 million in consulting and outside services, \$0.5 million in facilities-related expenses, and \$0.3 million in equipment and office-related expenses, partially offset by a \$1.2 million decrease in personnel-related expenses.

**Interest Income**

Interest income increased by \$3.5 million during the three months ended September 30, 2023, as compared to the three months ended September 30, 2022, due primarily to higher average investment balances and higher average rates of return in 2023.

**Unrealized Gain on Equity Securities**

Unrealized gain on equity securities was \$0.7 million during the three months ended September 30, 2023, as compared to an unrealized gain of \$3.5 million for the three months ended September 30, 2022. The unrealized gain on equity securities in each period was entirely due to the remeasurement of the fair value of our investment in Vaxcyte common stock.

**Non-cash interest expense related to the sale of future royalties**

Non-cash interest expense increased by \$5.9 million during the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. Non-cash interest expense was recognized on our deferred royalty obligation related to the June 2023 sale of future Vaxcyte royalties pursuant to the Purchase Agreement, using the effective interest method based on the imputed interest rate derived from estimated amounts and timing of future royalty payments to be earned and received by Blackstone from Vaxcyte under the 2015 License Agreement. No non-cash interest expense was recorded during the three months ended September 30, 2022.

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

Interest and other income (expense), net, decreased by \$49 thousand during the three months ended September 30, 2023, as compared to the three months ended September 30, 2022, due primarily to a decrease of \$0.3 million in interest incurred on our outstanding loan, partially offset by an increase of \$0.2 million from the financing component related to the Astellas Agreement.

Comparison of the Nine Months Ended September 30, 2023 and 2022

	Nine Months Ended September 30,			Change (%)
	2023	2022 (in thousands)	Change	
Revenues	\$ 40,010	\$ 59,140	\$ (19,130)	(32)%
Operating expenses				
Research and development	126,660	94,036	32,624	35%
General administrative	45,780	44,825	955	2%
Total operating expenses	172,440	138,861	33,579	24%
Loss from operations	(132,430)	(79,721)	(52,709)	66%
Interest income	9,952	1,327	8,625	650%
Unrealized gain on equity securities	2,023	323	1,700	526%
Non-cash interest expense related to the sale of future royalties	(6,378)	-	(6,378)	*
Interest and other income (expense), net	(8,640)	(4,039)	(4,601)	114%
Loss before provision for income taxes	(135,473)	(82,110)	(53,363)	65%
Provision for income taxes	2,385	2,500	(115)	(5)%
Net loss	<u>\$ (137,858)</u>	<u>\$ (84,610)</u>	<u>\$ (53,248)</u>	63%

\*Percentage not meaningful

**Revenue**

We have recognized revenue as follows during the indicated periods:

	Nine Months Ended September 30,			Change (%)
	2023	2022 (in thousands)	Change	
Bristol Myers Squibb Company ("BMS")	\$ 5,591	\$ 8,774	\$ (3,183)	(36)%
Merck Sharp & Dohme Corporation ("Merck")	2,776	11,367	(8,591)	(76)%
Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name "EMD Serono")	8	2,200	(2,192)	(100)%
Astellas Pharma Inc. ("Astellas")	23,593	4,985	18,608	373%
Tasly Biopharmaceuticals Co., Ltd. ("Tasly")	5,072	25,000	(19,928)	(80)%
Vaxcyte	2,970	2,814	156	6%
BioNova Pharmaceuticals, Ltd. ("BioNova")	-	4,000	(4,000)	(100)%
Total revenue	<u>\$ 40,010</u>	<u>\$ 59,140</u>	<u>\$ (19,130)</u>	(32)%

\*Percentage not meaningful

Total revenue decreased by \$19.1 million during the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. This was primarily due to a \$20.0 million decrease in Tasly revenue from an earned \$25.0 million upfront payment under the Tasly License Agreement in 2022, partially offset by a contingent payment of \$5.0 million earned in 2023, an \$8.6 million decrease in Merck revenue primarily due to an earned \$10.0 million contingent payment from Merck in 2022, a \$0.9 million decrease from the 2022 completion of the performance obligation associated with the extension of the research term for the first target program under the 2018 Merck Agreement, partially offset by a \$2.3 million increase in manufacturing activities supporting clinical trial supply, a \$4.0 million decrease in BioNova revenue due to an earned licensing option payment in 2022, and a \$3.2 million and \$2.2 million decrease in BMS and EMD Serono revenue, respectively, due to their decisions to end clinical development of CC-99712 and M1231, respectively, in 2023. These decreases were partially offset by an \$18.6 million increase from Astellas, of which \$9.5 million was from the ongoing performance related to partially unsatisfied performance obligations, \$5.3 million was from the financing component related to the Astellas Agreement, and \$3.8 million was from research and development services, and a \$0.1 million increase in Vaxcyte revenue.

### **Research and Development Expense**

Research and development expense increased by \$32.6 million, or 35%, during the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. The overall increase was due primarily to increases of \$11.6 million in consulting and outside services mainly due to increased CMO-related activities, \$11.1 million in personnel-related expenses due to higher headcount, \$8.5 million in clinical development expenses, \$3.0 million in facilities-related expenses, \$0.6 million in laboratory supplies, and \$0.5 million in equipment and office-related expenses, partially offset by a decrease of \$2.7 million in preclinical research expenses.

### **General and Administrative Expense**

General and administrative expense increased by \$1.0 million, or 2%, during the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. The overall increase was due primarily to increases of \$1.0 million in consulting and outside services, \$0.9 million in equipment and office-related expenses, and \$0.6 million in facilities-related expenses, partially offset by a \$1.5 million decrease in personnel-related expenses.

### **Interest Income**

Interest income increased by \$8.6 million during the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, due primarily to higher average investment balances and higher average rates of return in 2023.

### **Unrealized Gain on Equity Securities**

Unrealized gain on equity securities was \$2.0 million during the nine months ended September 30, 2023, as compared to an unrealized gain of \$0.3 million for the nine months ended September 30, 2022. The unrealized gain on equity securities in each period was entirely due to the remeasurement of the fair value of our investment in Vaxcyte common stock.

### **Non-cash interest expense related to the sale of future royalties**

Non-cash interest expense increased by \$6.4 million during the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. Non-cash interest expense was recognized on our deferred royalty obligation related to the June 2023 sale of future Vaxcyte royalties pursuant to the Purchase Agreement using the effective interest method based on the imputed interest rate derived from estimated amounts and timing of future royalty payments to be earned and received by Blackstone from Vaxcyte under the 2015 License Agreement. No non-cash interest expense was recorded during the nine months ended September 30, 2022.

### **Interest and Other Income (Expense), Net**

Interest and other income (expense), net, increased by \$4.6 million during the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, due primarily to the increase of \$5.3 million from the financing component related to the Astellas Agreement, partially offset by a decrease of \$0.7 million in interest incurred on our outstanding loan.

### **Liquidity and Capital Resources**

#### **Sources of Liquidity**

To date, we have incurred significant net losses, and negative cash flows from operations. Our operations have been funded primarily by payments received from our collaborators, and net proceeds from equity sales, debt, and a royalty monetization. As of September 30, 2023, we had cash, cash equivalents and marketable securities of \$321.1 million, equity securities of \$34.0 million, outstanding debt of \$7.1 million and an accumulated deficit of \$590.5 million.

#### **Upfront Payment from Blackstone**

In June 2023, we entered into a Purchase Agreement with Blackstone, pursuant to which we sold to Blackstone our 4% royalty, or revenue interest, in potential future net sales of Vaxcyte products, including VAX-24. We retain the right to

discover and develop vaccines for the treatment or prophylaxis of any disease that is not caused by an infectious pathogen, including cancer.

Blackstone made an upfront payment of \$140.0 million to us and will also pay up to an additional \$250.0 million upon the achievement of various return thresholds, as set forth in the Purchase Agreement.

#### ***At-The-Market Sales***

During the three and nine months ended September 30, 2023, we sold an aggregate of zero and 1,857,410 shares, respectively, of our common stock through our ATM Facility pursuant to the Sales Agreement with Jefferies. The gross proceeds from these sales during the nine months ended September 30, 2023 were approximately \$12.4 million, before deducting fees of approximately \$0.4 million, resulting in net proceeds of approximately \$12.0 million.

#### ***Contingent and Upfront Payments from Tasly***

In August 2023, Tasly received the first IND clearance by NMPA in Greater China. As a result of this achievement, we earned a \$5.0 million contingent payment from Tasly under the Tasly License Agreement. The contingent payment, net of withholding tax of \$0.5 million, resulted in a net payment to us of \$4.5 million received in October 2023.

During the three months ended September 30, 2023, we received a \$5.0 million contingent payment from Tasly related to the first patient dosed in our REFRaME trial for luvelta, net of withholding tax of \$0.5 million. The REFRaME study consists of two parts, Part I being the dose-finding portion and Part II being the portion of the study that will focus on the selected dose from Part I, and is intended to generate data to enable the potential registration of luvelta. Although we currently intend to conduct the REFRaME study to completion, we have the sole discretion to terminate the REFRaME study at any time. As such, we have agreed with Tasly, that in the event we terminate the REFRaME study prior to dosing the first patient in Part II, we will refund Tasly the contingent payment received by us within 30 days of such study termination.

During the year ended December 31, 2022, we earned a \$25.0 million nonrefundable upfront payment from Tasly under the Tasly License Agreement to grant Tasly an exclusive license to develop and commercialize luvelta in Greater China. The upfront payment, net of a withholding tax of \$2.5 million, resulted in a net payment to us of \$22.5 million received during the three months ended June 30, 2022.

#### ***Upfront Payments from Vaxcyte and Vaxcyte Equity Ownership***

In December 2022, we entered into a letter agreement (the "Vaxcyte Agreement") with Vaxcyte under which the Company granted to Vaxcyte (i) authorization to enter into an agreement with an independent alternate contract manufacturing organization, or CMO, to source cell-free extract solely for the products it licensed from the us, allowing Vaxcyte to have direct oversight over financial and operational aspects of the relationship with the CMO, and (ii) a right, but not an obligation, to obtain certain exclusive rights to internally manufacture and/or source extract from certain CMOs and the right to independently develop and make improvements to extract for use in connection with the exploitation of certain vaccine compositions (the "Option").

Pursuant to the Vaxcyte Agreement, we received from Vaxcyte a one-time, nonrefundable, non-creditable, upfront payment of \$10.0 million in cash, and 167,780 shares of Vaxcyte's common stock with a fair value of \$7.5 million at the date of the transaction in December 2022.

Additionally, pursuant to the Vaxcyte Agreement, we agreed with Vaxcyte to negotiate the terms and conditions of the Form Definitive Agreement to be entered into in the event Vaxcyte exercises the Option. In September 2023, we mutually agreed in writing with Vaxcyte upon the Form Definitive Agreement, and in October 2023, we received a \$5.0 million payment from Vaxcyte.

As of September 30, 2023, we held 667,780 shares of Vaxcyte common stock, which include the 167,780 shares received from Vaxcyte under the Vaxcyte Agreement. The estimated fair value of Vaxcyte common stock was \$34.0 million as of September 30, 2023.

#### ***Upfront Payment from Astellas***

In June 2022, we entered into a License and Collaboration Agreement with Astellas, for the development of immunostimulatory antibody-drug conjugates for up to three biological targets, to be identified by Astellas. Pursuant to the

agreement with Astellas, we received from Astellas a one-time, nonrefundable, non-creditable, upfront payment of \$90.0 million during the three months ended September 30, 2022.

#### **Contingent Payment from Merck**

In July 2022, the first patient was dosed in a Phase 1 study of an investigational candidate resulting from the 2018 Merck Agreement for the first program in our collaboration to develop novel cytokine derivative therapeutics for the treatment of cancer. As a result of this achievement, we earned and received a \$10.0 million contingent payment from Merck during the three months ended September 30, 2022.

#### **Term Loan**

For a description of our Loan and Security Agreement with Oxford Finance LLC and Silicon Valley Bank, please see Note 6 to our condensed financial statements.

#### **Leases**

In June 2021, we entered into a third amendment, or Third Amendment, to our manufacturing facility lease, dated May 18, 2011, as amended, by and between Alemany Plaza LLC, located at San Carlos, California, or San Carlos Lease, as an extension to the term of the San Carlos Lease for a period of five years, or the Lease Extension Period. Pursuant to the Third Amendment, the San Carlos Lease will expire on July 31, 2026, and it includes an option to renew the San Carlos Lease for an additional five years. The aggregate estimated base rent payments due over the Lease Extension Period is approximately \$4.2 million, subject to certain terms contained in the San Carlos Lease.

In June 2021, we entered into a first amendment, or First Amendment, to our manufacturing facility lease, dated March 4, 2015, as amended, by and between 870 Industrial Road LLC, located at San Carlos, California, or the Industrial Lease, as an extension to the term of the Industrial Lease for a period of five years, or the Industrial Lease Extension Period. Pursuant to the first Amendment, the Industrial Lease will expire on June 30, 2026, and it includes an option to renew the Industrial Lease for an additional five years. The aggregate estimated base rent payments due over the Industrial Lease Extension Period is approximately \$4.3 million, subject to certain terms contained in the Industrial Lease.

In September 2020, we entered into a sublease agreement, or the Sublease with Five Prime Therapeutics, Inc., or the Sublessor, for approximately 115,466 square feet, in a building located in South San Francisco, California, or the Premises. We use the Premises as our corporate headquarters and to conduct (or expand) research and development activities. We commenced making monthly payments for the first 85,755 square feet of the Premises, or Initial Premises, in July 2021, with occupancy of such space commencing in August 2021. We were provided early access to the Initial Premises in the fourth quarter of 2020 to conduct certain planning and tenant improvement work. The Sublease is subordinate to the lease agreement, effective December 12, 2016, between the Sublessor and HCP Oyster Point III LLC, or the Landlord. We commenced using the remaining 29,711 square feet of the Premises, or the Expansion Premises, on July 1, 2023 under the sublease agreement. The Sublease for both the Initial Premises and Expansion Premises will expire on December 31, 2027. With a commencement date on the Initial Premises of July 1, 2021, and Expansion Premises of July 1, 2023, the aggregate estimated base rent payments due over the term of the Sublease are approximately \$39.1 million, including the approximately \$5.2 million in potential financial benefit to us of base rent abatement to be provided by the Sublessor, subject to certain terms contained in the Sublease. The Sublease contains customary provisions requiring us to pay our pro rata share of utilities and a portion of the operating expenses and certain taxes, assessments and fees of the Premises and provisions allowing the Sublessor to terminate the Sublease upon the termination of the lease with the Landlord or if we fail to remedy a breach of certain of its obligations within specified time periods. Additionally, we posted a security deposit of \$0.9 million, which is reflected as restricted cash in non-current assets on our Balance Sheet as of September 30, 2023 and December 31, 2022.

#### **Funding Requirements**

Based upon our current operating plan, we believe that our existing capital resources will enable us to fund our operating expenses and capital expenditure requirements through at least the next twelve months after the date of this filing. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates into and through clinical development, to develop, acquire or in-license other potential product candidates, pay our obligations and to fund operations for the foreseeable future.

We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, marketing and distribution arrangements, royalty monetizations, or other sources of financing. Adequate additional funding may not be available to us on acceptable

terms, or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, and may cause us to delay, reduce the scope of or suspend one or more of our pre-clinical and clinical studies, research and development programs or commercialization efforts, and may necessitate us to delay, reduce or terminate planned activities in order to reduce costs. Due to the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

To the extent we raise additional capital through new collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

## Cash Flows

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

	Nine Months Ended September 30,	
	2023	2022
	(in thousands)	
Net cash (used in) provided by operating activities	\$ (125,688 )	\$ 27,413
Net cash provided by investing activities	19,589	2,860
Net cash provided by financing activities	140,679	36,092
Net increase in cash, cash equivalents and restricted cash	<u>\$ 34,580</u>	<u>\$ 66,365</u>

### Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2023 was \$125.7 million. Our net loss of \$137.9 million included non-cash charges of \$18.7 million for stock-based compensation, \$6.4 million for non-cash interest expense on our deferred royalty obligation, \$6.0 million for the accretion of discount on marketable securities, \$5.1 million for depreciation and amortization, \$2.4 million for non-cash lease expense, and \$2.0 million for the unrealized gain on equity securities as a result of the remeasurement of the estimated fair value of our investment in Vaxcyte common stock. Cash used in operating activities also reflected a net change in operating assets and liabilities of \$12.8 million, due to an increase of \$9.5 million in accounts receivable from our collaborators, a decrease of \$4.5 million in deferred revenue from revenue recognized under our collaboration agreements, a decrease of \$3.1 million in our operating lease liability, and a decrease of \$1.8 million in accrued compensation expense, which were partially offset by an increase of \$5.3 million in accounts payable, accrued expenses and other liabilities due to timing of payments, and a decrease of \$0.8 million in prepaid expenses and other assets.

Cash provided by operating activities for the nine months ended September 30, 2022 was \$27.4 million. Our net loss of \$84.6 million included non-cash charges of \$20.5 million for stock-based compensation, \$4.2 million for depreciation and amortization, \$2.0 million for non-cash lease expense, \$0.8 million for the amortization of premium on marketable securities, and \$0.3 million for the unrealized gain on equity securities as a result of the remeasurement of the estimated fair value of our investment in Vaxcyte common stock. Cash provided by operating activities also reflected a net change in operating assets and liabilities of \$84.8 million, due to an increase of \$85.2 million in deferred revenue primarily due to the upfront payment from Astellas, an increase of \$1.4 million in our operating lease liability, a decrease of \$1.2 million in accounts receivable from our collaborators, and an increase of \$1.0 million in accounts payable and other liabilities due to timing of payments, partially offset by an increase of \$2.9 million in prepaid expenses and other assets, and a decrease of \$1.0 million in accrued compensation expense.

### Cash Flows from Investing Activities

Cash provided by investing activities of \$19.6 million for the nine months ended September 30, 2023 was primarily related to maturities and sales of marketable securities of \$402.2 million, partially offset by purchases of marketable securities of \$379.7 million, and purchases of property and equipment of \$2.9 million, principally for laboratory equipment.

Cash provided by investing activities of \$2.9 million for the nine months ended September 30, 2022 was primarily related to maturities and sales of marketable securities of \$121.2 million and proceeds from sale of equity securities of \$0.6 million, partially offset by purchases of marketable securities of \$114.5 million and purchases of \$4.5 million, principally for laboratory equipment.

#### *Cash Flows from Financing Activities*

Cash provided by financing activities of \$140.7 million for the nine months ended September 30, 2023 was primarily related to \$136.2 million of net proceeds from the sale of future royalties, \$12.0 million of net proceeds from our ATM Facility sales of common stock, \$2.0 million of net proceeds received from participants in our employee equity plans, and \$0.3 million of proceeds received from the exercise of common stock options, partially offset by a debt repayment of \$9.4 million and a \$0.5 million tax payment related to the net shares settlement of vested restricted stock units.

