

**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, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38662

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) 392-8412

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

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

As of November 4, 2021, the registrant had 46,270,347 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
(In thousands, except share and per share amounts)

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,707	\$ 206,152
Marketable securities	159,231	120,341
Investment in equity securities	39,763	41,644
Accounts receivable	12,330	5,559
Prepaid expenses and other current assets	8,698	4,486
Total current assets	250,729	378,182
Property and equipment, net	23,319	12,935
Operating lease right-of-use assets	30,129	—
Marketable securities, non-current	64,279	—
Other non-current assets	2,144	2,122
Restricted cash	872	872
Total assets	<u>\$ 371,472</u>	<u>\$ 394,111</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 11,173	\$ 5,544
Accrued compensation	8,487	8,823
Deferred revenue—current	7,804	14,603
Operating lease liability - current	1,445	—
Debt—current	6,250	—
Other current liabilities	296	627
Total current liabilities	35,455	29,597
Deferred revenue, non-current	145	6,100
Operating lease liability - non-current	32,073	—
Deferred rent	—	1,340
Debt—non-current	18,714	24,545
Other noncurrent liabilities	1,505	481
Total liabilities	87,892	62,063
Stockholders' equity:		
Preferred stock, \$0.001 par value — 10,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 0 shares issued and outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value — 300,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 46,261,060 and 45,752,116 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	46	46
Additional paid-in-capital	578,850	559,746
Accumulated other comprehensive (loss) income	(30)	129
Accumulated deficit	(295,286)	(227,873)
Total stockholders' equity	283,580	332,048
Total Liabilities and Stockholders' Equity	<u>\$ 371,472</u>	<u>\$ 394,111</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,	
	2021	2020	2021	2020
Revenues (including amounts from related parties of \$0 during both the three and nine months ended September 30, 2021, and \$0 and \$2,813 during the three and nine months ended September 30, 2020, respectively)	8,517	\$ 17,823	\$ 51,226	\$ 34,444
Operating expenses				
Research and development	26,602	19,361	74,473	54,223
General and administrative	16,589	9,079	40,241	26,435
Total operating expenses	43,191	28,440	114,714	80,658
Loss from operations	(34,674)	(10,617)	(63,488)	(46,214)
Interest income	109	295	481	1,320
Unrealized gain (loss) on equity securities	4,483	29,778	(1,881)	78,638
Interest and other expense, net	(820)	(2,317)	(2,525)	(6,328)
Net (loss) income	\$ (30,902)	\$ 17,139	\$ (67,413)	\$ 27,416
Net (loss) income per share, basic	\$ (0.67)	\$ 0.46	\$ (1.46)	\$ 0.91
Net (loss) income per share, diluted	\$ (0.67)	\$ 0.45	\$ (1.46)	\$ 0.90
Weighted-average shares used in computing basic net (loss) income per share	46,162,544	36,887,266	46,060,010	29,994,917
Weighted-average shares used in computing diluted net (loss) income per share	46,162,544	37,877,552	46,060,010	30,349,856

See accompanying notes to unaudited interim condensed financial statements.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
Net (loss) income	\$ (30,902)	\$ 17,139	\$ (67,413)	\$ 27,416
Other comprehensive (loss) income:				
Unrealized (loss) gain on available-for-sale securities	15	(161)	(159)	72
Comprehensive (loss) income	<u>\$ (30,887)</u>	<u>\$ 16,978</u>	<u>\$ (67,572)</u>	<u>\$ 27,488</u>

See accompanying notes to unaudited interim condensed financial statements.