Cash provided by financing activities of \$36.1 million for the nine months ended September 30, 2022 was primarily related to \$40.9 million of net proceeds from our ATM Facility sales of common stock, \$1.6 million of net proceeds received from participants in our employee equity plans and \$0.3 million of proceeds received from the exercise of common stock options, partially offset by debt repayment of \$6.3 million and a \$0.5 million tax payment related to the net shares settlement of vested restricted stock units.

#### **Contractual Obligations and Other Commitments**

In addition to the contractual obligations and commitments as noted above and elsewhere in this Quarterly Report on Form 10-Q with regards to the leases and term loans, we enter into agreements in the normal course of business, including with contract research organizations for clinical trials, contract manufacturing organizations for certain manufacturing services, and vendors for preclinical studies and other services and products for operating purposes, which are generally cancelable upon written notice.

#### **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated, and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and estimates discussed in our Annual Report on Form 10-K for the year ended December 31, 2022, except for the applicable accounting policies and estimates related to the deferred royalty obligation and related non-cash interest expense under the Purchase Agreement with Blackstone entered into in June 2023. We treat the sale of Vaxcyte future royalties to Blackstone as a deferred royalty obligation, as we have significant continuing involvement in the generation of the cash flows. Due to our continuing involvement, we will account for any royalties earned as non-cash revenue. As royalties are remitted to Blackstone from Vaxcyte, the balance of the deferred royalty obligation will be effectively amortized over the estimated life of the royalty term arrangement. We recorded the proceeds from this transaction as a liability on our Balance Sheets related to the sale of future royalties to be amortized to interest expense using the effective interest rate method over the estimated life of the royalty term arrangement. The liability related to the sale of future royalties and the related interest expense are based on our current estimates of future royalties expected to be earned by Blackstone from Vaxcyte over the estimated life of the royalty term arrangement. We will periodically assess the estimated royalties to be earned using forecasts from external sources. To the extent our future estimates of earned royalties are greater or less than previous estimates or the estimated timing of such payments is materially different than our previous estimates, we will prospectively recognize related non-cash interest expense.

#### **Recent Accounting Pronouncements**

See Note 2 to our financial statements included elsewhere in this report for more information.



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

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality.

We had cash, cash equivalents and marketable securities of \$321.1 million and \$302.3 million as of September 30, 2023 and December 31, 2022, respectively, which consisted primarily of money market funds, commercial paper, corporate debt securities, asset-based securities, U.S. government securities, U.S. agency securities and supranational debt securities. Such interest earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant. Additionally, we had equity securities of \$34.0 million as of September 30, 2023, consisting solely of common stock of Vaxcyte.

Equity risk is the risk we will incur economic losses due to adverse changes in equity prices. Our potential exposure to changes in equity prices results from our Vaxcyte common stock holdings. Therefore, we are subject to market risk if such holdings materially decrease in value. A hypothetical 10 percent decrease in the market price for our equity investments as of September 30, 2023 would decrease the fair value by \$3.4 million. We intend to manage equity price risk going forward by continuously evaluating market conditions.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in market interest rates would not have a material impact on our financial statements. We do not believe that our cash, cash equivalents or marketable securities have significant risk of default or illiquidity.

As of September 30, 2023 and December 31, 2022, we had \$7.1 million and \$16.3 million, respectively, in debt outstanding, net of debt discount. Until June 30, 2023, our existing debt with Oxford and SVB bore interest at a floating per annum rate equal to the greater of (i) 8.07% or (ii) the sum of (a) the greater of (1) the thirty (30) day U.S. LIBOR rate reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue or (2) 1.67%, plus (b) 6.40%. In June 2023, we entered into an amendment to the LSA with Oxford and SVB (the "5th LSA Amendment"). Under the 5th LSA Amendment, effective July 1, 2023, the loan bears interest at the floating per annum rate of interest equal to the greater of (i) 8.07% and (ii) the sum of (a) a specific published 1-month secured overnight financing rate (SOFR) reported on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 0.10%, plus (c) 6.40%. There was an immaterial impact of the 5th LSA Amendment on our financial statements. This debt matures on March 1, 2024 and was interest-only through March 1, 2022. Such interest-bearing debt carries a limited degree of interest rate risk. If overall interest rates had increased or decreased by 100 basis points during the periods presented our interest expense would not have been materially affected.

**Item 4. Controls and Procedures.****Evaluation of Disclosure Controls and Procedures**

As of September 30, 2023, management, with the participation of our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer), performed an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act 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 the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2023, our disclosure controls and procedures were effective at a reasonable assurance level.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

### Item 1A. Risk Factors

#### RISK FACTORS

*Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.*

#### Summary of Risk Factors

Our business is subject to a number of risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this summary. Some of these risks include:

- We have a limited operating history, a history of significant losses and may never achieve or maintain profitability.
- We will need substantial additional funds to advance development of our product candidates and failure to obtain sufficient funding may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations. Continued unfavorable conditions in the capital markets may pose difficulties to us in accessing additional capital on reasonable, or even any, terms to continue our product and platform development or other operations.
- Our product candidates are in early stages of development and may fail, be impacted by competitive products or suffer delays that materially and adversely affect their commercial viability. Our business is dependent on the success of our product candidates based on our proprietary XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms and, in particular, our most advanced product candidate, STRO-002, or luveltamab tazevibulin or luvelta, and our other product candidates.
- If we do not achieve our development goals in the timeframes we anticipate and project, the commercialization of our products may be delayed and, as a result, our stock price may decline.
- Our approach to the discovery and development of our therapeutic treatments is based on novel technologies that are unproven and may not result in marketable products.
- We depend on our information technology systems, and any failure of these systems, or those of our CROs, third-party vendors, or other contractors or consultants we may utilize, could harm our business. Security breaches, cyber-attacks, loss of data, and other disruptions could compromise sensitive information related to our business or other personal information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, reputation, results of operations, financial condition and prospects.
- Our information technology systems could face serious disruptions that could adversely affect our business.

- Our failure to comply with privacy and data protection laws or to adequately secure the personal information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our client base, member base and revenue.
- If our collaborations with third parties to develop and commercialize certain product candidates are not successful, we may not be able to capitalize on the market potential of our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms and the product candidates.
- We currently manufacture a portion of our product candidates internally and also rely on third-party manufacturing and supply partners to provide us with components of our product candidates and materials used for the manufacture of the product candidates. Our inability to manufacture sufficient quantities of our product candidates or such materials, or the loss of our third-party suppliers, or our or their 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.
- We face competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.
- If we are not able to obtain and enforce patent protection for our technologies or product candidates, development and commercialization of our product candidates may be adversely affected.
- Our collaborators may fail to abide by the terms of the agreements with us, which would require us to seek to enforce our agreements in accordance with the dispute resolution procedures set forth therein. These procedures may require us to engage in litigation or arbitration to enforce our rights, which can be expensive, time-consuming, and distracting to our management and Board of Directors and that may ultimately end up being unsuccessful.
- If we are unable to develop, obtain regulatory approval for or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed. Changes in regulatory policy may render our strategies for obtaining regulatory approval less effective or completely ineffective, preventing us from obtaining regulatory approval for our product candidates on time or at all.

## Risks Related to Our Business

***We are a clinical stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have a history of significant losses, expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability, which could result in a decline in the market value of our common stock.***

We are a clinical stage biopharmaceutical company with a limited operating history on which to base your investment decision. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk.

To date, we have no products approved for commercial sale, have not generated any revenue from commercial product sales and, as of September 30, 2023, had an accumulated deficit of \$590.5 million. For the nine months ended September 30, 2023, and the year ended December 31, 2022, our net loss was \$137.9 million and \$119.2 million, respectively. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. In addition, our expenses could increase beyond expectations if we are required by the FDA, or foreign regulatory agencies, to perform studies or clinical trials in addition to those studies and clinical trials that we currently anticipate conducting for our product candidates, or if there are any delays in our or our partners completing clinical trials or the development of any of our product candidates. Our technologies and product candidates are in early stages of development, and we are subject to the risks of failure inherent in the development of product candidates based on novel technologies. In addition, we have limited experience as a clinical stage company and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry. Furthermore, we do not expect to generate any revenue from commercial product sales for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies and clinical trials and the regulatory approval process for our product candidates and manufacturing clinical and early commercial supply of our product candidates. We expect our net

losses to increase substantially as we progress further into clinical development of our lead programs and create additional infrastructure to support operations as a public company. However, the amount of our future losses is uncertain. We may never generate revenues from the commercial sale of our or our collaborators' products. Our ability to achieve profitability, if ever, will depend on, among other things, our, or our existing or future collaborators', successful development of product candidates, evaluating the related commercial opportunities, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms, establishing a sales and marketing organization or suitable third-party alternatives for any approved product, and raising sufficient funds to finance business activities. If we, or our existing or future collaborators, are unable to develop our technologies and commercialize one or more of our product candidates or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve profitability, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

***We will need substantial additional funds to advance development of our product candidates. This additional financing may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations. Continued unfavorable conditions in the capital markets may pose difficulties to us in accessing additional capital on reasonable, or even any, terms to continue our product and platform development or other operations. In addition, market volatility, high levels of inflation and interest rate fluctuations may increase our cost of capital or otherwise restrict our access to potential sources of future liquidity.***

The development of biopharmaceutical product candidates is capital-intensive. If our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our development, regulatory, manufacturing, marketing and sales capabilities. We have used substantial funds to develop our technology and product candidates and will require significant funds to conduct further research and development and preclinical testing and clinical trials of our product candidates, to seek regulatory approvals for our product candidates, to manufacture extract and products, if any, which may be approved for commercial sale, to establish marketing and sales capabilities to commercialize our product candidates, and to provide support to our collaborators in the development of their products. In addition, we expect to continue to incur additional costs associated with operating as a public company.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our two proprietary clinical-stage product candidates luvelta, or STRO-002, and STRO-001, and the development of our technology platform, including our in-house manufacturing capabilities. Clinical trials for our product candidates have required substantial funds to date and will continue to require substantial funds to complete. As of September 30, 2023, we had \$321.1 million in cash, cash equivalents and marketable securities. We expect to incur substantial expenditures in the foreseeable future as we seek to advance luvelta, STRO-001, STRO-003 and STRO-004 and any future product candidates through clinical development, manufacturing, the regulatory approval process and, if approved, commercial launch activities, as well as in connection with the continued development of our technology platform and manufacturing capabilities. Based on our current operating plan, we believe that our available cash, cash equivalents and marketable securities will be sufficient to fund our operations through at least the next 12 months. However, our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect, and we may need to seek additional funds sooner than planned. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for approved products. The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of preclinical and worldwide clinical development activities;
- the costs associated with the development of our internal manufacturing and research and development facilities and processes;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we have entered or may in the future enter into collaborations and research and development agreements;
- the timing and amount of milestone and other payments we may receive under our collaboration agreements;
- our ability to maintain our current licenses and research and development programs and to establish new collaboration arrangements;

- the costs involved in prosecuting, defending and enforcing patent and other intellectual property claims;
- the costs of manufacturing our product candidates and those of our collaborators using our proprietary XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms;
- the cost and timing of regulatory approvals;
- the cost of commercialization activities if our product candidates or any future product candidates are approved for sale, including marketing, sales and distribution costs;
- our efforts to enhance operational systems and hire and retain personnel, including personnel to support development of our product candidates and satisfy our obligations as a public company; and
- general economic, industry and market conditions, including market volatility, high levels of inflation and interest rate fluctuations.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise pursue on our own. We cannot provide assurance that anticipated collaborator payments will, in fact, be received. We do not expect to realize revenue from sales of commercial products or royalties from licensed products in the foreseeable future, if at all, and, in no event, before our product candidates are clinically tested, approved for commercialization and successfully marketed. To date, we have primarily financed our operations through payments received under our collaboration and other associated agreements, the sale of equity securities, debt financing and a royalty monetization agreement. We will be required to seek additional funding in the future and currently intend to do so through additional collaborations and/or licensing agreements, public or private equity offerings or debt financings, credit or loan facilities, royalty monetization or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control, including the factors impacting potential interest rates for any debt financings. Additional funds may not be available to us on acceptable terms or at all.

In addition, macroeconomic conditions can cause turmoil in the global banking system. For example, in March 2023, Silicon Valley Bank, or SVB, one of our banking partners and lenders, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Under the terms of our Loan and Security Agreement, we were required to keep substantially all of our cash and investments with SVB, the substantial majority of which was held in a custodial account with another institution, for which SVB Asset Management was the advisor. While we were afforded full access to our cash and investments with SVB, and have since amended our Loan and Security Agreement to provide us with greater cash management flexibility, we may be impacted by other disruptions to the U.S. banking system, including potential delays in our ability to transfer funds whether held with SVB or otherwise and in short-term potential delays in making payments to vendors while new banking relationships are established.

Subject to limited exceptions, our Loan and Security Agreement with Oxford and SVB prohibits us from incurring indebtedness without the prior written consent of Oxford and SVB. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Our current debt financing involves, and future debt financings, if available, are likely to involve, restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities receive any distribution of our corporate assets. Failure to obtain capital when needed on acceptable terms may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Our product candidates are in early stages of development and may fail in development or be impacted by competitive products or suffer delays that materially and adversely affect their commercial viability. If we or our collaborators are unable to complete development of or commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.***

We have no products on the market and all of our product candidates for cancer therapy are in clinical development. Our most advanced product candidate, luvelta, is in a registration-directed Phase 2/3 trial, REFRAme. Additionally, we have sole worldwide rights to develop CC-99712, a BCMA targeting-ADC, following the termination of our collaboration with BMS, which was effective October 7, 2023. Further, Merck initiated patient dosing in a Phase 1 clinical trial for MK-1484 in July 2022, a product candidate resulting from our cytokine-derivative collaboration. In the first quarter of 2022, Vaxcyte announced that it had initiated a Phase 1/2 clinical proof-of-concept study of its lead product candidate, VAX-24, its 24-valent pneumococcal conjugate vaccine candidate, under investigation for the prevention of invasive pneumococcal disease in adults and announced clinical data in April 2023. In August 2023, the National Medical Products Administration, or NMPA, of China, approved Tasly's IND application to use luvelta in clinical trials for advanced malignant solid tumors in China.

Additionally, we have programs that 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 product candidates, either alone or with third parties, and we cannot guarantee you that we will ever obtain regulatory approval for any of our product 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 product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates.

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

- negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by patients in our clinical trials or by individuals using drugs or therapeutic biologics similar to our product candidates;
- difficulty achieving successful continued development of our internal manufacturing processes, including process development and scale-up activities to supply products for preclinical studies, clinical trials and commercial sale;
- our inability to successfully transfer our manufacturing expertise and techniques to third-party contract manufacturers;
- inability of us or any third-party contract manufacturer to scale up manufacturing of our product candidates and those of our collaborators to supply the needs of clinical trials and commercial sales, and to manufacture such products in conformity with regulatory requirements using our proprietary XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms;
- delays in submitting INDs or comparable foreign applications or delays or failures in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in enrolling patients in our clinical trials;
- high drop-out rates of our clinical trial patients;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- inability to obtain alternative sources of supply for which we have a single source for product candidate components or materials;

- occurrence of epidemics, pandemics or contagious diseases, such as the novel strain of coronavirus, and potential effects on our business, clinical trial sites, supply chain and manufacturing facilities;
- greater than anticipated costs of our clinical programs;
- harmful side effects or inability of our product candidates to meet efficacy endpoints during clinical trials, which can be unpredictable even in light of earlier non-clinical and clinical data;
- failure to demonstrate in our clinical trials a sufficient response rate or duration of response;
- failure to demonstrate a benefit-risk profile acceptable to the FDA or other regulatory agencies;
- unfavorable FDA or other regulatory agency inspection and review of one or more of our clinical trial sites or manufacturing facilities;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual 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 in particular; and
- varying interpretations of our data by the FDA and similar foreign regulatory agencies.

We or our collaborators' inability to complete development of or commercialize our product 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.

***Our business is dependent on the success of our product candidates based on our proprietary XpressCF® and XpressCF+® platforms and, in particular, our proprietary product candidates, luvelta, STRO-001, STRO-003 and STRO-004. Existing and future preclinical studies and clinical trials of our product candidates may not be successful. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.***

We have invested a significant portion of our efforts and financial resources in the development of our proprietary XpressCF® and XpressCF+® platforms and our proprietary product candidates, luvelta, STRO-001, STRO-003 and STRO-004. Our ability to generate commercial product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of luvelta, STRO-001, STRO-003 and STRO-004. We have not previously submitted a new drug application, or NDA, or a biologics license application, or BLA, to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and in selected foreign countries. While the scope of regulatory approvals generally is similar in other countries, in order to obtain separate regulatory approvals in other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of our product candidates, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions.

The success of luvelta, STRO-001, STRO-003 and STRO-004 and our other future product candidates will depend on many factors, including the following:

- successful enrollment of patients in, and the completion of, our clinical trials;
- receiving required regulatory approvals for the development and commercialization of our product candidates;



- establishing our commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- establishing successful technology transfers and collaborations to develop our product candidates with licensees, including our licensees with rights to luvelta and STRO-001 in Greater China;
- obtaining and maintaining patent, trademark and trade secret protection and non-patent exclusivity for our product candidates and their components;
- enforcing and defending our intellectual property rights and claims and avoiding or defending against intellectual property rights and claims from third parties;
- achieving desirable therapeutic properties for our product candidates' intended indications;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with third parties;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- maintaining an acceptable safety profile of our product candidates through clinical trials and following regulatory approval; and
- achieving commercially relevant success in the market post approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business, financial condition, results of operations and prospects.

Additionally, we have in the past and may in the future create benchmark molecules for comparative purposes. For example, we have created a benchmark FolR $\alpha$  targeting antibody-drug conjugate, or ADC, using conventional technology that results in a heterogeneous ADC mixture. We have compared luvelta to this benchmark molecule in multiple preclinical models. We believe the results of these tests help us understand how the therapeutic index of luvelta compares to competitors' product candidates. However, we cannot be certain that any benchmark molecule that we create is the same as the molecule we are attempting to recreate, and the results of the tests comparing any such benchmark molecule to any other potential or current product candidate may be different than the actual results of a head-to-head test of any such other potential or current product candidate against a competitor molecule. Additional preclinical and clinical testing will be needed to evaluate the therapeutic index of our potential or current product candidates, and to understand their therapeutic potential relative to other product candidates in development. While we believe our ADCs may be superior to other investigative agents in development, without head-to-head comparative data, we will not be able to make claims of superiority to other products in our promotional materials, if our product candidates are approved.

***If we do not achieve our projected development goals in the time frames we anticipate and project, the commercialization of our products may be delayed and our stock price may decline.***

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory, commercial and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

For example, even with the approval of vaccines for COVID-19, any significant resurgence of COVID-19, or the emergence of other health pandemics may further delay enrollment in trials due to prioritization of hospital resources toward the pandemic, restrictions on travel, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results. Global instability such as war or local conflicts within regions where our clinical trials are conducted could result in delays in patient dosing

schedules and may require modifications to overall trial design. For example, we intend to open a clinical trial site in Israel, which may face enrollment, operational or other difficulties due to conflicts within the region.

***Our approach to the discovery and development of our therapeutic treatments is based on novel technologies, including unprecedented Immunostimulatory Antibody Drug Conjugate, or iADC, and dual Antibody Drug Conjugates, or ADC<sup>2</sup> technology, that are unproven and may not result in marketable products.***

We are developing a pipeline of product candidates using our proprietary XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms. We believe that product candidates identified with our product discovery platform may offer an improved therapeutic approach by taking advantage of precision design and rapid empirical optimization, thereby reducing the dose-limiting toxic effects associated with existing products. However, the scientific research that forms the basis of our efforts to develop product candidates based on our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms is ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms is both preliminary and limited.

To date, we have tested our first clinical stage product candidates, luvelta and STRO-001, our former partner BMS has tested CC-99712, our partner Merck has tested MK-1484, and our former partner EMD Serono has tested M1231 in a limited number of clinical trial patients. In addition, Vaxcyte has tested its lead product candidate, VAX-24, a 24-valent pneumococcal conjugate vaccine, in a limited number of clinical trial patients. We may ultimately discover that our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms and any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness. XpressCF<sup>®</sup> product candidates may also be unable to remain stable in the human body for the period of time required for the drug to reach the target tissue or they may trigger immune responses that inhibit the ability of the product candidate to reach the target tissue or that cause adverse side effects in humans. We currently have only limited data, and no conclusive evidence, to suggest that we can introduce these necessary properties into these product candidates derived from our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms. We may spend substantial funds attempting to introduce these properties and may never succeed in doing so. In addition, product candidates based on our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. Although our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms and certain product candidates have produced successful results in animal studies, they may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. Further, in our oncology clinical trials to date, we have used achievement of stable disease as evidence for disease control (stable disease, partial response or complete response) by our product candidates; however, the FDA does not view stable disease as an objective response for the purposes of FDA approval.

We most recently presented updated data from the dose escalation portion of our STRO-001 Phase 1 trial in December 2020. As of October 30, 2020, most treatment emergent adverse events were grade 1 or 2, with the most common grade 1-2 treatment emergent adverse events, or TEAEs, of nausea, fatigue, chills, anemia, headache, dyspnea, abdominal pain, vomiting, decreased appetite and pyrexia, and no ocular or neuropathy toxicity signals have been observed. Two grade 3 and no grade 4 treatment emergent adverse events were observed, one instance each of anemia and dyspnea. Subsequent to a previously announced protocol amendment in 2019 requiring pre-treatment screening imaging for patients at risk for thromboses, no thromboembolic events have been observed. We have completed phase 1 dose escalation in the STRO-001 Phase 1 trial following identification of the maximum tolerated dose.

We presented updated data from the dose escalation portion of our luvelta Phase 1 trial for treatment of platinum-resistant ovarian cancer in May 2021. Based on data from the trial through April 23, 2021, luvelta was generally well tolerated and was mostly associated with mild adverse events. Eighty-six percent (86%) of observed adverse events were grade 1 or grade 2. The most common Grade 3 and 4 TEAEs were reversible neutropenia (64%). Grade 3 arthralgia (13%), fatigue (10%), and neuropathy (8%) were observed and managed with standard medical treatment, including dose reductions or delays.

We released preliminary final results of the dose-expansion portion of our luvelta Phase 1 trial for treatment of platinum-resistant ovarian cancer in January 2023 and updated results in June 2023. Safety signals from this portion of the trial were consistent with data from the dose-escalation cohort. Neutropenia was the leading TEAE that resulted in a treatment delay or dose reduction. Arthralgia was the second most common Grade 3+ TEAE and second most common TEAE leading to dose reduction. There were also limited observed cases of febrile neutropenia, including one Grade 5 event at the 5.2 mg/kg starting dose level and one Grade 3 event at the 4.3 mg/kg starting dose level. The trial protocol was subsequently updated to require dose reduction for Grade 4 neutropenia. We also initiated an exploratory cohort C to assess the safety of treatment with luvelta at 5.2 mg/kg in combination with prophylactic pegfilgrastim and presented preliminary data from ten patients from this cohort in January 2023.

Data from single patient IND usage of STRO-002 in a pediatric RAM phenotype of AML has also been presented by the treating physicians in December 2022. The data from this presentation indicated that STRO-002 was generally well-tolerated as a monotherapy agent and in combination with standard of care therapies.

Preliminary data from Cohort B evaluating STRO-002 in relapsed/recurrent endometrial cancer was presented in October 2023. Safety signals from this Cohort were generally consistent with those observed in the expansion cohort assessing luvelta for the treatment of ovarian cancer.

If product candidates based on our XpressCF® and XpressCF+® platforms are unable to demonstrate sufficient safety and efficacy data to obtain marketing approval, we may never succeed in developing a marketable product, we may not become profitable and the value of our common stock will decline. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied product candidates. We are not aware of any company currently developing a therapeutic using our approach to ADC, iADC or ADC<sup>2</sup> development and no regulatory authority has granted approval for such a therapeutic. We believe the FDA has limited experience with therapeutics in oncology or other disease areas developed in cell-free-based synthesis systems, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. For example, our XpressCF® ADC product candidates contain cleavable or non-cleavable linker-warhead combinations or novel warheads that may result in unforeseen events when administered in a human. We and our existing or future collaborators may never receive approval to market and commercialize any product candidate. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or an existing or future collaborator may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If the products resulting from our XpressCF® platform prove to be ineffective, unsafe or commercially unviable, our entire platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.***

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and preliminary results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. While certain relevant members of our company have significant clinical experience, we in general have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product 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 patients. In addition, results from compassionate use of our product candidates, such as luvelta to treat pediatric CFB/GLIS AML, may not be confirmed in Company-sponsored trials and/or may negatively impact the prospects for marketing approval for our product candidates. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

***Interim, top-line, or preliminary data from our clinical trials that we announce 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 have publicly disclosed, and in the future will disclose, preliminary or top-line data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. 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. Therefore, final results from the studies may differ from the top-line results initially reported, and the final results may indicate different conclusions once additional data have been evaluated. As such, top-line data should be viewed with caution until the final data are available. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive data, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the final results differ from the interim, top-line, or preliminary data, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain

approval for, and to commercialize, our product candidates may be harmed, which may negatively affect our business, financial condition, results of operations, and prospects.

Moreover, from time to time, we have publicly disclosed, and in the future may disclose, interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the outcomes may materially change as patient enrollment continues and more data become available. Adverse differences between top-line, preliminary, or interim data, on the one hand, and final data, on the other, could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses, or may interpret or weigh the importance of data differently, which could negatively affect the approvability or commercialization of the particular product candidate.

***The market may not be receptive to our product candidates based on a novel therapeutic modality, and we may not generate any future revenue from the sale or licensing of product candidates.***

Even if regulatory approval is obtained for a product candidate, we may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost, competition in the therapeutic area(s) we have received or may receive approval for, and whether it will otherwise be accepted in the market. Historically, there have been concerns regarding the safety and efficacy of ADCs, and an ADC drug was voluntarily withdrawn from the market for an extended period of time. These historical concerns may negatively impact the perception market participants have on ADCs, including our product candidates. Additionally, the product candidates that we are developing are based on our proprietary XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms, which are new technologies. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt an ADC product, or a product or treatment based on our novel cell-free production technologies, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. Market acceptance of our product candidates will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the safety and efficacy of our product candidates;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory authority;
- relative convenience and ease of administration of our product candidates;
- the willingness of patients to accept any new methods of administration;
- the success of our physician education programs;
- the availability of coverage and adequate reimbursement from government and third-party payors;
- the pricing of our products, particularly as compared to alternative treatments; and
- the availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

Because our product candidates are based on new technology, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, our estimates regarding potential market size for any indication may be materially different from what we discover to exist at the time we commence commercialization, if any, for a product, which could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if any product candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***iADC and ADC<sup>2</sup> are novel technologies, which makes it difficult to predict the time, risks and cost of development and of subsequently obtaining regulatory approval of these potential product candidates.***

Certain of our preclinical product candidates are based on our proprietary iADC and ADC<sup>2</sup> technology. Some of our future success depends on the successful development of this technology and products based on it. To our knowledge, no regulatory authority has granted approval to any person or entity, including us, to market and commercialize therapeutics using our novel and unprecedented iADC or ADC<sup>2</sup> technology. We may never receive approval to market and commercialize any potential iADC or ADC<sup>2</sup> product candidate.

If we uncover any previously unknown risks related to our iADC and ADC<sup>2</sup> technology, or if we experience unanticipated or unsolvable problems or delays in developing our iADC or ADC<sup>2</sup> product candidates, we may be unable to complete our preclinical studies and clinical trials, meet the obligations of our collaboration and license agreements or commercialize our product candidates on a timely or profitable basis. If serious adverse events or unacceptable side effects are observed in preclinical studies or clinical trials of a product candidate based on our iADC or ADC<sup>2</sup> technology, or if iADCs or ADC<sup>2</sup>s were shown to have limited efficacy, our ability to develop other product candidates based on our iADC or ADC<sup>2</sup> technology would be adversely affected.

***We have entered, and may in the future seek to enter, into collaborations with third parties for the development and commercialization of our product candidates using our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms. If we fail to enter into such collaborations, or such collaborations are not successful, we may not be able to capitalize on the market potential of our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms and resulting product candidates.***

Since 2014, we have entered into collaborations with Astellas Pharma Inc., or Astellas, Merck Sharp & Dohme LLC., a subsidiary of Merck & Co., Inc., or Merck, Celgene Corporation, or Celgene, a wholly owned subsidiary of Bristol Myers Squibb Company, or BMS, Merck KGaA, Darmstadt Germany (operating in the United States under the name “EMD Serono”, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany in the US), BioNova Pharmaceuticals Limited, or BioNova, and Tasly Biopharmaceuticals Co., Ltd, or Tasly, to develop and commercialize certain cancer and other therapeutics. Our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms have also supported a spin-out company, Vaxcyte Inc., focused on discovery and development of vaccines for the treatment and prophylaxis of infectious disease. In addition, we may in the future seek third-party collaborators for research, development and commercialization of other therapeutic technologies or product candidates. Biopharmaceutical companies are our prior and likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements. With respect to our existing collaboration agreements, and what we expect will be the case with any future collaboration agreements, we have and would expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaborators’ abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates currently pose, and will continue to pose, the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on preclinical studies or clinical trial results, changes in the collaborators’ strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

As a result of the foregoing, our current and any future collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. Moreover, if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***To date, no product developed on a cell-free manufacturing platform has received approval from the FDA, so the requirements for the manufacturing of products using our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms are uncertain.***

We have invested in our own current Good Manufacturing Practices, or cGMP, compliant manufacturing facility in San Carlos, California. In this facility, we are developing and implementing novel, proprietary cell-free production technologies to supply our planned preclinical and clinical trials. However, before we may initiate a clinical trial or commercialize any of our product candidates, we must demonstrate to the FDA that the chemistry, manufacturing and controls for our product candidates meet applicable requirements, and in the European Union, or EU, a manufacturing authorization must be obtained from the appropriate EU regulatory authorities. The FDA has allowed clinical trial use of our product candidates luvelta and STRO-001, and our former partner BMS's CC-99712 product candidate, and our former partner EMD Serono's M1231 product candidate, and our partner Merck's MK-1484 product candidate, portions of which are manufactured in our San Carlos manufacturing facility; however, because no product manufactured on a cell-free manufacturing platform has yet been approved in the United States, there is no manufacturing facility that has demonstrated the ability to comply with FDA requirements for later stage clinical development or commercialization, and, therefore, the time frame for demonstrating compliance to the FDA's satisfaction is uncertain. Delays in establishing that our manufacturing process and facility comply with cGMPs or disruptions in our manufacturing processes, implementation of novel in-house technologies or scale-up activities, may delay or disrupt our development efforts.

We expect that development of our own manufacturing facility will provide us with enhanced control of material supply for preclinical studies, clinical trials and the commercial market, enable more rapid implementation of process changes and allow for better long-term margins. However, we have limited experience as a company in establishing and operating a manufacturing facility and there exist only a small number of contract manufacturing organizations, or CMOs, with the experience necessary to manufacture our product candidates. We may have difficulty hiring experts for internal manufacturing or finding and maintaining relationships with external CMOs and, accordingly, our production capacity could be limited.

We have initiated technology transfers to enable large scale manufacture of extract and the reagents necessary to manufacture our products using our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms. These large scale technology transfers may fail or be delayed, resulting in impacts to our development timelines and the costs associated with manufacturing our development products.

***Our existing collaborations with Astellas, Merck, Vaxcyte, BioNova and Tasly are important to our business. If our collaborators cease development efforts under our existing or future collaboration agreements, fail to fulfill their contract obligations, or if any of those agreements are terminated, these collaborations may fail to lead to commercial products and we may never receive milestone payments or future royalties under these agreements.***

We have entered into collaborations with other biotechnology companies to develop or commercialize several of our product candidates, and such collaborations currently represent a significant portion of our product pipeline and discovery and preclinical programs. A substantial portion of our revenue to date has been derived from our collaboration agreements with Astellas, Merck, BMS, EMD Serono, Vaxcyte, BioNova, and Tasly, and a significant portion of our future revenue and cash resources is expected to be derived from some of these agreements, our royalty monetization agreement, or the Purchase Agreement, with an affiliate of Blackstone Life Sciences, or Blackstone, or other similar agreements into which we may enter in the future. Revenue from research and development collaborations depends upon continuation of the collaborations, payments for research and development and other services and product supply, and the achievement of milestones, contingent payments and royalties, if any, derived from future products developed from

our research. If we are unable to successfully advance the development of our product candidates, achieve milestones or earn contingent payments under our collaboration agreements or royalty monetization agreement, future revenue and cash resources will be substantially less than expected.

We are unable to predict the success of our collaborations and we may not realize the anticipated benefits of our strategic collaborations. Our collaborators have discretion in determining and directing the efforts and resources, including the ability to discontinue all efforts and resources, they apply to the development and, if approval is obtained, commercialization and marketing of the product candidates covered by such collaborations. As a result, our collaborators may elect to de-prioritize our programs, change their strategic focus or pursue alternative technologies in a manner that results in reduced, delayed or no revenue to us. For example, in March 2023, EMD Serono informed us of its decision to close the Phase 1a trial of M1231 in patients with solid tumors and not initiate a previously planned expansion study. EMD Serono stated that the decision was based on strategic portfolio considerations. In June 2023, BMS informed us of its decision to deprioritize the development of CC-99712 and end our collaboration agreement. As with EMD Serono, BMS's decision was the result of a portfolio prioritization decision. Additionally, Merck initiated patient dosing in a Phase 1 clinical trial for MK-1484, a cytokine derivative of IL-2 discovered and developed under our collaboration, in July 2022. Merck has worldwide rights to MK-1484 and sole discretion in the clinical development and commercialization for this product candidate. In December 2021, Merck did not extend the research term for another target program of the collaboration and that program reverted to us. Our collaborators may have other marketed products and product candidates under collaboration with other companies, including some of our competitors, and their corporate objectives may not be consistent with our best interests. Our collaborators may also be unsuccessful in developing or commercializing our products. If our collaborations are unsuccessful, our business, financial condition, results of operations and prospects could be adversely affected. Our collaborators may fail to live up to the terms of their agreements with us, which would require us to seek to enforce our agreements in accordance with the dispute resolution procedures set forth therein. These procedures may require us to engage in litigation or arbitration to enforce our rights, which can be expensive, time-consuming and distracting to our management and Board of Directors. Further, the type and timing of resolution of such disputes are difficult to predict; and there is the potential that we could fail to enforce our rights either in part or in whole. Lastly, even if we successfully enforce our rights under our agreements with our collaborators, there is the possibility that we could fail to recover our expectancy following the litigation or arbitration, particularly for collaborators that are not subject to the jurisdiction of U.S. courts.

In addition, any dispute or litigation proceedings we may have with our collaborators in the future could delay development programs, reduce or eliminate potential milestone or other payments, create uncertainty as to ownership of intellectual property rights, distract management from other business activities and generate substantial expense. For example, in February 2022, Tasly indicated to us that it would like to discuss and renegotiate the terms of the Tasly License Agreement; and in April 2022, we entered into an amendment to the Tasly License Agreement amending the initial payment and certain milestone payments. If we encounter similar situations with Tasly or other collaboration partners, we may fail to recognize the expected future revenue and may be unable to collaborate under the terms of the applicable arrangement.

Moreover, to the extent that any of our existing or future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these product candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may not successfully engage in strategic transactions, including any additional collaborations we seek, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expenses and present significant distractions to our management.***

From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases or sales and out- or in-licensing of product candidates or technologies that we believe will complement or augment our existing business. In particular, we will evaluate and, if strategically attractive, seek to enter into additional collaborations, including with major biotechnology or biopharmaceutical companies. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations, or the collaborator terminates the collaboration. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future strategic partners. Additionally, antitrust or other competition laws, including increased enforcement within the United States in the healthcare space, may also limit our ability to enter into collaborations with certain businesses or to fully realize the benefits of strategic transactions. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner's resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States,

the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership, without regard to the merits of the challenge, and industry and market conditions generally. Moreover, if we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets due to an inability to successfully integrate them with our existing technologies and may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

We cannot assure you that following any such collaboration, or other strategic transaction, we will achieve the expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. Also, such strategic alliance, joint venture or acquisition may be prohibited. For example, our Loan and Security Agreement, in the absence of the related lenders' prior written consent, restricts our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and would have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any additional collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

***We expect to rely on third parties to conduct certain of our preclinical studies or clinical trials. If those third parties do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development program could be delayed with potentially material and adverse effects on our business, financial condition, results of operations and prospects.***

We have relied in some cases and intend to rely in the future on third-party clinical investigators, clinical research organizations, or CROs, clinical data management organizations and consultants to assist or provide the design, conduct, supervision and monitoring of preclinical studies and clinical trials of our product candidates. Because we intend to rely on these third parties and will not have the ability to conduct all preclinical studies or clinical trials independently, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires preclinical studies to be conducted in accordance with good laboratory practices and clinical trials to be conducted in accordance with good clinical practices, including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our preclinical studies or clinical trials as a result of our reliance on third parties could have a material and adverse effect on our business, financial condition, results of operations and prospects.