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

	Preferred Stock		Common Stock		Additional Paid-In- Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at December 31, 2020	—	\$ —	45,752,116	\$ 46	\$ 559,746	\$ 129	\$ (227,873)	\$ 332,048
Exercise of common stock options	—	—	129,161	—	1,360	—	—	1,360
Issuance of common stock under Employee Stock Purchase Plan	—	—	93,346	—	873	—	—	873
Vesting of restricted stock units	—	—	147,349	—	—	—	—	—
Stock transaction associated with taxes withheld on restricted stock units	—	—	(18,366)	—	(407)	—	—	(407)
Stock-based compensation expense	—	—	—	—	3,952	—	—	3,952
Net unrealized loss on available-for-sale securities	—	—	—	—	—	(129)	—	(129)
Net loss	—	—	—	—	—	—	(30,359)	(30,359)
Balances at March 31, 2021	—	\$ —	46,103,606	\$ 46	\$ 565,524	\$ —	\$ (258,232)	\$ 307,338
Exercise of common stock options	—	—	40,902	—	452	—	—	452
Return and retirement of common stocks	—	—	(6,804)	—	—	—	—	—
Vesting of restricted stock units	—	—	3,750	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	5,907	—	—	5,907
Net unrealized loss on available-for-sale securities	—	—	—	—	—	(45)	—	(45)
Net loss	—	—	—	—	—	—	(6,152)	(6,152)
Balances at June 30, 2021	—	\$ —	46,141,454	\$ 46	\$ 571,883	\$ (45)	\$ (264,384)	\$ 307,500
Exercise of common stock options	—	—	15,911	—	160	—	—	160
Issuance of common stock under Employee Stock Purchase Plan	—	—	52,463	—	892	—	—	892
Vesting of restricted stock units	—	—	81,375	—	—	—	—	—
Stock transaction associated with taxes withheld on restricted stock units	—	—	(30,143)	—	(580)	—	—	(580)
Stock-based compensation expense	—	—	—	—	6,495	—	—	6,495
Net unrealized gain on available-for-sale securities	—	—	—	—	—	15	—	15
Net loss	—	—	—	—	—	—	(30,902)	(30,902)
Balances at September 30, 2021	—	\$ —	46,261,060	\$ 46	\$ 578,850	\$ (30)	\$ (295,286)	\$ 283,580

	Preferred Stock		Common Stock		Additional Paid-In- Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at December 31, 2019	—	\$ —	23,098,969	\$ 23	\$ 293,346	\$ 165	\$ (195,745)	\$ 97,789
Exercise of common stock options	—	—	12,937	—	56	—	—	56
Issuance of common stock under Employee Stock Purchase Plan	—	—	74,465	—	646	—	—	646
Vesting of restricted stock units	—	—	41,050	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,707	—	—	2,707
Issuance of common stock warrants in connection with debt refinancing	—	—	—	—	619	—	—	619
Net unrealized loss on available-for-sale securities	—	—	—	—	—	(137)	—	(137)
Net loss	—	—	—	—	—	—	(19,595)	(19,595)
Balances at March 31, 2020	—	\$ —	23,227,421	\$ 23	\$ 297,374	\$ 28	\$ (215,340)	\$ 82,085
Exercise of common stock options	—	—	1,257	—	8	—	—	8
Vesting of restricted stock units	—	—	250	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	3,011	—	—	3,011
Issuance of common stock in connection with public offering, net of issuance costs of \$ 6,626	—	—	12,650,000	13	91,398	—	—	91,411
Net unrealized gain on available-for-sale securities	—	—	—	—	—	370	—	370
Net income	—	—	—	—	—	—	29,872	29,872
Balances at June 30, 2020	—	\$ —	35,878,928	\$ 36	\$ 391,791	\$ 398	\$ (185,468)	\$ 206,757
Exercise of common stock options	—	—	12,308	—	108	—	—	108
Issuance of common stock under Employee Stock Purchase Plan	—	—	12,527	—	639	—	—	639
Vesting of restricted stock units	—	—	110,676	—	—	—	—	—
Stock transaction associated with taxes withheld on restricted stock units	—	—	(30,461)	—	(314)	—	—	(314)
Stock-based compensation expense	—	—	—	—	3,112	—	—	3,112
Issuance of common stock in connection with At-The-Market sale, net of issuance costs of \$ 561	—	—	2,000,000	2	16,837	—	—	16,839
Net unrealized loss on available-for-sale securities	—	—	—	—	—	(161)	—	(161)
Net income	—	—	—	—	—	—	17,139	17,139
Balances at September 30, 2020	—	\$ —	37,983,978	\$ 38	\$ 412,173	\$ 237	\$ (168,329)	\$ 244,119