***If we are unable to obtain sufficient raw and intermediate materials on a timely basis or if we experience other manufacturing or supply difficulties, our business may be adversely affected.***

The manufacture of certain of our product candidates requires the timely delivery of sufficient amounts of raw and intermediate materials. We work closely with our suppliers to ensure the continuity of supply, but cannot guarantee these efforts will always be successful. Further, while efforts are made to diversify our sources of raw and intermediate materials, in certain instances we acquire raw and intermediate materials from a sole supplier. While we believe that alternative sources of supply exist where we rely on sole supplier relationships, there can be no assurance that we will be able to quickly establish additional or replacement sources for some materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our ability to manufacture our product candidates in a timely or cost-effective manner.

***We currently manufacture a portion of our product candidates internally and also rely on third-party manufacturing and supply partners to supply components of our product candidates and materials used to manufacture our product candidates. Our inability to manufacture sufficient quantities of our product candidates, or the loss of our third-party suppliers, or our or their 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.***

Manufacturing is a vital component of our business strategy. To ensure timely and consistent product supply we currently use a hybrid product supply approach wherein certain elements of our product candidates are manufactured internally at our manufacturing facilities in San Carlos, California, and other elements are manufactured at qualified third-party CMOs. Since our own manufacturing facilities may be limited or unable to manufacture certain of our preclinical and clinical trial product materials and supplies, we rely on third-party contract manufacturers to manufacture such clinical trial product materials and supplies for our or our collaborator's needs. For example, we have entered into a manufacturing agreement with EMD Millipore Corporation to provide manufacturing services for certain linker-warhead materials used in our STRO-001 product candidate and to perform conjugation of the applicable linker-warhead with the antibody component of our luvelta, STRO-001 and STRO-003 product candidates. We have also entered into agreements with Capua Bioservices, S.p.A. and with AGC Biologics GmbH for the manufacture of certain reagents used in the manufacture of our products with our XpressCF® and XpressCF+® platforms. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements. In addition, replacement of a manufacturer may require a technology transfer to the new manufacturer, which involves technical risk that the transfer may not succeed or may be delayed, and which can incur significant costs.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. We, and 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 we or 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 our or their manufacturing facilities for the manufacture of elements of our product 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 or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty applying such skills or technology ourselves, or in transferring such 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 product 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 product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. 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 product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product 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 continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of an existing or future collaborator;
- losses resulting from an inability to utilize reserved manufacturing capacity because of delays or difficulties encountered in the supply chain;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Additionally, we and our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, unstable political environments, or epidemics, pandemics, or contagious diseases, such as the COVID-19 pandemic, or failures or delays in our manufacturing supply chain. For example, restrictions on travel imposed by governments, including China, or restrictions on person-in-plant permissions imposed by our contract manufacturers may limit the ability of our subject matter experts to visit our manufacturers and assist with technology transfers. If we or our contract manufacturers were to encounter interruptions from any of these events or other unforeseen events, our ability to provide our product candidates to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

***We, or third-party manufacturers, may be unable to successfully scale-up manufacturing of our product candidates or materials used to manufacture components of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.***

In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates, or materials used in manufacturing components of our product candidates, in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Scaling up a biologic manufacturing process is a difficult and uncertain task, and we may not be successful in transferring our production system or our third-party manufacturers may not have the necessary capabilities to complete the implementation and development process. If we are unable to adequately validate or scale-up the manufacturing process at our own manufacturing facilities or those of our current manufacturers, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates at our manufacturing facility or with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

***The manufacture of biologics is complex and we or our third-party manufacturers may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our products for patients, if approved, could be delayed or stopped.***

Our product candidates are considered to be biologics and the process of manufacturing biologics and materials used to manufacture components of our products can be complex, time-consuming, highly regulated and subject to multiple risks. We and our contract manufacturers must comply with cGMPs, regulations and guidelines for the manufacturing of biologics used in clinical trials and, if approved, marketed products. To date, we and our contract manufacturers have limited experience in the manufacturing of cGMP batches of our product candidates and materials used to manufacture components of our product candidates.

Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at our manufacturing facilities or those of our third-party manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Moreover, if the FDA determines that our manufacturing facilities or those of our third-party manufacturers are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency, timely availability of raw materials and other technical challenges. Even if we or our collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

We cannot assure you that any stability or other issues relating to the manufacture of any of our product candidates or products will not occur in the future. If we or our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products, such as epidemics, pandemics or contagious diseases, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, financial condition, results of operations and prospects.

As part of our process development efforts, we also may make changes to our manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

***We may not be successful in our efforts to use our XpressCF® and XpressCF+® platforms to expand our pipeline of product 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 XpressCF® and XpressCF+® platforms. Luvelta is our most advanced clinical stage program and STRO-001 is our next most advanced clinical stage program, and our preclinical and research programs may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product 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. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

***We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we focus our research and development efforts on certain selected product candidates. As a result, we may forgo or delay pursuit of opportunities with other product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. For example, in June 2023, we announced our Purchase Agreement with Blackstone.

***Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics for our product candidates could harm our drug development strategy and operational results.***

If companion diagnostics are developed in conjunction with clinical programs, the FDA may require regulatory approval of a companion diagnostic as a condition to approval of the product candidate. For example, as we are developing luvelta for treatment of patients having ovarian cancer with elevated FolRα expression levels, we are likely to be required to obtain FDA approval or clearance of a companion diagnostic, concurrent with approval of luvelta, to test for elevated FolRα expression. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on third parties to perform these functions. We have entered into an agreement to develop diagnostic assays suitable for use as a companion diagnostic for luvelta. Companion diagnostics are subject to regulation by the FDA and foreign regulatory authorities as medical devices and require separate regulatory approval or clearance prior to commercialization. Similarly, if we use a diagnostic test to determine which patients are most likely to benefit from STRO-001 for the treatment of multiple myeloma and NHL by designing our pivotal trial or trials of STRO-001 in that indication to require that clinical trial patients have elevated CD74 expression as a criterion for enrollment, then we will likely be required to obtain FDA approval or clearance of a companion diagnostic, concurrent with approval of STRO-001, to test for elevated CD74 expression; we may also be required to demonstrate to the FDA the predictive utility of the companion diagnostic—namely, that the diagnostic selects for patients in whom the biologic therapy will be effective or more effective compared to patients not selected for by the diagnostic.

If we or our collaborators, or any third party, are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so:

- the development of our product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our planned clinical trials;
- our product candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and
- we may not realize the full commercial potential of any product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients with the specific genetic alterations targeted by our product candidates.

In addition, although we believe genetic testing is becoming more prevalent in the diagnosis and treatment of various diseases and conditions, our product candidates may be perceived negatively compared to alternative treatments that do not require the use of companion diagnostics, either due to the additional cost of the companion diagnostic or the need to

complete additional procedures to identify genetic markers prior to administering our product candidates. If any of these events were to occur, our business would be harmed, possibly materially.

***We face competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.***

The development and commercialization of drugs and therapeutic biologics is highly competitive. Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to successfully compete. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, as well as with technologies and product candidates being developed at universities and other research institutions. Our competitors have developed, are developing or will develop product candidates and processes competitive with our product candidates and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments, including those based on novel technology platforms, that enter the market. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are trying, or may try, to develop product candidates. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical and antibody and immunoregulatory therapeutics fields. While we believe that our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms, associated intellectual property and our scientific and technical know-how give us a competitive advantage in this space, competition from many sources exists or may arise in the future. Our competitors include larger and well funded biopharmaceutical, biotechnological and therapeutics companies, including companies focused on cancer immunotherapies and ADCs, such as Abbvie Inc, ADC Therapeutics SA, Astellas Pharma Inc., AstraZeneca PLC, BMS, Daiichi Sankyo Company, Eisai, Co., Ltd., Eli Lilly & Company, Exelixis, Inc., Genentech, Inc., or Genentech, Gilead Sciences Inc., GlaxoSmithKline PLC, ImmunoGen, Inc., Johnson & Johnson, Merck Sharp & Dohme LLC, Novartis AG, Pfizer Inc., or Pfizer, Roche Holding Ltd, Sanofi S.A., Seagen, Inc., and as well as numerous small companies. Moreover, we also compete with current and future therapeutics developed at research-stage biotechnology companies, universities and other research institutions.

We are aware of several companies that are developing ADCs, cytokine derivatives, bispecific antibodies and cancer immunotherapies, including companies developing ADCs directed to the same target as Iuvelta. For example, Immunogen recently received approval for a folate receptor  $\alpha$  targeted ADC, ELAHERE<sup>™</sup>. BMS and Eisai are also collaborating on development of a similarly targeted ADC, known as MORAb-202; and we anticipate more FolRa-targeting ADCs and other potential FolRa-targeting modalities to be evaluated in the clinic in the coming years. Many of these companies are well-capitalized and, in contrast to us, have significant clinical experience, and may include our existing or future collaborators. In addition, these companies compete with us in recruiting scientific and managerial talent.

Our success will depend partially on our ability to develop and protect therapeutics that are safer and more effective than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, or less expensive than the therapeutics we develop.

If our most advanced product candidates are approved, they will compete with a range of therapeutic treatments that are either in development or currently marketed. Currently marketed oncology therapeutics include a range of biologic modalities with the top selling products by class spanning tumor targeting monoclonal antibodies, such as Johnson & Johnson's Darzalex; to ADCs, such as Genentech's Kadcyla; to immune checkpoint inhibitors, such as Merck's Keytruda; to T cell-engager immunotherapies, such as Amgen, Inc.'s Blincyto; and to CAR-T cell therapies, such as Gilead's Yescarta. In addition, numerous compounds are in clinical development for cancer treatment. The clinical development pipeline for cancer includes small molecules, antibodies, vaccines, cell therapies and immunotherapies from a variety of companies and institutions.

Many of our competitors, either alone or with strategic partners, have significantly greater financial, technical, manufacturing, marketing, sales, supply, and human resources or experience than we have. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive, or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

***Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan.***

We are highly dependent on the research and development, clinical development, manufacturing, and business development expertise of our management team, advisors and other specialized personnel. The loss of one or more members of our management team or other key employees or advisors could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel because of the highly technical nature of our product candidates and XpressCF® and XpressCF+® platform technologies and the specialized nature of the regulatory approval process. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates will be limited, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations.***

As of September 30, 2023, we had 298 full-time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in product development and began our first clinical trials for our first two product candidates in 2018 and 2019. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development, regulatory and manufacturing capabilities or contract with other organizations to provide these capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***If any of our product candidates are approved for marketing and commercialization and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to commercialize successfully any such future products.***

We currently have limited sales, marketing and distribution capabilities or experience. If any of our product candidates are approved, we will need to develop additional internal sales, marketing and distribution capabilities to commercialize such products, which would be expensive and time consuming, or enter into collaborations with third parties to perform these services. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products or decide to co-promote products with collaborators, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and there can be no assurance that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance of any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business, financial condition, results of operations and prospects could be materially and adversely affected.

***Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets, for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our

product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and do not receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be materially and adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

***Price controls imposed in foreign markets may adversely affect our future profitability.***

In some countries, particularly member states of the EU, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our therapeutic candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations and prospects could be materially and adversely affected.

***Price controls imposed in the U.S. may affect our future profitability.***

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in recent Executive Orders, several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Current and future presidential budget proposals and future legislation may contain further drug price control measures that could be enacted. Congress and current and future U.S. presidential administrations may continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing 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. If such pricing controls are enacted and are set at unsatisfactory levels, our business, financial condition, results of operations and prospects could be materially and adversely affected.

***Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.***

As we are conducting clinical trials of our product candidates, we may be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. While we currently have product liability insurance that we believe is appropriate for our stage of development, we may need to obtain higher levels prior to later stages of clinical development or marketing any of our product candidates. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

As with all companies, we are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, inappropriately share confidential and proprietary information externally, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, 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 governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

Moreover, our employees are increasingly utilizing social media tools and our website as a means of communication. Despite our efforts to monitor social media communications, there is risk that the unauthorized use of social media by our employees to communicate about our products or business, or any inadvertent disclosure of material, nonpublic information through these means, may result in violations of applicable laws and regulations, which may give rise to liability and result in harm to our business. In addition, there is also risk of inappropriate disclosure of sensitive information, which could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse impact on our business, financial condition, results of operations and prospects.

***We depend on our information technology systems, and any failure of these systems, or those of our CROs, third-party vendors, or other contractors or consultants we may utilize, could harm our business. Security breaches, cyber-attacks, loss of data, and other disruptions could compromise sensitive information related to our business or other personal information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, reputation, results of operations, financial condition and prospects.***

We collect, use and store information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, use, store and transmit large amounts of confidential information, including intellectual property, proprietary business information health information, and personal information. We have established physical, electronic and organizational measures designed to safeguard and secure our systems to prevent a data security incident (which may include, for example: data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or information technology incidents caused by threat actors, technological vulnerabilities or human error), and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result, a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, CROs, third-party vendors, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us or our CROs or other contractors or consultants we may utilize to mitigate a data security incident and security vulnerabilities could be significant, and while we have implemented security measures designed to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. We have incurred successful



phishing attempts in the past, although we believe that these attempts were detected and neutralized without any compromise to our data and prior to any significant impact to our business. We have also implemented measures to prevent such attacks, but we may still be subject to similar attacks in the future. We are also aware of publicly disclosed security breaches at certain third parties on which we rely. If such an event were to occur, whether to us or a third party on which we rely, and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Further, if we are unable to generate or maintain access to essential patient samples or data for our research and development and manufacturing activities for our programs, our business could be materially adversely affected.

Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. Such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing rules and regulations, regulations promulgated by the Federal Trade Commission and state breach notification laws. We also may be subject to European privacy laws, such as the General Data Protection Regulation, or GDPR. We would also be exposed to a risk of loss or litigation and potential liability under laws, regulations and contracts that protect the privacy and security of personal information that may result in regulatory scrutiny, fines, private right of action settlements, and other consequences. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules and possible government oversight. Our failure to comply with such laws or to adequately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our client base, member base and revenue.

***Our information technology systems could face serious disruptions that could adversely affect our business.***

Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines, and connection to the Internet, face the risk of systemic failure that could disrupt our operations. A significant disruption in the availability of our information technology and other internal infrastructure systems could cause interruptions and delays in our research and development and manufacturing work.

In addition, a significant percentage of our employees work remotely from time to time, which presents certain risks to our business. For example, remote work presents significant demands on our information technology resources and systems and can be at risk for phishing and other malicious activity, which can result in an increase to the number of points of potential exposure, such as laptops and mobile devices, that need to be secured. Any failure to effectively manage these risks, including to timely identify and appropriately respond to any security incidents, may adversely affect our business.

In our ongoing efforts to innovate and optimize operational efficiency, we have integrated artificial intelligence, or AI, into various aspects of our workplace. While AI presents opportunities for enhanced productivity and innovation, it also introduces inherent risks that could adversely impact our business. Proper use of AI can lead to improved decision-making, cost reduction, and competitive advantage. However, improper use, including algorithmic biases, ethical considerations, data privacy issues, and potential regulatory non-compliance, could result in reputational damage, legal liabilities, and financial losses. The rapidly evolving regulatory landscape surrounding AI also poses a risk, as new laws and regulations could impose additional compliance burdens, resulting in increased operational costs. We are committed to implementing robust governance and control mechanisms to mitigate these risks, but there can be no assurance that such measures will adequately prevent or mitigate the adverse effects that the integration and use of AI may have on our business, financial condition, and results of operations.

***The terms of our Loan and Security Agreement require us to meet certain covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.***

The Loan and Security Agreement is secured by a lien covering all of our assets, excluding our intellectual property. Subject to the terms of the Loan and Security Agreement, we have the option to prepay all, but not less than all, of the amounts borrowed under the Loan and Security Agreement, subject to certain penalty payments, prior to the March 1, 2024, maturity date, at which time all amounts borrowed will be due and payable.

The Loan and Security Agreement contains customary affirmative and negative covenants, indemnification provisions and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain certain intellectual property rights. The negative covenants include, among others, restrictions on transferring or licensing our assets, changing our business,

incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on our assets, in each case subject to customary exceptions. If we default under the Loan and Security Agreement, the lenders will be able to declare all obligations immediately due and payable and take control of our collateral, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. The Loan and Security Agreement previously included a covenant requiring us to keep substantially all of our cash and investments with SVB, the substantial majority of which was held in a custodial account with another institution, for which SVB Asset Management was the advisor. In March and April 2023, we amended our Loan and Security Agreement to allow us to hold cash and investments at multiple financial institutions. Further, if we are liquidated, the rights of Oxford and SVB to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Oxford, acting as collateral agent for the lenders, could declare a default under the Loan and Security Agreement upon the occurrence of any event that Oxford and SVB interpret as a material adverse change as defined under the Loan and Security Agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the collateral agent of an event of default could significantly harm our business, financial condition, results of operations and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

***If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be affected adversely.***

Our research, development and manufacturing involve the use of hazardous chemicals and materials, including radioactive materials. We maintain quantities of various flammable and toxic chemicals in our facilities in South San Francisco and San Carlos, California that are required for our research, development and manufacturing activities. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous chemicals and materials. We believe our procedures for storing, handling and disposing these materials in our South San Francisco and San Carlos facilities comply with the relevant guidelines of the two municipalities, the county of San Mateo, the state of California and the Occupational Safety and Health Administration of the U.S. Department of Labor. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, including employee and contractor training and procedures regarding safe handling and disposal, the risk of accidental or mistaken contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials or from other hazards potentially present in our workplaces, such as high voltage electricity, process steam or other hot material, liquid nitrogen or other cold material, materials stored under pressure, laboratory instruments that incorporate powerful lasers or magnets, sonic resonance, heavy machinery, and the like, this insurance may not provide adequate coverage against potential liabilities. While we maintain pollution legal liability insurance for our manufacturing facility in San Carlos, California, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials in our other locations. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

***Our current operations are in two cities in the San Francisco Bay Area, and we, or the third parties upon whom we depend, may be adversely affected by earthquakes, other natural disasters, pandemics, including any significant resurgence of the COVID-19 pandemic, or other catastrophic events and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our current operations are located in our facilities in South San Francisco and San Carlos, California. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather condition, epidemic, pandemic or contagious disease, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes, epidemics, pandemics or contagious diseases, or other natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage, epidemics, pandemics or contagious disease, or other events occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research or manufacturing facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our

disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear, and may heighten or intensify existing risk of natural disasters. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flows, financial condition or results of operations.***

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the 2017 Tax Act, enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the 2017 Tax Act may affect us, and certain aspects of the 2017 Tax Act may be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, modified certain provisions of the 2017 Tax Act. Beginning in 2022, the 2017 Tax Act eliminates the option to currently deduct research and development expenditures and requires taxpayers to capitalize and amortize U.S. based and non-U.S. based research and development expenditures over five and fifteen years, respectively, pursuant to IRC Section 174. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, and the deductibility of expenses under the 2017 Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

***Our ability to use net operating loss carryforwards to offset taxable income could be limited.***

Our net operating loss carryforwards generated in tax years ending on or prior to December 31, 2017, are only permitted to be carried forward for 20 years under applicable U.S. tax law. Under the 2017 Tax Act, as modified by the CARES Act, our federal net operating losses generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses, is limited to 80% of taxable income.

In addition, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if we experience an "ownership change" which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, our ability to use our pre-change net operating loss carryforwards to offset our post-change income may be limited. Based on Section 382 studies performed for certain prior periods, it is more likely than not that we experienced an ownership change on November 20, 2019 and December 31, 2022, which imposed limitations on the use of our net operating losses arising before that date. In addition, we may have experienced other ownership changes in the past and may also experience ownership changes in the future as a result of equity offerings or other shifts in our stock ownership, some of which are outside our control. As a result, our use of federal NOL carryforwards could be limited. State net operating loss carryforwards may be similarly limited. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Any such limitations may result in greater tax liabilities than we would incur in the absence of such limitations and any increased liabilities could adversely affect our business, results of operations, financial position and cash flows.

***Our investment in Vaxcyte is subject to risk***

As of September 30, 2023, we held Vaxcyte common stock with a fair value of \$34.0 million. Vaxcyte common stock is publicly traded and therefore subject to the various risk factors associated with any publicly traded company, including risks associated with Vaxcyte's business, its business outlook, cash flow requirements and financial performance, the state of the market and the general economic climate, including the impact of health pandemics, geopolitical conflicts, rising interest rates, and inflation. Vaxcyte common stock has been subject to substantial volatility, and the change in fair value of our interests in Vaxcyte will materially impact our reported net income or net loss in our financial statements.

***Our cash and investments could be adversely affected if the financial institutions in which we hold our cash and investments fail.***

We regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit and similar regulatory insurance limits outside the United States and governments may not guarantee all depositors if such financial institutions were to fail, as the U.S. government did with SVB depositors, in the event of further bank closures and continued instability in the global banking system. Any future adverse developments in the global banking system could directly or indirectly negatively impact our business, financial condition, results of operations and prospects. Further, if we enter into a credit, loan or other similar facility with a financial institution, certain covenants included in such facility may require as security that we keep a significant portion of our cash with the institution providing such facility. If a depository institution where we maintain deposits fails or is subject to adverse conditions in the financial or credit markets, we may not be able to recover all, if any, of our deposits, which could adversely impact our operating liquidity and financial performance.

***Our 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, or U.S. GAAP, are subject to interpretation by the Financial Accounting Standards Board, or the FASB, the American Institute of Certified Public Accountants, the SEC and various bodies formed to promulgate and interpret appropriate accounting principles. For example, in May 2014, the FASB issued accounting standards update No. 2014-09 (Topic 606), Revenue from Contracts with Customers, which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. We adopted this new accounting standard as of January 1, 2019. Any difficulties in implementing this guidance could cause us to fail to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us. Additionally, the implementation of this guidance or a change in other principles or interpretations could have a significant effect on our financial results, and could affect the reporting of transactions completed before the announcement of a change. Furthermore, we have adopted Topic 606 through the modified retrospective method. This will impact the comparability of our financial results, which might lead investors to draw incorrect conclusions that could harm investor interest in holding or purchasing our equity.

**Risks Related to Intellectual Property**

***If we are not able to obtain, maintain and enforce sufficient patent and other intellectual property protection for our technologies or product candidates, development and commercialization of our product candidates may be adversely affected.***

Our success depends in part on our, our licensor's and our collaborators' ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, methods used to manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. We, our licensors and collaborators may not be able to apply for patents on certain aspects of our product candidates in a timely fashion or at all. Further, we, our licensors and collaborators may not be able to prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we, our licensors and collaborators will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. It is also possible that we, our licensors, and our collaborators will fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently-developed invention. Such competitor's patent application may pose obstacles to our ability to obtain or limit the scope of patent protection we may obtain. We may not have the right to control the preparation, filing and prosecution of all patent applications that we license from third parties, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our licensors or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. Also, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the 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 be certain that we, our licensors or collaborators were the first to make the inventions claimed in our patents or pending patent applications, or

were the first to file for patent protection of such inventions, or if such patents rights may otherwise become invalid. Composition of matter patents for biological and pharmaceutical therapeutic candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications directed to composition of matter of our therapeutic candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our therapeutics for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, clinicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. Our existing issued and granted patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable or that any issued or granted patents will include claims that are sufficiently broad to cover our product candidates or to provide meaningful protection from our competitors. Moreover, the patent position of biotechnology and biopharmaceutical companies can be highly uncertain because it involves complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our position in the market.

The U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and biopharmaceutical patents. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. While we will endeavor to try to protect our product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and sometimes unpredictable.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, there can be no assurance that:

- others will not or may not be able to make, use or sell compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors, or our existing or future collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license;
- we or our licensors, or our existing or future collaborators are the first to file patent applications covering certain aspects of our inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- a third party may not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable and infringed;
- any issued patents that we own or have licensed will provide us with any competitive advantages, or will not be challenged by third parties;
- we may develop additional proprietary technologies that are patentable;

- the patents of others will not have a material or adverse effect on our business, financial condition, results of operations and prospects; and
- our competitors may conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

In addition, our in-licensed patents may be subject to a reservation of rights by the licensor, its affiliates and one or more third parties. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties or allow third parties to use our licensed technology. The government can also exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patent protection for certain aspects of our product candidates, we also consider trade secrets, including confidential and unpatented know-how important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Other companies or organizations may challenge our or our licensors' patent rights or may assert patent rights that prevent us from developing and commercializing our products.***

Therapeutics in oncology or other disease areas developed in cell-free-based synthesis systems are a relatively new scientific field. We have obtained grants and issuances of, and have obtained a license from a third party on an exclusive basis to, patents related to our proprietary XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms. The issued patents and pending patent applications in the United States and in key markets around the world that we own or license claim many different methods, compositions and processes relating to the discovery, development, manufacture and commercialization of antibody-based and other therapeutics.

As the field of antibody-based therapeutics continues to mature, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue and, if they do, as to when, to whom, and with what claims. In addition, third parties may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material and adverse effect on our business, financial condition, results of operations and prospects or our ability to successfully compete.

***We may not be able to protect our intellectual property rights throughout the world.***

Obtaining a valid and enforceable issued or granted patent covering our technology in the United States and worldwide can be extremely costly, and our or our licensors' or collaborators' intellectual property rights may not exist in

some countries outside the United States or may be less extensive in some countries than in the United States. In jurisdictions where we or our licensors or collaborators have not obtained patent protection, competitors may seek to use our or their technology to develop their own products and further, may export otherwise infringing products to territories where we or they have patent protection, but where it is more difficult to enforce a patent as compared to the United States. Competitor products may compete with our future products in jurisdictions where we do not have issued or granted patents or where our or our licensors' or collaborators' issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly relating to biopharmaceuticals. This could make it difficult for us or our licensors or collaborators to prevent the infringement of our or their patents or marketing of competing products in violation of our or their proprietary rights generally in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

We generally file a provisional patent application first (a priority filing) at the USPTO. An international application under the Patent Cooperation Treaty, PCT, is usually filed within twelve months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in the United States, EU, Japan, Australia and Canada and, depending on the individual case, also in any or all of, inter alia, Brazil, China, Hong Kong, India, Israel, Mexico, New Zealand, South Africa, South Korea and other jurisdictions. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted by others. It is also quite common that depending on the country, various scopes of patent protection may be granted on the same product candidate or technology.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our licensors or collaborators encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors or collaborators are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business, financial condition, results of operations and prospects may be adversely affected.

No earlier than June 1, 2023, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation.

***We, our licensors or collaborators, or any future strategic partners may need to resort to litigation to protect or enforce our patents or other proprietary rights, all of which could be costly, time consuming, delay or prevent the development and commercialization of our product candidates, or put our patents and other proprietary rights at risk.***

Competitors may infringe our patents or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products or our technology, the defendant could counterclaim that our patent is 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, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that an individual connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have a material and adverse effect on our business, financial condition, results of operations and prospects. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. 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 a material adverse effect on the price of our common stock. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights.

***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our therapeutics.***

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe existing or future third-party patents. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our therapeutic candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our therapeutics. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our therapeutics or the use of our therapeutics. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our therapeutics.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our therapeutics are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.



We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

***Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, and we, our licensors or collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.***

We, our licensors or collaborators, or any future strategic partners may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. 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, oppositions and *inter partes* review proceedings before the USPTO, and corresponding foreign patent offices. For example, one of our European patents related to technology auxiliary to our XpressCF<sup>®</sup> platform is involved in an opposition proceeding at the European Patent Office, or EPO, and was revoked by the EPO in 2021. In April 2022, an appeal was filed; the process for this appeal is ongoing. This may prevent us from asserting this patent against our competitors practicing otherwise infringing methods in relevant European countries where this patent has been granted. There are many issued and pending patents that might claim aspects of our product candidates and modifications that we may need to apply to our product candidates. There are also many issued patents that claim antibodies, portions of antibodies, cytokines, half-life extending polymers, linkers, cytotoxins, or other warheads that may be relevant for the products we wish to develop. Thus, it is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may be delayed or may not be able to market products or perform research and development or other activities covered by these patents which could have a material and adverse effect on our business, financial condition, results of operations and prospects. We are obligated under certain of our license and collaboration agreements to indemnify and hold harmless our licensors or collaborators for damages arising from intellectual property infringement by use. For example, we are obligated under the Stanford Agreement to indemnify and hold harmless Stanford for damages arising from intellectual property infringement by us resulting from exercise of the license from Stanford. If we, our licensors or collaborators, or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay damages, potentially including treble damages, if we are found to have infringed willfully. In addition, we, our licensors or collaborators, or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we or our existing or future collaborators may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation could divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

Because the antibody-based therapeutics landscape is still evolving, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. There are numerous companies that have pending patent applications and issued patents broadly covering antibodies generally, covering antibodies directed against the same targets as, or targets similar to, those we are pursuing, or covering linkers and cytotoxic warheads similar to those that we are using in our product candidates. For example, we are aware of an issued patent, expected to expire in 2031, that relates to strained alkyne reagents that can be used as synthetic precursors for certain of our linker-warheads. We are also aware of an issued patent expected to expire in 2028, relating to methods for targeting maytansinoids to a selected population of cells with a cell-binding agent conjugated to a maytansinoid with a non-cleavable linker. We are further aware of an issued patent, expected to expire in 2034, relating to certain conjugates comprising a genus of hemiasterlin derivatives that may be potentially relevant to products incorporating our hemiasterlin-derived linker-warhead. If any of these patents are valid and not yet expired when, and if, we receive marketing approval for luvelta or STRO-001, as applicable, we may need to seek a license to one or more of these patents, each of which may not be available on commercially reasonable terms or at all. Failure to receive a license to any of these patents, or other potentially relevant patents currently unknown to us, could delay commercialization of any or all of luvelta, STRO-001, STRO-003 or STRO-004. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our products or product candidates or elements thereof, or our manufacture or uses relevant to our development plans. In such cases, we may not

be in a position to develop or commercialize products or product candidates until such patents expire or unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms and related technologies and product candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms and related technologies and product candidates. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, including potentially treble damages and attorneys' fees for willful infringement, and we may be forced to abandon our product candidates or seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, U.S. applications filed before November 29, 2000, and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technologies could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products. Third-party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our products. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. 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. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and 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. Moreover, such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

***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 product candidates or we could lose certain rights to grant sublicenses.***

Our current licenses impose, and any future licenses we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement and/or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an

unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell any future products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot determine currently the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technologies and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

***We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.***

Many of our employees were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing, our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product 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.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

***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 non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and/or rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance 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. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

***Changes in U.S. patent and ex-U.S. patent laws could diminish the value of patents in general, thereby impairing our ability to protect our products.***

Changes in either the patent laws or interpretation of the patent laws in the United States or in other ex-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the United States, numerous recent changes to the patent laws and proposed changes to the rules of the USPTO that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the America Invents Act, enacted within the last several years involves significant changes in patent legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, some of which cases either narrow the scope of patent protection available in certain circumstances or weaken the rights of patent owners in certain situations. For example, the decision by the U.S. Supreme Court in *Association for Molecular Pathology v. Myriad Genetics, Inc.* precludes a claim to a nucleic acid having a stated nucleotide sequence that is identical to a sequence found in nature and unmodified. We currently are not aware of an immediate impact of this decision on our patents or patent applications because we are developing product candidates that contain modifications that we believe are not found in nature. However, this decision has yet to be clearly interpreted by courts and by the USPTO. We cannot assure you that the interpretations of this decision or subsequent rulings will not adversely impact our patents or patent applications. 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 decisions by the U.S. Congress, the federal courts and the USPTO, and similar legislative and regulatory bodies in other countries in which we may pursue patent protection, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

***We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. 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. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

## Risks Related to Government Regulation

***Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. If we are unable to develop, obtain regulatory approval for and commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed. Changes in regulatory policy may render our strategies for obtaining regulatory approval less effective or completely ineffective, preventing us from obtaining regulatory approval for our product candidates on time or at all.***

All of our product candidates are in preclinical or early clinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. 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 development process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits, 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 safety profiles, notwithstanding promising results in earlier trials.

We commenced a Phase 1 clinical trial of STRO-001, an ADC directed against CD74, for certain cancers in April 2018 and commenced a luvelta Phase 1 trial focused on ovarian and endometrial cancers in March 2019. Additionally, in the fourth quarter of 2021, we initiated a new cohort of the Phase 1 study of luvelta for endometrial cancer and an additional Phase 1 study for the treatment of ovarian cancer with luvelta in combination with bevacizumab. We expect to announce data from the study of the combination of luvelta with bevacizumab for the treatment of ovarian cancer in the second half of 2023. In addition, we announced in June 2023 the initiation of a Phase 2/3 pivotal study of luvelta for the treatment of platinum-resistant ovarian cancer. Commencing our future clinical trials is subject to finalizing the trial design and submitting an IND or similar submission with the FDA or similar foreign regulatory authority. Even after we submit our IND or comparable submissions in other jurisdictions, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional preclinical studies or amend our protocols or impose stricter conditions on the commencement of clinical trials.

We or our collaborators may experience delays in completing our preclinical studies and initiating or completing clinical trials of our product candidates. We do not know whether planned preclinical studies and clinical trials will be completed on schedule or at all, or whether planned clinical trials will begin on time, need to be redesigned, have patients enrolled on time or be completed on schedule, if at all. We or our collaborators may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval to commercialize our product candidates. Our development programs may be delayed for a variety of reasons, including delays related to:

- the FDA, EMA or other regulatory authorities requiring us or our collaborators to submit additional data or imposing other requirements before permitting us to initiate a clinical trial;
- obtaining regulatory approval to commence a clinical trial;
- the FDA or other regulatory authorities placing a clinical trial on clinical hold;
- a temporary U.S. federal government shutdown;
- 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 clinical trial sites;
- clinical trials of our product candidates producing negative or inconclusive results, and we or our collaborators deciding, or regulators requiring us, to conduct additional clinical trials, including testing in more subjects, or abandoning product development programs;
- third-party contractors used by us or our collaborators failing to comply with regulatory requirements or meeting their contractual obligations in a timely manner, or at all;
- obtaining institutional review board, or IRB, approval at each clinical trial site;

- recruiting suitable patients to participate in a clinical trial;
- developing and validating any companion diagnostic that would be used in a clinical trial;
- developing and validating an appropriate scoring algorithm to support a biomarker enrichment strategy for certain of our product candidates;
- cost of clinical trials being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites;
- epidemics, pandemics or contagious diseases, such as COVID-19;
- conflicts or civil unrest such as those currently active in Eastern Europe and the Middle East affecting the conduct of clinical studies or availability of clinical supply; or
- manufacturing sufficient quantities of our product candidates for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications being investigated by us. Furthermore, we expect to rely on our collaborators, CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we expect to enter into agreements governing their committed activities, we have limited influence over their actual performance.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

Further, a clinical trial may be suspended or terminated by us, our collaborators, the IRBs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board for such trial, or placed on clinical hold 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 drug or therapeutic biologic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates 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 revenues. Any of these occurrences could materially and adversely affect our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

***We and/or our collaborators may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates.***

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs and therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is

possible that none of the product candidates we may develop, either alone or with our collaborators, will obtain the regulatory approvals necessary for us or our existing or future collaborators to begin selling them.

Although our employees have experience in conducting and managing clinical trials from prior employment at other companies, we, as a company, have no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate, and may be further delayed due to one or more temporary federal government shutdowns. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty their application. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We or our collaborators may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any. For example, the Oncology Center of Excellence within the FDA has recently advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, may require sponsors to spend additional time and resources to further explore a product candidate's dose-response relationship to facilitate optimum dose selection in a target population. Other recent Oncology Center of Excellence initiatives have included Project FrontRunner, a new initiative with a goal of developing a framework for identifying candidate drugs for initial clinical development in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options. We are considering these policy changes as they relate to our programs. We may also be affected by ex-US regulatory requirements, given that our trials may be conducted globally; current and unforeseen new EU-specific clinical trial conduct regulations, such as IVDR and GDPR, may delay or increase the difficulty and expense of conducting our clinical studies.

Given that the product candidates we are developing, either alone or with our collaborators, represent a new approach to the manufacturing and type of therapeutic biologics, the FDA and its foreign counterparts have not yet established any definitive policies, practices or guidelines in relation to these product candidates. Moreover, the FDA may respond to any BLA that we may submit by defining requirements that we do not anticipate. Such responses could delay clinical development of our product candidates. In addition, because there may be approved treatments for some of the diseases for which we may seek approval, in order to receive regulatory approval, we may need to demonstrate through clinical trials that the product candidates we develop to treat these diseases, if any, are not only safe and effective, but safer or more effective than existing products. Furthermore, in recent years, there has been increased public and political pressure on the FDA with respect to the approval process for new drugs and therapeutic biologics, and FDA standards, especially regarding product safety, appear to have become more stringent.

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions. In addition, the FDA has the authority to require a risk evaluation and mitigation strategy, or REMS, as part of a BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved biologic, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects.



***Delays in obtaining regulatory approval of our manufacturing process may delay or disrupt our commercialization efforts. To date, no product using a cell-free manufacturing process in the United States has received approval from the FDA.***

Before we can begin to commercially manufacture our product candidates in third-party or our own facilities, we must obtain regulatory approval from the FDA for a BLA that describes in detail the chemistry, manufacturing, and controls for the product. A manufacturing authorization must also be obtained from the appropriate EU regulatory authorities. The timeframe required to obtain such approval or authorization is uncertain. In addition, we must pass a pre-approval inspection of our manufacturing facility by the FDA before any of our product candidates can obtain marketing approval, if ever. In order to obtain approval, we will need to ensure that all of our processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any products that we may develop.

***Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.***

Any regulatory approvals that we or our existing or future collaborators obtain for our product 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 Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. If we rely on third-party manufacturers, we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. If we or our existing or future collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, delay of approval or refusal by the FDA or similar foreign regulatory bodies to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

Subsequent discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

The FDA policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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, which would adversely affect our business.