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,	
	2021	2020
Operating activities		
Net (loss) income	\$ (67,413)	\$ 27,416
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	3,529	3,125
Amortization of premium on marketable securities	1,982	293
Stock-based compensation	16,354	8,830
Noncash lease expenses	3,841	—
Unrealized loss (gain) on equity securities	1,881	(78,638)
Remeasurement of liability awards	73	3,165
Other	406	558
Changes in operating assets and liabilities:		
Accounts receivable	(6,771)	(1,185)
Prepaid expenses and other assets	(4,534)	823
Accounts payable	4,484	(716)
Accrued compensation	(336)	(127)
Other liabilities	629	(747)
Deferred rent	—	(129)
Deferred revenue	(12,754)	(11,591)
Change in operating lease liability	(1,470)	—
Net cash used in operating activities	(60,099)	(48,923)
Investing activities		
Purchases of marketable securities	(226,109)	(113,999)
Maturities of marketable securities	106,750	82,300
Sales of marketable securities	14,049	22,000
Purchases of equipment and leasehold improvements	(12,786)	(5,504)
Net cash used in investing activities	(118,096)	(15,203)
Financing activities		
Proceeds from public offering	—	115,438
Payment of issuance costs	—	(7,188)
Proceeds from debt refinancing	—	25,000
Payment of debt	—	(10,000)
Proceeds from exercise of common stock options	1,972	172
Taxes paid related to net shares settlement of restricted stock units	(987)	(314)
Proceeds from employee stock purchase plan	1,765	1,285
Net cash provided by financing activities	2,750	124,393
Net (decrease) increase in cash, cash equivalents and restricted cash	(175,445)	60,267
Cash, cash equivalents and restricted cash at beginning of period	207,024	4,975
Cash, cash equivalents and restricted cash at end of period	\$ 31,579	\$ 65,242
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 1,536	\$ 1,165
Supplemental disclosure of non-cash investing and financing information:		
Purchases of equipment included in accounts payable	\$ 2,165	\$ 11
Embedded interest associated with program fees	\$ 561	\$ 1,544
Warrants issued to lenders	\$ —	\$ 619
Remeasurement of operating lease right-of-use assets for lease modification	\$ 4,227	\$ —

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 drug discovery, development and manufacturing company focused on leveraging its integrated cell-free protein synthesis and site-specific conjugation platform, XpressCF®, to create a broad variety of optimally designed, next-generation protein therapeutics, initially for cancer and autoimmune disorders. 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.

Liquidity

The Company has incurred significant losses and has negative cash flows from operations. As of September 30, 2021, the Company had an accumulated deficit of \$295.3 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, 2021, the Company had unrestricted cash, cash equivalents and marketable securities of \$ 254.2 million, which is 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 and marketable securities as of September 30, 2021 will enable the Company to maintain its operations for a period of at least 12 months following the filing date of its 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 of the information and footnotes required by U.S. GAAP for complete financial statements. The December 31, 2020 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 in 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 and certain accrued liabilities. Actual results could differ from such estimates or assumptions.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including revenue, expenses, manufacturing, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as the economic impact on local, regional, national and international customers, suppliers, service providers and markets. The Company has made estimates of the impact of COVID-19 within its financial statements and there may be changes to those estimates in future periods. 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, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021, 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, 2020.

Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Updates ("ASU") 2016-13 (Topic 326), Financial Instruments Credit Losses. The guidance modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. The Company adopted ASU 2016-13 in the third quarter of 2021 using the modified retrospective adoption approach. As a result of this adoption, the Company presents these financial assets, which include the accounts receivable and available-for-sale debt securities, at the net amount the Company expects to collect. The amendment also requires the Company to record credit losses related to available-for-sale debt securities as an allowance through net income rather than reducing the carrying amount under the historical, other-than-temporary-impairment model. The adoption of ASU 2016-13 did not have a material impact on the Company's financial statements and related disclosures for the quarter ended September 30, 2021.