We also 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.

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, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. 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 employees and stop critical activities.

The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions, and could greatly impact healthcare and the pharmaceutical industry.

Separately, in response to the COVID-19 pandemic, for a period of time, the FDA temporarily postponed most inspections of foreign manufacturing facilities along with routine surveillance inspections of domestic manufacturing facilities. The FDA has since developed a rating system to determine what categories of regulatory activity can take place in a given geographic region. As of May 2021, the FDA was either continuing, on a case-by-case basis, to conduct "mission-critical" inspections (foreign and domestic) or, where possible to do so safely, resuming prioritized domestic inspections, which generally include preapproval, pre-license, surveillance, and for-cause inspections. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to future health pandemics. 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 may face difficulties from healthcare legislative reform measures.***

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act, or together, the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry.

There have been legislative and judicial efforts to modify, repeal or otherwise invalidate all or certain aspects of the ACA, including measures taken during the former presidential administration. By way of example, the Tax Cuts and Jobs Act, or the TCJA, was enacted, effective January 1, 2019, and included, among other things, a provision repealing 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 that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future.

The 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on certain high-cost employer-sponsored insurance plans and the medical device excise tax on non-exempt medical devices, 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 increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In addition, CMS published a final rule that would give states greater marketplaces, which may have the effect of relaxing essential health benefits required under the ACA for plans sold through such marketplaces.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. U.S. federal government agencies also currently face potentially significant spending reductions, which may further impact healthcare expenditures. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A joint select committee on deficit reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute will remain in effect through 2032, unless additional Congressional action is taken. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Moreover, payment methodologies, including payment for companion diagnostics, may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. In addition, CMS has begun bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting and, beginning in 2018, CMS will pay for clinical laboratory services based on a weighted average of reported prices that private payors, Medicare Advantage plans, and Medicaid Managed Care plans pay for laboratory services. Further, on March 16, 2018, CMS finalized its National Coverage Determination, or NCD, for certain diagnostic laboratory tests using next generation sequencing that are approved by the FDA as a companion *in vitro* diagnostic and used in a cancer with an FDA-approved companion diagnostic indication. Under the NCD, diagnostic tests that gain FDA approval or clearance as an *in vitro* companion diagnostic will automatically receive full coverage and be available for patients with recurrent, metastatic relapsed, refractory or stages III and IV cancer. Additionally, the NCD extended coverage to repeat testing when the patient has a new primary diagnosis of cancer.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program

reimbursement methodologies for drug products. The FDA released a final rule in September 2020 providing guidance for states to build and submit importation plans for drugs from Canada.

Further, in November 2020, HHS 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 rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The rule also created a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of this final rule was delayed by the Biden administration until January 1, 2023 and subsequently delayed by the Inflation Reduction Act, or IRA, until January 1, 2032. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products. It is unclear to what extent these new requirements will be implemented and to what extent these regulations or any future legislation or regulations by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability.

On September 9, 2021, the Biden Administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. These initiatives recently culminated in the enactment of the IRA in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although this will only apply to high-expenditure single-source biologics that have been approved for at least 11 years (7 years for drugs). The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in October 2022 for Medicare Part D and January 2023 for Medicare Part B, the IRA also penalizes drug manufacturers that increase prices of Medicare Part D and Part B drugs at a rate greater than the rate of inflation. In addition, the law eliminates the “donut hole” under Medicare Part D beginning in 2025 by significantly lowering the enrollee maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees’ prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. At the state level, legislatures are increasingly passing legislation and implementing 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law. We may choose to seek an expanded access program for our product candidates, or to utilize comparable rules in other countries that allow the use of a drug, on a named patient basis or under a compassionate use program.

We expect that the ACA, the IRA 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. 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.

***Our operations and relationships with healthcare providers, healthcare organizations, customers and third-party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.***

Our current and future arrangements with healthcare providers, healthcare organizations, third-party payors and customers expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our product candidates. In addition, we may be subject to patient data privacy and security regulation by the U.S. federal government and the states and the foreign governments in which we conduct our business. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal and state 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 federal criminal and civil false claims and civil monetary penalties laws, including the federal False Claims Act, which can be imposed through civil whistleblower or qui tam actions against individuals or entities, prohibits, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment 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 federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA, which imposes criminal and civil liability, 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 federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain types of advanced practice nurses, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, 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;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and

- certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug and therapeutic biologics manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information, state and local laws that require 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.

If we or our collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. These enforcement actions include, among others:

- exclusion from participation in government-funded healthcare programs;
- exclusion of company products from coverage under federal health care programs; and
- exclusion from eligibility for the award of government contracts for our products.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management’s attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

***Our failure to comply with privacy and data security laws, regulations and standards may cause our business to be materially adversely affected.***

We maintain a quantity of sensitive information, including confidential business and patient health information in connection with our clinical trials, and are subject to US and international laws and regulations governing the privacy and security of such information. Each of these laws is subject to varying interpretations and constantly evolving. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. In contrast, the EU and United Kingdom (“UK”) GDPR, which applies extraterritorially, imposes several strict requirements for controllers and processors of personal information. These include higher standards for obtaining consent from individuals to process their personal information, increased requirements pertaining to the processing of special categories of personal information (such as health information) and pseudonymized (i.e., key-coded) data, and heightened transfer requirements of personal information from the European Economic Area/UK/Switzerland to countries not deemed to have adequate data protections laws (e.g., the U.S. is one such country as of January 1, 2023, although active treaty negotiations between the U.S. and the EU may change that status in 2023). The GDPR also provides that countries in the European Economic Area may establish their own laws and regulations further restricting the processing of certain personal information, including genetic data, biometric data, and health data. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million (approximately \$22.6 million) or 4 percent of the annual global revenues of the noncompliant company, whichever is greater.

In the United States, in addition to HIPAA, various federal (for example, the Federal Trade Commission) and state regulators have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international, or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, California, which continues to be a critical state with respect to evolving consumer privacy laws after enacting the California Consumer Privacy Act (the “CCPA”), later amended by ballot measure through the California Privacy Rights Act (the “CPRA”). The CPRA took effect in January 2023 and enforcement will begin

on July 1, 2023, subject to regulations promulgated through a newly created enforcement agency called the California Privacy Protection Agency (“CPPA”). Failure to comply with the CCPA and the CPRA may result in significant civil penalties, injunctive relief, or statutory or actual damages as determined by the CPPA and California Attorney General through its investigative authority. Notably, comparable consumer privacy laws are set to take effect in 2023 in other states including the Virginia Consumer Data Protection Act (effective January 1, 2023), the Colorado Privacy Act and the Connecticut Data Privacy Act (both effective July 1, 2023), and the Utah Consumer Privacy Act (effective December 31, 2023). Compliance with this new privacy legislation may result in additional costs and expense of resources to maintain compliance. There is also discussion in the U.S. of a new comprehensive federal data privacy law to which we would become subject if it is enacted.

We cannot provide assurance that (i) current or future legislation will not prevent us from generating or maintaining personal information, or (ii) that patients will consent to the use of their personal information (as necessary). Either of these circumstances may prevent us from undertaking or publishing essential research and development, manufacturing, and commercialization, which could have a material adverse effect on our business, results of operations, financial condition, and prospects.

Federal, state, and foreign government requirements include obligations of companies to notify regulators and/or individuals of security breaches or other similar reportable incidents experienced by us, or our vendors, contractors, or organizations with whom we had specific contractual obligations to protect our data. Further, the improper access to, use of, or disclosure of our data or a third-party’s personal information could subject us to individual or consumer class action litigation and governmental investigations and proceedings by federal, state, and local regulatory entities in the United States and by international regulatory entities. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules and possible government oversight.

In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. It is possible that if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, or severe criminal or civil sanctions, all of which may have a material adverse effect on our business, operating results, reputation, and financial condition. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, distract management or divert resources from other initiatives and projects, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Any failure or perceived failure by us to comply with any applicable federal, state, or similar foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties, or judgments. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition, and prospects.

***Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.***

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government authorities, private health insurers and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of coverage and reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products. If the price we are able to charge for any products we develop, or the coverage and reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be affected adversely.

There may be significant delays in obtaining reimbursement for newly approved drugs or therapeutic biologics, and coverage may be more limited than the purposes for which the drug or therapeutic biologic is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug or therapeutic biologic will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution.

Interim reimbursement levels for new drugs or therapeutic biologics, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drugs or therapeutic biologics that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs or therapeutic biologics may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs or therapeutic biologics from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval processes apart from Medicare determinations. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new drugs or therapeutic biologics that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***If in the future we are unable to establish U.S. or global sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if they are approved and we may not be able to generate any revenue.***

We currently have a limited team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. To commercialize any product candidates after approval, we must build, on a territory-by-territory basis, marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we may decide to establish an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. For example, some state and local jurisdictions have licensing and continuing education requirements for pharmaceutical sales representatives, which requires time and financial resources. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our product candidates that we obtain approval to market.

With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.***

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, an abbreviated pathway for the approval of biosimilar biological products (both highly similar and interchangeable biological products) was created. The abbreviated 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 existing reference



product. The BPCIA provides a period of exclusivity for products granted "reference product exclusivity," under which an application for a biosimilar product referencing such products cannot be approved by the FDA until 12 years after the first licensure date of the reference product licensed under a BLA. On March 6, 2015, the FDA approved the first biosimilar product under the BPCIA. FDA has accelerated licensure of biosimilar products since the first biosimilar was approved in 2015. However, FDA has yet to deem a biosimilar product interchangeable with the reference product. While FDA has implemented certain procedures intended to implement the BPCIA, other processes remain in development and may be adopted by the FDA; any such processes could have a material adverse effect on the future commercial prospects for our biological products.

A biological product submitted for licensure under a BLA is eligible for a period of exclusivity that commences on the date of its licensure, unless its date of licensure is not considered a date of first licensure because it falls within an exclusion under the BPCIA. There is a risk that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Most states have enacted substitution laws that permit substitution of only interchangeable biosimilars. The extent to which a highly similar biosimilar, once approved, will be substituted for any one of our reference products that may be approved 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.

***If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by the product candidates, our ability to market and derive revenue from the product candidates could be compromised.***

Undesirable side effects caused by our product candidates could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in more restrictive labeling or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Given the nature of ADCs, it is likely that there may be side effects associated with their use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects. 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 product candidates for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trials or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate.

In the event that any of our product candidates receive regulatory approval and we or others identify undesirable side effects caused by one of our products, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;

- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these occurrences could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***While we have been granted a Fast Track Designation by the FDA for luvelta, it may not lead to a faster development or regulatory review or approval process.***

We have been granted a Fast Track Designation for luvelta for the treatment of patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior lines of systemic therapy. As part of our business strategy, we may also seek Fast Track Designation for other of our product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, as we have for luvelta, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program, which may happen in connection with luvelta or other of our product candidates if granted Fast Track Designation.

***While we have been granted Orphan Drug Designation by the FDA for STRO-001 for the treatment of multiple myeloma and for STRO-002 for the treatment of Pediatric (CBF/GLIS) AML, if we decide to seek Orphan Drug Designation for some of our other product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for orphan drug exclusivity.***

We have been granted Orphan Drug Designation by the FDA for STRO-001 for the treatment of multiple myeloma and for luvelta for the treatment of Pediatric CBF/GLIS AML and our former collaborator BMS was granted Orphan Drug Designation by the FDA for CC-99712. As part of our business strategy, we may seek Orphan Drug Designation for our other product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and therapeutic biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug or therapeutic biologic as an orphan drug if it is a drug or therapeutic biologic intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or therapeutic biologic will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as tax advantages and user fee waivers. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Even if we obtain Orphan Drug Designation for our product candidates in specific indications, we may not be the first to obtain marketing approval of these product candidates for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs or therapeutic biologics with different principal molecular structural features can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug or therapeutic biologic with the same principal molecular structural features for the same condition if the FDA concludes that the later drug or therapeutic biologic is safer, more effective or makes a major contribution to patient care. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug or therapeutic biologic nor gives the drug or therapeutic biologic any advantage in the regulatory review or approval process. In addition, while we may seek Orphan Drug Designation for our product candidates, we may never receive such designations.

The tax reform legislation signed into law on December 22, 2017 reduced the amount of the qualified clinical research costs for a designated orphan product that a sponsor may claim as a credit from 50% to 25%. This may further limit the advantage and may impact our future business strategy of seeking the Orphan Drug Designation.

***If we decide to pursue accelerated approval for any of our product candidates, it may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.***

In the future, we may decide to pursue accelerated approval for one or more of our product candidates. Under the FDA's accelerated approval program, the FDA may approve a drug or biologic for a serious or life-threatening disease or condition that provides a meaningful advantage over available therapies based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. For drugs or biologics granted accelerated approval, post-marketing confirmatory trials are required to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence, and the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. If we were to pursue accelerated approval for a product candidate for a disease or condition, we would do so on the basis that there is no available therapy for that disease or condition or that our product candidate provides a benefit over available therapy. If standard of care were to evolve or if any of our competitors were to receive full approval on the basis of a confirmatory trial for a drug or biologic for a disease or condition for which we are seeking accelerated approval before we receive accelerated approval, the disease or condition would no longer qualify as one for which there is no available therapy, and accelerated approval of our product candidate would not occur without a showing of benefit over available therapy. Many cancer therapies rely on accelerated approval, and the treatment landscape can change quickly as the FDA converts accelerated approvals to full approvals on the basis of successful confirmatory trials. We are currently in discussions with the FDA and EMA to refine our trial design for a registration-directed trial of luvelta; however, whether any trial is sufficient to receive FDA approval under the accelerated approval pathway will depend on the design and safety and efficacy results of such trial and will only be determined by the FDA upon review of the trial design and a submitted BLA.

Moreover, the FDA may withdraw approval of any product candidate approved under the accelerated approval pathway if, for example:

- the trial or trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with such product;
- other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post-approval trial of our product candidate with due diligence; or  
we disseminate false or misleading promotional materials relating to the relevant product candidate.

In addition, the FDA may terminate the accelerated approval program or change the standards under which accelerated approvals are considered and granted in response to public pressure or other concerns regarding the accelerated approval program. Changes to or termination of the accelerated approval program could prevent or limit our ability to obtain accelerated approval of any of our clinical development programs. Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, the FDA has convened its Oncologic Drugs Advisory Committee to review what the FDA has called "dangling" or delinquent accelerated approvals, where confirmatory studies have not been completed or where results did not confirm benefit, but for which marketing approval continues in effect, and some companies have subsequently voluntarily requested

withdrawal of approval of their products. In addition, the Oncology Center of Excellence has recently announced Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post-marketing processes, with the goal to enhance the balance of access and verification of benefit for therapies available to patients with cancer and hematologic malignancies. In addition, the recent enactment of The Food and Drug Omnibus Reform Act, or FDORA, included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

### **Risks Related to Our Common Stock**

***Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.***

We expect our operating results to be subject to quarterly and annual fluctuations. Our net income or loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup> platforms, our product candidates or future development programs;
- the fair value of our holding of common stock of Vaxcyte;
- results of preclinical and clinical trials, or the addition or termination of clinical trials or funding support by us, or existing or future collaborators or licensing partners;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors;
- the impact of accounting principles and tax laws, including as a result of recent tax law changes;
- epidemics, pandemics or contagious diseases, such as COVID-19; and
- changes in general market and economic conditions.

If our quarterly and annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly and annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly and annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***Anti-takeover provisions in our 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.***

Our restated certificate of incorporation and our restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed “for cause” and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of “blank check” preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, our restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, or the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Furthermore, our amended and restated bylaws also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act (a Federal Forum Provision). While the Supreme Court of the State of Delaware has held that such provisions are facially valid under Delaware law, there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case; application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court.

These choice of 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 any of our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the specified courts could face additional litigation costs in pursuing any such claim. The specified courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find these provisions of our governance documents inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, Section 203 of the DGCL may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

***Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***The market price of our stock may be volatile, and you could lose all or part of your investment.***

The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, investors may not be able to sell their common stock at or above the purchase price. The market price for our common stock may be influenced by many factors, including the other risks described in this section and the following:

- results of preclinical studies and clinical trials of our product candidates, or those of our competitors or our existing or future collaborators;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning current or future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic uncertainty and capital markets disruptions, including rising interest rates and inflation, which have been substantially impacted by geopolitical instability due to the impact of geopolitical tensions with China and the ongoing military conflicts in Eastern Europe and the Middle East;
- any adverse impact of health pandemics, including on our clinical trials and clinical trial operations;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates and products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles or tax laws;
- terrorist acts, acts of war or periods of widespread civil unrest, including the ongoing armed conflict in Eastern Europe and the Middle East;
- natural disasters, epidemics, pandemics or contagious diseases, and other calamities;
- political instability, including the occurrence of a temporary federal government shutdown; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

***The future sale and issuance of equity or of debt securities that are convertible into equity will dilute our share capital.***

We may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock.

***A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock. For example, in April 2021, we entered into the Sales Agreement with Jefferies, pursuant to which, from time to time, we may offer and sell through Jefferies up to \$100.0 million of our common stock pursuant to one or more "at the market" offerings. Sales of our common stock under the Sales Agreement with Jefferies could be subject to business, economic or competitive uncertainties and contingencies, many of which may be beyond our control, and which could cause actual results from the sale of our common stock to differ materially from expectations. Any future sales of common stock through our "at the market" offering program will result in dilution and may have a negative impact on the price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

## General Risk Factors

### ***Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.***

Our business, financial condition or results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets, and, the global economy has continued to be impacted by increasing interest rates and inflation. Likewise, the capital and credit markets may be adversely affected by rising geopolitical tensions, such as the deteriorating relationship between the United States and China, or the ongoing conflicts in Eastern Europe and the Middle East, and the possibility of a wider European, Middle Eastern, or global conflict, and global sanctions imposed in response thereto. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

### ***If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the analysts or the content and opinions included in their reports. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, financial condition and results of operations, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

### ***The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain additional executive management and qualified board members. The additional requirements we must comply with may strain our resources and divert management's attention from other business concerns.***

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the listing requirements of The Nasdaq Global Select Market, and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly, and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Additionally, we may be subject to stockholder activism, which can be costly and time-consuming, disrupting our operations and diverting the attention of management and may lead to additional compliance costs and impact the manner in which we operate our business. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. In order to comply with these requirements, we may need to hire more employees in the future or engage outside consultants, or may have difficulty attracting and retaining sufficient employees, which would increase our costs and expenses.

As a result of no longer being an emerging growth company, we have incurred, and will continue to incur, significant additional expenses that we did not previously incur in complying with the Sarbanes-Oxley Act and rules implemented by the SEC. The cost of compliance with Section 404 of the Sarbanes-Oxley Act has required us to incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements.