In February 2016, the FASB issued ASU 2016-02 (Topic 842), Leases (Accounting Standards Codification, or "ASC", 842). ASC 842 supersedes the lease recognition requirements in ASC 840, Leases. ASC 842 clarifies the definition of a lease and requires lessees to recognize right-of-use assets and lease liabilities for all leases, including those classified as operating leases under previous lease accounting guidance. The Company adopted ASC 842 on July 1, 2021, effective as of January 1, 2021. There was no impact on the Company's accumulated deficit as of January 1, 2021 as a result of the adoption of this standard. Results for the three and nine months ended September 30, 2021 are presented under Topic 842. Other prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under previous lease guidance, ASC Topic 840: Leases ("Topic 840"). The Company elected the package of practical expedients permitted under the transition guidance of the new standard, which allowed the Company to carry forward its historical assessment on whether a contract is or contains a lease, lease classification, and initial direct costs. Upon adoption on January 1, 2021, the Company recognized operating lease right-of-use ("ROU") assets of \$29.7 million, and current and non-current operating lease liabilities of \$ 2.9 million and \$27.8 million, respectively. In connection with the adoption of this standard, deferred rent of \$1.3 million and prepaid rent of \$ 0.3 million, which was previously recorded in prepaid expenses and other current assets on the balance sheet as of December 31, 2020, were derecognized. Finance lease assets and liabilities were not material. The adoption of ASC 842 did not have a material impact to the Company's condensed statements of operations and condensed statements of cash flows. Please see Note 7 for additional information regarding the Company's leases.

Accounting policies

Leases

The Company determines if an arrangement is or contains a lease at contract inception by assessing whether the arrangement contains an identified asset and whether the lessee has the right to control such asset. The Company is required to classify leases as either finance or operating leases and to record a ROU asset and a lease liability for all leases with a term greater than 12 months regardless of the lease classification. The lease classification will determine whether the lease expense is recognized based on an effective interest rate method or on a straight-line basis over the term of the lease. The Company determines the initial classification and measurement of its ROU assets and lease liabilities at the lease commencement date and thereafter, if modified. The Company does not have material finance leases.

For leases with a term greater than 12 months, the Company records the related ROU asset and lease liability at the present value of lease payments over the term of the lease. The term of the Company's leases equals the non-cancellable

period of the lease, including any rent-free periods provided by the lessor, and also includes options to extend or terminate the lease that the Company is reasonably certain to exercise. The ROU asset equals the carrying amount of the related lease liability, adjusted for any lease payments made prior to lease commencement and lease incentives provided by the lessor. Variable lease payments are expensed as incurred and do not factor into the measurement of the applicable ROU asset or lease liability.

The Company has elected, for all classes of underlying assets, not to recognize ROU assets and lease liabilities for leases with a term of 12 months or less. Lease cost for short-term leases is recognized on a straight-line basis over the lease term. The Company has also elected to not separate lease and non-lease components for its leases and, as a result, accounts for lease and non-lease components as one component.

The Company's leases do not provide a readily determinable implicit rate. Therefore, the Company estimates its incremental borrowing rate to discount the lease payments based on information available at lease commencement. The Company determines its incremental borrowing rate based on the rate of interest that the Company would have to pay to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment.

Lease payments may be fixed or variable; however, only fixed payments are included in the Company's lease liability calculation. Lease costs for the Company's operating leases are recognized on a straight-line basis within operating expenses over the lease term. The Company's lease agreements may contain variable non-lease components such as common area maintenance, operating expenses or other costs, which are expensed as incurred.

Cash, Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the balance sheets that sum to the total of the same amounts shown in the statements of cash flows.

	September 30,	
	2021	2020
	(in thousands)	
Cash and cash equivalents	\$ 30,707	\$ 64,370
Restricted cash	872	872
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	<u>\$ 31,579</u>	<u>\$ 65,242</u>

Investments in Equity Securities

Subsequent to the closing of the initial public offering ("IPO") of Vaxcyte, Inc. in June 2020, the fair value of Vaxcyte's common stock became readily determinable. As a result, beginning June 2020, 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 unrealized gains and losses recorded in the Company's 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 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.

Revenue Recognition

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, 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 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 such 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.