We became a "smaller reporting company" as of December 31, 2022. We will continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250.0 million or (ii) our annual



revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700.0 million. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and are eligible to take advantage of certain of the reduced disclosure obligations regarding compensation disclosures in 2023. As a smaller reporting company and a “non-accelerated filer”, we still need to comply with Section 404(a) of the Sarbanes-Oxley Act, which will continue to require substantial management time and expense.

In addition, changing laws, regulations, and standards relating to corporate governance, stockholder litigation, and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, making some activities more time consuming, and increasing the likelihood and expense of litigation. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve or otherwise change over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters, higher costs necessitated by ongoing revisions to disclosure and governance practices, and increased expenses and management attention due to actual or threatened litigation. We intend to invest resources to comply with evolving laws, regulations and standards (or changing interpretations of them), and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If our efforts to comply with these laws, regulations, and standards differ from the activities intended by regulatory or governing bodies, regulatory authorities may initiate legal proceedings against us, and our business may be adversely affected. Being a public company and complying with the associated rules and regulations, and being subject to heightened likelihood of litigation, makes it more expensive for us to obtain director and officer liability insurance, the costs of which can fluctuate significantly from year-to-year due to general market conditions in obtaining such insurance, but in recent years have risen significantly, consistent with the increase in market rates. As a result, we may be required to accept reduced coverage, incur substantially higher costs to obtain coverage or may be unable to obtain coverage on economically reasonable terms, or at all. These factors could also make it more difficult for us to attract and retain qualified executives and qualified members of our board of directors, particularly to serve on our audit committee, our compensation committee, and our nominating and corporate governance committee.

As a result of disclosure of information in filings required of a public company, our business and financial condition has become more visible, which may result in threatened or actual litigation, including by competitors. If such claims are successful, our business and operating results could be adversely affected, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and operating results.

In addition, as a result of our disclosure obligations as a public company, we could face pressure to focus on short-term results, which may adversely affect our ability to achieve long-term profitability.

***We may be subject to securities litigation, which is expensive and could divert management attention.***

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

## **Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities.**

### **Unregistered Sales of Equity Securities**

None

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

None.

### **Item 4. Mine Safety Disclosures.**

Not applicable.

### **Item 5. Other Information.**

None.

**Item 6. Exhibits.**

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, below.

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Exhibit No.	Filed/Furnished Herewith
3.1	<a href="#">Amended and Restated Certificate of Incorporation</a>					X
10.1†^	<a href="#">Third Amendment to the Vaxcyte License Agreement between the Registrant and Vaxcyte, Inc.</a>					X
31.1	<a href="#">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.</a>					X
31.2	<a href="#">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.</a>					X
32.1*	<a href="#">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.</a>					X
32.2*	<a href="#">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.</a>					X
101.INS	Inline XBRL Instance Document - The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	The cover page from this Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, formatted in Inline XBRL and contained in Exhibit 101.					X

\* This certification is deemed not filed for purposes of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

† Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulations S-K.

^ Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

**SIGNATURES**

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

Date: November 13, 2023

SUTRO BIOPHARMA, INC.

By: /s/ William J. Newell  
William J. Newell  
Chief Executive Officer

Date: November 13, 2023

By: /s/ Edward C. Albini  
Edward C. Albini  
Chief Financial Officer



**SUTRO BIOPHARMA, INC.**

**RESTATED CERTIFICATE OF INCORPORATION**

Sutro Biopharma, Inc., a Delaware corporation, hereby certifies as follows:

1. The name of the corporation is Sutro Biopharma, Inc. The date of the filing of its original Certificate of Incorporation with the Secretary of State was April 21, 2003, under the name Fundamental Applied Biology, Inc.

2. The Restated Certificate of Incorporation of the corporation attached hereto as Exhibit "A", which is incorporated herein by this reference, and which restates, integrates and further amends the provisions of the Certificate of Incorporation of this corporation as previously amended and/or restated, has been duly adopted by this corporation's Board of Directors and by the stockholders in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware, with the approval of the corporation's stockholders having been given by written consent without a meeting in accordance with Section 228 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, this corporation has caused this Restated Certificate of Incorporation to be signed by its duly authorized officer and the foregoing facts stated herein are true and correct.

Dated: June 14, 2023 SUTRO BIOPHARMA, INC.

By: /s/ William J. Newell  
Name: William J. Newell  
Title: Chief Executive Officer

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**EXHIBIT “A”**

**SUTRO BIOPHARMA, INC.  
RESTATED CERTIFICATE OF INCORPORATION**

**ARTICLE I  
NAME**

The name of the corporation is Sutro Biopharma, Inc. (the “*Corporation*”).

**ARTICLE II  
AGENT FOR SERVICE OF PROCESS**

The address of the Corporation’s registered office in the State of Delaware is Corporation Trust Center, 1209 Orange Street, Wilmington, County of New Castle, Delaware 19801. The name of the registered agent of the Corporation at that address is The Corporation Trust Company.

**ARTICLE III  
PURPOSE**

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the “*General Corporation Law*”).

**ARTICLE IV  
AUTHORIZED STOCK**

**1. Total Authorized.** The total number of shares of all classes of stock that the Corporation has authority to issue is Three Hundred Ten Million (310,000,000) shares, consisting of two classes: Three Hundred Million (300,000,000) shares of Common Stock, \$0.001 par value per share (“*Common Stock*”), and Ten Million (10,000,000) shares of Preferred Stock, \$0.001 par value per share (“*Preferred Stock*”).

**2. Designation of Additional Series.**

2.1 The Board of Directors of the Corporation (the “*Board*”) is authorized, subject to any limitations prescribed by the law of the State of Delaware, to provide for the issuance of the shares of Preferred Stock in one or more series, and, by filing a Certificate of Designation pursuant to the applicable law of the State of Delaware (“*Certificate of Designation*”), to establish from time to time the number of shares to be included in each such series, to fix the designation, vesting, powers (including voting powers), preferences and relative, participating, optional or other special rights, if any, of the shares of each such series and any qualifications, limitations or restrictions thereof, and, except where otherwise provided in the applicable Certificate of Designation, to thereafter increase (but not above the total number of authorized shares of the Preferred Stock) or decrease (but not below the number of shares of such series then outstanding) the number of shares of any such series. The number of authorized shares of Preferred Stock may also be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote

of the holders of two-thirds of the voting power of all of the then-outstanding shares of capital stock of the Corporation entitled to vote thereon, without a separate vote of the holders of the Preferred Stock, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law, unless a separate vote of the holders of one or more series is required pursuant to the terms of any Certificate of Designation; provided, however, that if two-thirds of the Whole Board (as defined below) has approved such increase or decrease of the number of authorized shares of Preferred Stock, then only the affirmative vote of the holders of a majority of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, without a separate vote of the holders of the Preferred Stock (unless a separate vote of the holders of one or more series is required pursuant to the terms of any Certificate of Designation), shall be required to effect such increase or decrease. For purposes of this Restated Certificate of Incorporation (as the same may be amended and/or restated from time to time, including pursuant the terms of any Certificate of Designation designating a series of Preferred Stock, this "Certificate of Incorporation"), the term "Whole Board" shall mean the total number of authorized directors whether or not there exist any vacancies in previously authorized directorships.

2.2 Except as otherwise expressly provided in any Certificate of Designation designating any series of Preferred Stock pursuant to the foregoing provisions of this Article IV, any new series of Preferred Stock may be designated, fixed and determined as provided herein by the Board without approval of the holders of Common Stock or the holders of Preferred Stock, or any series thereof, and any such new series may have powers, preferences and rights, including, without limitation, voting powers, dividend rights, liquidation rights, redemption rights and conversion rights, senior to, junior to or *pari passu* with the rights of the Common Stock, any series of Preferred Stock or any future class or series of capital stock of the Corporation.

2.3 Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Corporation for their vote; provided, however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (including any Certificate of Designation relating to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation (including any Certificate of Designation relating to any series of Preferred Stock).

## **ARTICLE V AMENDMENT OF BYLAWS**

The Board shall have the power to adopt, amend or repeal the Bylaws of the Corporation (as the same may be amended and/or restated from time to time, the "***Bylaws***"). Any adoption, amendment or repeal of the Bylaws by the Board shall require the approval of a majority of the Whole Board. The stockholders shall also have power to adopt, amend or repeal the Bylaws; provided, however, that notwithstanding any other provision of this Certificate of Incorporation or any provision of law that might otherwise permit a lesser or no vote, but in addition to any vote of the holders of any class or series of stock of the Corporation required by applicable law or by this Certificate of Incorporation (including any Preferred Stock issued pursuant to a Certificate of

Designation), the affirmative vote of the holders of at least two-thirds of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required for the stockholders to adopt, amend or repeal any provision of the Bylaws; provided further, that, in the case of any proposed adoption, amendment or repeal of any provisions of the Bylaws that is approved by the Board and submitted to the stockholders for adoption thereby, if two-thirds of the Whole Board has approved such adoption, amendment or repeal of any provisions of the Bylaws, then only the affirmative vote of the holders of a majority of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to adopt, amend or repeal any provision of the Bylaws.

## **ARTICLE VI MATTERS RELATING TO THE BOARD OF DIRECTORS**

**1. Director Powers.** Except as otherwise provided by the General Corporation Law or this Certificate of Incorporation, the conduct of the affairs of the Corporation shall be managed by or under the direction of the Board. In addition to the powers and authority expressly conferred upon them by applicable law or by this Certificate of Incorporation or the Bylaws of the Corporation, the directors are hereby empowered to exercise all such powers and do all such acts and things as may be exercised or done by the Corporation.

**2. Number of Directors.** Subject to the special rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the total number of directors constituting the Whole Board shall be fixed from time to time exclusively by resolution adopted by a majority of the Whole Board.

**3. Classified Board.** Subject to the special rights of the holders of one or more series of Preferred Stock to elect additional directors under specified circumstances, the directors shall be divided, with respect to the time for which they severally hold office, into three classes designated as Class I, Class II and Class III, respectively (the "***Classified Board***"). The Board may assign members of the Board already in office to the Classified Board, which assignments shall become effective at the same time the Classified Board becomes effective. Directors shall be assigned to each class in accordance with a resolution or resolutions adopted by the Board. The number of directors in each class shall be divided as nearly equal as reasonably possible. At each annual meeting of stockholders, directors elected to succeed those directors of the class whose terms then expire shall be elected for a term of office expiring at the third succeeding annual meeting of stockholders after their election.

**4. Term and Removal.** Each director shall hold office until the annual meeting at which such director's term expires and until such director's successor is duly elected and qualified, or until such director's earlier death, resignation, disqualification or removal. Any director may resign at any time upon notice to the Corporation given in writing or by any electronic transmission permitted in the Bylaws. Subject to the special rights of the holders of any series of Preferred Stock, no director may be removed from the Board except for cause and only by the affirmative vote of the holders of at least two-thirds of the voting power of the then-outstanding shares of capital stock of the Corporation entitled to vote thereon, voting together as a single class. No



decrease in the authorized number of directors constituting the Whole Board shall shorten the term of any incumbent director.

**5. Board Vacancies and Newly Created Directorships.** Subject to the special rights of the holders of any series of Preferred Stock, any vacancy occurring in the Board for any cause, and any newly created directorship resulting from any increase in the authorized number of directors, shall, unless (a) the Board determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders or (b) as otherwise provided by law, be filled only by the affirmative vote of a majority of the directors then in office, even if less than a quorum, or by a sole remaining director, and shall not be filled by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for a term expiring at the annual meeting of stockholders at which the term of office of the class to which the director has been assigned expires and until such director's successor shall have been duly elected and qualified, or until such director's earlier death, resignation, disqualification or removal.

**6. Vote by Ballot.** Election of directors need not be by written ballot unless the Bylaws shall so provide.

## **ARTICLE VII DIRECTOR AND OFFICER LIABILITY**

**1. Limitation of Liability.** To the fullest extent permitted by law, neither a director of the Corporation nor an officer of the Corporation shall be personally liable for monetary damages for breach of fiduciary duty as a director or an officer, as applicable. Without limiting the effect of the preceding sentence, if the General Corporation Law is hereafter amended to authorize the further elimination or limitation of the liability of a director or an officer, then the liability of a director of the Corporation or an officer of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law, as so amended.

**2. Change in Rights.** Neither any amendment nor repeal of this Article VII, nor the adoption of any provision of this Certificate of Incorporation inconsistent with this Article VII, shall eliminate, reduce or otherwise adversely affect any limitation on the personal liability of a director of the Corporation or an officer of the Corporation existing at the time of such amendment, repeal or adoption of such an inconsistent provision.

## **ARTICLE VIII MATTERS RELATING TO STOCKHOLDERS**

**1. No Action by Written Consent of Stockholders.** Subject to the rights of any series of Preferred Stock then outstanding, no action shall be taken by the stockholders of the Corporation except at a duly called annual or special meeting of stockholders and no action shall be taken by the stockholders of the Corporation by written consent in lieu of a meeting.

**2. Special Meeting of Stockholders.** Special meetings of the stockholders of the Corporation may be called only by the Chairperson of the Board, the Chief Executive Officer, the Lead Independent Director (as defined in the Bylaws), the President, or the Board acting pursuant to a resolution adopted by a majority of the Whole Board and may not be called by any other person or persons.

**3. Advance Notice of Stockholder Nominations and Business Transacted at Special Meetings.** Advance notice of stockholder nominations for the election of directors of the Corporation and of business to be brought by stockholders before any meeting of stockholders of the Corporation shall be given in the manner provided in the Bylaws. Business transacted at special meetings of stockholders shall be limited to the purpose or purposes stated in the notice of meeting.

#### **ARTICLE IX CHOICE OF FORUM**

Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware, to the fullest extent permitted by law, shall be the sole and exclusive forum for: (a) any derivative action or proceeding brought on behalf of the Corporation; (b) any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any director, officer, stockholder, employee or agent of the Corporation to the Corporation or the Corporation's stockholders; (c) any action asserting a claim against the Corporation or any director, officer, stockholder, employee or agent of the Corporation arising pursuant to any provision of the General Corporation Law, this Certificate of Incorporation or the Bylaws or as to which the General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware; (d) any action to interpret, apply, enforce or determine the validity of this Certificate of Incorporation or the Bylaws; or (e) any action asserting a claim against the Corporation or any director, officer, stockholder, employee or agent of the Corporation governed by the internal affairs doctrine. The provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934.

Any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the Corporation shall be deemed to have notice of and to have consented to the provisions of this Article IX.

#### **ARTICLE X AMENDMENT OF CERTIFICATE OF INCORPORATION**

If any provision of this Certificate of Incorporation becomes or is declared on any ground by a court of competent jurisdiction to be illegal, unenforceable or void, portions of such provision, or such provision in its entirety, to the extent necessary, shall be severed from this Certificate of Incorporation, and the court will replace such illegal, void or unenforceable provision of this Certificate of Incorporation with a valid and enforceable provision that most accurately reflects the Corporation's intent, in order to achieve, to the maximum extent possible, the same economic, business and other purposes of the illegal, void or unenforceable provision. The balance of this Certificate of Incorporation shall be enforceable in accordance with its terms.

The Corporation reserves the right to amend or repeal any provision contained in this Certificate of Incorporation in the manner prescribed by the laws of the State of Delaware and all rights conferred upon stockholders are granted subject to this reservation; provided, however, that, notwithstanding any other provision of this Certificate of Incorporation or any provision of law that might otherwise permit a lesser vote or no vote (but subject to Section 2 of Article IV hereof), but in addition to any vote of the holders of any class or series of the stock of the Corporation

required by law or by this Certificate of Incorporation, the affirmative vote of the holders of at least two-thirds of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to amend or repeal this Article X or Article V, Article VI, Article VII or Article VIII; provided, further, that if two-thirds of the Whole Board has approved such amendment or repeal of any provisions of this Certificate of Incorporation, then only the affirmative vote of the holders of at least a majority of the voting power of all of the then-outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class (in addition to any other vote of the holders of any class or series of stock of the Corporation required by law or by this Certificate of Incorporation), shall be required to amend or repeal such provisions of this Certificate of Incorporation.



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

**THIRD AMENDMENT TO AMENDED AND RESTATED SUTROVAX AGREEMENT**

This Third Amendment (“**Amendment No. 3**”) to the Amended and Restated SutroVax Agreement, dated as of October 12, 2015, as amended on May 9, 2018 and May 29, 2018 (“**Amended and Restated Agreement**”), is made as of September 28, 2023 (“**Amendment No. 3 Effective Date**”) by and between Sutro Biopharma, Inc., having its principal place of business at 310 Utah Avenue, Suite 150, South San Francisco, CA 94080, USA (“**Sutro**”), and Vaxcyte, Inc., having its principal place of business at 825 Industrial Road, Suite 300, San Carlos, CA 94070 (“**Vaxcyte**”). Sutro and Vaxcyte are each referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

**WHEREAS**, Vaxcyte and Sutro have entered into that certain letter agreement regarding an Option on Extract Rights, dated December 19, 2022 (the “**Option Agreement**”), pursuant to which Vaxcyte purchased from Sutro an option to obtain certain exclusive rights to manufacture Extract for use in the research, development, use, sale, offering for sale, export, import, commercialization or other exploitation of Vaccine Compositions, as more fully set forth therein;

**WHEREAS**, Vaxcyte and Sutro have mutually agreed upon the Form Definitive Agreement to be entered into between the Parties in the event that Vaxcyte exercises the option in accordance with the terms of the Option Agreement (and an executed copy of such agreement is being held in escrow pending Vaxcyte’s exercise of the option in accordance with the terms of the Option Agreement);

**WHEREAS**, Vaxcyte has paid, or will pay, to Sutro the remaining five million dollars (\$5,000,000) portion of the Option Purchase Price (as defined in the Option Agreement) that is now payable in accordance with the terms of the Option Agreement as a result of the Parties mutually agreeing upon the Form Definitive Agreement; and

**WHEREAS**, the Parties wish to amend certain provisions of the Amended and Restated Agreement, including with respect to certain amendments contemplated by the Option Agreement to take effect upon the Parties’ mutual agreement on the Form Definitive Agreement.

**NOW, THEREFORE**, in consideration of the foregoing and the mutual agreements, provisions and covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Parties hereby agree as follows:

- 1.All references in the Amended and Restated Agreement to “SutroVax” are hereby replaced with “Vaxcyte.”
- 2.The following shall be inserted as Section 1.8A of the Amended and Restated Agreement:

1.8A [\*\*\*].

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3. Section 1.21 of the Amended and Restated Agreement is restated as follows:

1.21 “**Sutro Core Know-How**” means any processes, documents, materials or other Sutro Know-How owned or controlled by Sutro that relate to the manufacture or supply of Extracts (including, but not limited to, any such Sutro Know-How regarding the generation and/or use of strains from which Extract is produced).

4. Section 1.22 of the Amended and Restated Agreement is restated as follows:

1.22 “**Sutro Know-How**” means all information and materials pertaining to the Extracts or Vaccine Compositions, or the manufacture, use or, in the case of Vaccine Compositions, development thereof, as the case may be, that are owned or controlled by Sutro or (subject to Section 15.2) its Affiliates at any time during the Term, including (i) practices, protocols, methods, techniques, specifications, formulae, standard operating procedures, analytical methods, material and vendor lists, (ii) analytical, quality control and stability data, batch records, and other chemistry, manufacturing and control (CMC) data, (iii) regulatory documentation, and (iv) tangible materials and reagents; in each case as and to the extent reasonably necessary or useful for Vaxcyte to exercise the rights granted to it under this Agreement. Notwithstanding the foregoing, in no event shall Sutro Know-How include any information or materials of Sutro’s third-party collaborators or sublicensees, except for such information or materials pertaining to the Sutro Platform which Sutro has the right to provide to Vaxcyte in accordance with this Agreement.

5. Section 1.25 of the Amended and Restated Agreement is restated as follows:

1.25 [Intentionally left blank]

6. Section 1.26 of the Amended and Restated Agreement is restated as follows:

1.26 [Intentionally left blank]

7. The following sentence is added to the end of Section 1.33 of the Amended and Restated Agreement (the definition of “Valid Claim”):

References to “Sutro Patents” in this Section 1.33 shall exclude any Patents included in any [\*\*\*] IP or any Jointly-Owned IP.

8. Section 4.5 of the Amended and Restated Agreement is hereby restated in its entirety as follows:

4.5 **Grant-Back.** Subject to the terms and conditions of this Agreement, Vaxcyte hereby grants to Sutro and its Affiliates, and shall cause its Sublicensees to grant to Sutro and its Affiliates, an exclusive (including as to Vaxcyte, its Affiliates and Sublicensees), perpetual, royalty-free, worldwide license, with the right to sublicense through multiple tiers, to exploit any Vaxcyte Platform

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Improvements [\*\*\*]. For purposes of this Section 4.5, “**Vaxcyte Platform Improvements**” means [\*\*\*].

9. Section 6.2 of the Amended and Restated Agreement is hereby deleted in its entirety and replaced with the following:

6.2 Royalties shall be due under Section 6.1, on a Vaccine Composition-by-Vaccine Composition basis, until the end of the Royalty Term for such Vaccine Composition, provided that the amounts set forth in Section 6.1 shall be reduced, on a country-by-country and Vaccine Composition-by-Vaccine Composition basis, by [\*\*\*] during any portion of the Royalty Term in which there is not at least one Valid Claim of Sutro Patents covering the manufacture, use, sale, offer for sale or importation of the applicable Vaccine Composition in the country of sale.

10. Section 6.7 of the Amended and Restated Agreement is hereby deleted in its entirety and replaced with the following:

6.7 All amounts payable pursuant to Section 6.1 and 6.6 of this Agreement shall be due quarterly (i) within [\*\*\*] following the end of each Calendar Quarter in respect of Net Sales by Vaxcyte or its Affiliate, or within [\*\*\*] following Vaxcyte’s receipt of royalty payments from its Sublicensee with respect to Net Sales by such Sublicensee, and (ii) within [\*\*\*] after the end of each Calendar Quarter in respect of Net Sublicense Fees, received in such quarter. Each such payment shall be accompanied by a statement of Net Sales and Net Sublicense Fees for the applicable Calendar Quarter and the calculation of amounts payable hereunder, [\*\*\*].

11. Section 8.6(a) of the Amended and Restated Agreement is hereby restated in its entirety as follows:

The provisions of Articles 1, 6 (with respect to payments accrued prior to the effective date of termination), 8, 10, 12, 13, 14 and 15, and Section 4.5, Section 9.1(b-1), Section 9.1(b-2), Section 9.1(b-4), Section 9.1(b-5), and Section 9.1(d), shall survive termination of this Agreement for any reason; and

12. Section 9.1(b) of the Amended and Restated Agreement is hereby restated in its entirety as follows:

(b-1) **Ownership of Intellectual Property.** Notwithstanding anything to the contrary in the Existing Agreements, as between the Parties and their respective Affiliates:

(i) Vaxcyte and Sutro shall jointly own any New IP that is a method of using Extract or [\*\*\*] that relates to both the Vaccine Field and to other applications outside the Vaccine Field (such methods, including all intellectual property rights therein, the “**Jointly-Owned IP**”);

(ii) [\*\*\*] shall solely own all New IP (excluding the Jointly-Owned IP, which shall be subject to joint-ownership as provided herein) that is a

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method of using Extract or [\*\*\*] that relates solely to the [\*\*\*] (such methods, including all intellectual property rights therein, the “[\*\*\*] **Extract IP**”);

(iii) [\*\*\*] shall solely own all New IP (excluding Jointly-Owned IP, which shall be subject to joint-ownership as provided herein, and [\*\*\*] Extract IP) (the “[\*\*\*] **IP**” and any Patent claiming such [\*\*\*] IP, a “[\*\*\*] **New IP Patent**”); and

(iv) Notwithstanding anything to the contrary in this Agreement, [\*\*\*] shall solely own any and all inventions and intellectual property rights therein (and Patents and know-how with respect thereto) conceived, made, developed or otherwise invented by or on behalf of [\*\*\*], its Affiliates or sublicensees that are directed to the composition, formulation or use of a [\*\*\*] through the use of Extract or [\*\*\*]) (the “[\*\*\*] **IP**”).

(b-2) **Certain Definitions.** For purposes of this Agreement, (I) “**New IP**” means, collectively and including all intellectual property rights therein, any and all (a) [\*\*\*] and (b) other improvements to the Sutro Platform, that are, in each case of the foregoing clauses (a) and (b), developed by or on behalf of Vaxcyte, its Affiliates or Sublicensees pursuant to (A) this Agreement, (B) that certain Supply Agreement, dated May 29, 2018, as amended (the “**Supply Agreement**”), (C) that certain letter agreement [\*\*\*], dated December 19, 2022 (the “[\*\*\*] **Letter Agreement**”), (D) [\*\*\*] or (E) otherwise, in each case of the foregoing clauses (A)-(E) by and between Vaxcyte and Sutro, and (II) [\*\*\*].

(b-3) **Licensed-Back IP; Effect on Royalties.** The [\*\*\*] IP shall be (and is hereby) licensed back to Vaxcyte under Section 4.1(a), in the same manner as Sutro Patents and Sutro Know-How are licensed thereunder. Each Party’s interest in the Jointly-Owned IP shall be subject to the licenses granted under this Agreement, such that [\*\*\*] shall have the exclusive right to exploit and freely sublicense the Jointly-Owned IP [\*\*\*], and [\*\*\*] shall have the exclusive right to exploit and sublicense the Jointly-Owned IP [\*\*\*] in accordance with this Agreement, in each case, without the obligation to obtain any consent from (or account to) the other Party in respect thereof. Notwithstanding anything to the contrary herein, Sutro acknowledges and agrees that neither Sutro’s ownership of any such [\*\*\*] IP nor Sutro’s ownership interest in any Jointly-Owned IP shall cause the Royalty Term to extend [\*\*\*] (i.e., such ownership or ownership interest [\*\*\*] in respect of the references to [\*\*\*] in the definition of [\*\*\*], the definition of [\*\*\*] or in [\*\*\*]).

(b-4) **Assignment of Intellectual Property.** If and to the extent that Vaxcyte or its Affiliates or Sublicensees obtains any ownership interest in or to any [\*\*\*] IP, Vaxcyte hereby assigns, and shall cause its Affiliates to assign, to Sutro all such ownership interest in [\*\*\*] IP. In addition, if and to the extent necessary to effectuate the joint ownership between Vaxcyte and Sutro of the Jointly-Owned IP, Vaxcyte hereby assigns, and shall cause its Affiliates and Sublicensees to assign, to Sutro its and their ownership interest in and to the Jointly-Owned IP as is

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necessary to fully effectuate such joint ownership contemplated in Section 9.1(b-1)(i).

**(b-5) Patent Prosecution.**

(i) Sutro shall not file (and shall prohibit its Affiliates from filing) any Patents claiming any [\*\*\*] IP or [\*\*\*] Extract IP. Vaxcyte shall not file (and shall prohibit its Affiliates, Approved CMOs and Approved Contractors from filing) any Patents claiming [\*\*\*] IP or Jointly-Owned IP, and Vaxcyte will reasonably cooperate with Sutro in connection with any filings for such Patents.

(ii) Notwithstanding anything to the contrary herein, [\*\*\*] shall have the first right to control the prosecution of Patent applications covering Jointly-Owned IP (each, a “**Joint Patent**”); provided, that:

(I) The Parties shall reasonably cooperate and collaborate in good faith with respect to any such prosecution and strategy related thereto, and [\*\*\*] shall keep [\*\*\*] up-to-date and reasonably informed, including by providing to [\*\*\*] drafts of all Patent applications and other material submissions and communications with any applicable Governmental Authorities (including, for clarity, patent offices) reasonably in advance of any submission thereof to enable [\*\*\*] to comment thereon;

(II) [\*\*\*] shall take [\*\*\*] direction in respect of such Joint Patent (including in respect of prosecution strategy and claims) [\*\*\*]; provided, that [\*\*\*]; and

(III) With respect to matters not covered under Section 9.1(b-5)(ii)(II) [\*\*\*] shall reasonably consider incorporating [\*\*\*] comments; [\*\*\*].

(iii) [\*\*\*] shall, at the request of [\*\*\*] and to the extent permitted by applicable law, file a continuation or divisional Patent application from each such Joint Patent, which continuation or divisional has claims [\*\*\*] (each a “[\*\*\*] **Patent**”). [\*\*\*] shall prosecute each such [\*\*\*] Patent according to [\*\*\*] reasonable instructions and [\*\*\*]. Upon issuance of each such [\*\*\*] Patent, [\*\*\*] shall, and hereby does, and shall cause its Affiliates to, assign to [\*\*\*] or its Affiliates’ right, title and interest in and to each such [\*\*\*] Patent. With respect to any Joint Patent and related [\*\*\*] Patent [\*\*\*], the Parties shall coordinate and cooperate in good faith regarding, and discuss in good faith, the appropriate claim strategies for such continuations and divisionals [\*\*\*].

(iv) Notwithstanding anything to the contrary in this Agreement, if prior to the filing of any Joint Patent, [\*\*\*] notifies [\*\*\*] that it wishes to protect [\*\*\*], then the Parties shall discuss in good faith and mutually agree upon

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a reasonable approach to take in respect thereof prior to filing any such Joint Patent (subject to the escalation procedure set forth in Section 9.1(b-5)(v)). [\*\*\*].

(v) In respect of any Joint Patent, if the Party controlling prosecution determines it does not want to pursue (or does not want to continue to pursue or maintain) such Joint Patent (such Party, the “**Declining Party**”), then the other Party shall have the right to pursue (or, as applicable, continue to pursue and maintain) such Joint Patent on its own (such Party, the “**Step-In Party**”). In such event, [\*\*\*].

(vi) If, in connection with this Section 9.1(b-5), the Parties are obligated to discuss in good faith and mutually agree upon a reasonable approach to take, and representatives of the Parties are unable to mutually agree upon such a reasonable approach, either Party may [\*\*\*], ARTICLE XIV shall apply.

13. Section 9.1(c) of the Amended and Restated Agreement is hereby restated in its entirety as follows:

(c) [Intentionally left blank]

14. Section 9.1(d) of the Amended and Restated Agreement is hereby restated in its entirety as follows:

(d) Subject to ownership of the [\*\*\*] IP, Jointly-Owned IP, [\*\*\*] Extract IP and [\*\*\*] IP, it is understood and agreed that, as between the Parties, inventions (and Patent rights therein) shall be owned by [\*\*\*]. Accordingly, subject to ownership of the [\*\*\*] IP, Jointly-Owned IP, [\*\*\*] Extract IP and [\*\*\*] IP, as between the Parties, [\*\*\*].

15. Section 9.2(a) of the Amended and Restated Agreement are hereby restated in their entirety as follows:

(a) **Generally.**

(i) **Notice.** If either Party reasonably believes that any [\*\*\*] Patent (including any [\*\*\*] New IP Patent), Joint Patent, [\*\*\*] Patent or Patent covering [\*\*\*] Extract IP (“[\*\*\*] **Extract Patent**”) is being infringed by a Third Party with respect to activities within the scope of the Vaccine Field, or is subject to a declaratory judgment action arising from such activities (a “**Vaccine Field Infringement**”), such Party shall promptly notify the other Party and the Parties shall discuss in good faith how best to respond.

(ii) [\*\*\*] **Enforcement.** As between the Parties, [\*\*\*] shall have the first right but not the obligation, itself or through a designee, to enforce [\*\*\*], including (1) initiating or prosecuting an infringement or other appropriate suit or action against such Third Party, and (2) defending any declaratory

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judgment action with respect thereto (the type of action described in each of (1) and (2), an “**Enforcement Action**”).

(iii) [\*\*\*] **Enforcement.** As between the Parties, [\*\*\*] shall have the first right, but not the obligation, itself or through a designee, to enforce [\*\*\*] (i.e., (x) initiating or prosecuting an infringement or other appropriate suit or action against a Third Party, and (y) defending any declaratory judgment action with respect thereto) [\*\*\*]. As between the Parties, [\*\*\*] shall have the sole right to initiate and control any Enforcement Action [\*\*\*] with respect to any Vaccine Field Infringement.

(iv) **Secondary Enforcement.** Reasonably in advance of undertaking any Enforcement Action under Section 9.2(a) (ii) or Section 9.2(a)(iii), the Party with the first right to undertake such Enforcement Action (the “**Lead Enforcement Party**”) shall notify the other Party of its intent to take such Enforcement Action. In the event a Party does not initiate an Enforcement Action with respect to a particular Patent for which it is the Lead Enforcement Party within [\*\*\*] of a request from the other Party to do so, such other Party shall have the right, but not the obligation, itself or through a designee, to initiate and control such Enforcement Action at its discretion and expense; provided, that the Lead Enforcing Party shall cooperate and provide reasonable to the extent necessary to join the Lead Enforcing Party as a necessary or indispensable party to any such Enforcement Action (to the extent applicable).

(v) **Recoveries.** Any amounts recovered by Vaxcyte or Sutro with respect to an Enforcement Action under this Section 9.2(a) will be used first to reimburse the reasonable costs and expenses, including attorneys’ fees, incurred in bringing and maintaining the applicable Enforcement Action, then to satisfy any Third Party obligations with respect to such recovery, and any remainder by Vaxcyte or Sutro shall be allocated between the Parties as follows: (A) if Vaxcyte is the enforcing Party: [\*\*\*] shall be paid to Sutro, and the remainder shall be retained by Vaxcyte; and (B) if Sutro is the enforcing Party: [\*\*\*] shall be retained by Sutro, and [\*\*\*] shall be paid to Vaxcyte; provided, that if another patent controlled by Vaxcyte or its licensee is also being enforced with respect to the same infringing party or product, then the portion retained by Sutro under the foregoing clauses (b) shall be [\*\*\*] (and [\*\*\*] shall be paid to Vaxcyte).

16. Section 9.2(b) of the Amended and Restated Agreement is hereby restated in its entirety as follows:

(b) Other Sutro Patents. As between the Parties, Sutro shall have the sole right, but not the obligation, itself or through a designee, at its cost to enforce (i.e., (x) initiating or prosecuting an infringement or other appropriate suit or action against a Third Party, and (y) defending any declaratory judgment action with respect thereto) [\*\*\*].

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17. Section 9.2(c) of the Amended and Restated Agreement is hereby restated in its entirety as follows:

(c) **Cooperation.** If a Party brings an Enforcement Action in accordance with this Section 9.2, the other Party shall reasonably cooperate, including, if required to bring such action, joining as a named party. The Parties shall keep one another informed of the status of their respective activities regarding any Enforcement Action pursuant to this Section 9.2 or settlement thereof, and the Parties shall assist one another and cooperate in any such action at the other's reasonable request. Neither Party shall have the right to settle any Enforcement Action under this Section 9.2 in a manner that [\*\*\*].

18. Section 9.3 of the Amended and Restated Agreement is hereby restated in its entirety as follows:

9.3 **Patent Term Extensions.** Notwithstanding Section 9.1 above, but subject to the terms of the [\*\*\*] In-License with respect to [\*\*\*] Patents in-licensed thereunder, [\*\*\*] shall have the exclusive right, itself or through a designee, to seek patent term extensions and similar supplemental protections (“**Patent Term Extensions**”) as may be available with respect to [\*\*\*]; provided that [\*\*\*] shall not have the right to seek or obtain [\*\*\*].

19. Sections 15.2(a)-(b) of the Amended and Restated Agreement are hereby restated in their entirety as follows:

15.2 In the event of a Change of Control of either Party, notwithstanding Section 15.1 above:

(a) In the event of a Change of Control of Sutro, (A) [\*\*\*], and (B) [\*\*\*].

(b) In the event of a Change of Control of Vaxcyte, (A) [\*\*\*], and (B) [\*\*\*].

20. **Effect of Amendment.** Except as expressly modified herein, all terms and conditions set forth in the Amended and Restated Agreement shall remain in full force and effect.

21. **Counterparts; Electronic or Facsimile Signatures.** This Amendment No. 3 may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Amendment No. 3 may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

*[signature page follows]*

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**In Witness Whereof**, the Parties hereto have caused this Amendment No. 3 to be executed and entered into by their duly authorized representatives as of the Amendment No. 3 Effective Date.

**VAXCYTE, INC.**

By: /s/ Grant E. Pickering \_\_\_\_\_

Name: Grant E. Pickering

Title: Chief Executive Officer

Date: September 28, 2023

**SUTRO BIOPHARMA INC.**

By: /s/ William J. Newell \_\_\_\_\_

Name: William J. Newell

Title: Chief Executive Officer

Date: September 28, 2023

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

I, William J. Newell certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Sutro Biopharma, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2023

/s/ William J. Newell  
William J. Newell  
*Chief Executive Officer*  
*(Principal Executive Officer)*

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

I, Edward C. Albini, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Sutro Biopharma, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2023

/s/ Edward C. Albini  
Edward C. Albini  
*Chief Financial Officer*  
*(Principal Accounting Officer and Principal Financial Officer)*

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

I, William J. Newell, Chief Executive Officer of Sutro Biopharma, Inc. (the “Company”), do hereby 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 Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2023 (the “Report”) fully complies with the requirements of Section 13(a) or 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.

Dated: November 13, 2023

/s/ William J. Newell

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William J. Newell

*Chief Executive Officer*

*(Principal Executive Officer)*

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

I, Edward C. Albini, Chief Financial Officer of Sutro Biopharma, Inc. (the “Company”), do hereby 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 Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2023 (the “Report”) fully complies with the requirements of Section 13(a) or 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.

Dated: November 13, 2023

/s/ Edward C. Albini

Edward C. Albini

*Chief Financial Officer*

*(Principal Financial Officer and Principal Accounting Officer)*

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