3. Fair Value Measurements

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

	September 30, 2021			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets:				
Money market funds	\$ 30,108	\$ 30,108	\$ -	\$ -
Commercial paper	56,568	-	56,568	-
Corporate debt securities	70,276	-	70,276	-
Equity securities	39,763	39,763	-	-
Asset-backed securities	37,595	-	37,595	-
U.S. government securities	37,631	37,631	-	-
Supranational debt securities	21,440	-	21,440	-
Total	\$ 293,381	\$ 107,502	\$ 185,879	\$ -

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

	December 31, 2020			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets:				
Money market funds	\$ 204,632	\$ 204,632	\$ -	\$ -
Commercial paper	42,208	-	42,208	-
Corporate debt securities	25,716	-	25,716	-
Equity securities	41,644	41,644	-	-
Asset-backed securities	12,632	-	12,632	-
U.S. government securities	39,785	39,785	-	-
Total	\$ 366,617	\$ 286,061	\$ 80,556	\$ -

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 Vaxcyte common stock shares 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 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, 2021 and December 31, 2020, the Company did not hold any securities that were classified as Level 3 within the valuation hierarchy.

Investments in Equity Securities

Subsequent to the closing of the IPO of Vaxcyte in June 2020, the fair value of Vaxcyte's common stock became readily determinable. As a result, beginning June 2020, 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 unrealized gains and losses recorded in the Company's statements of operations.

As of September 30, 2021, the Company held 1,567,324 shares of Vaxcyte common stock with an estimated fair value of \$ 39.8 million. Related to Vaxcyte common stock, the Company recognized an unrealized gain of \$4.5 million for the three months ended September 30, 2021 and unrealized loss of \$ 1.9 million for the nine months ended September 30, 2021.

4. Cash Equivalents and Marketable Securities

Cash equivalents and marketable securities consisted of the following:

	September 30, 2021			
	Amortized Cost Basis	Unrealized Gains	Unrealized (Losses)	Fair Value
	(in thousands)			
Money market funds	\$ 30,108	\$ —	\$ —	\$ 30,108
Commercial paper	56,568	—	—	56,568
Corporate debt securities	70,290	7	(21)	70,276
Asset-based securities	37,607	2	(14)	37,595
U.S. government securities	37,624	7	—	37,631
Supranational debt securities	21,451	—	(11)	21,440
Total	253,648	16	(46)	253,618
Less amounts classified as cash equivalents	(30,108)	—	—	(30,108)
Total marketable securities	\$ 223,540	\$ 16	\$ (46)	\$ 223,510

	December 31, 2020			
	Amortized Cost Basis	Unrealized Gains	Unrealized (Losses)	Fair Value
	(in thousands)			
Money market funds	\$ 204,632	\$ —	\$ —	\$ 204,632
Commercial paper	42,208	—	—	42,208
Corporate debt securities	25,669	48	(1)	25,716
Asset-based securities	12,593	39	—	12,632
U.S. government securities	39,743	44	(2)	39,785
Total	324,845	131	(3)	324,973
Less amounts classified as cash equivalents	(204,632)	—	—	(204,632)
Total marketable securities	<u>\$ 120,213</u>	<u>\$ 131</u>	<u>\$ (3)</u>	<u>\$ 120,341</u>

As of September 30, 2021 and December 31, 2020, \$ 64.3 million and zero, respectively, of marketable securities had maturities of more than one year and are classified as long-term assets.

There were \$85.7 million and \$14.7 million of investments in an unrealized loss position of \$ 46,000 and \$3,000 as of September 30, 2021 and December 31, 2020, respectively. During the three and nine months ended September 30, 2021 and 2020, 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 gains on the portfolio after September 30, 2021, 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, 2021. 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, 2021 and as a result, the Company did not reclassify any amounts out of accumulated other comprehensive income 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, 2020, or as further described below, for additional information on each of our 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 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, 2021.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Bristol Myers Squibb Company ("BMS")	\$ 1,118	\$ 7,119	\$ 7,784	\$ 10,673
Merck Sharp & Dohme Corporation ("Merck") (1)	6,414	9,055	38,175	18,837
Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name "EMD Serono")	249	1,507	2,844	4,656
Vaxcyte (2)	736	142	2,423	278
Total revenue	\$ 8,517	\$ 17,823	\$ 51,226	\$ 34,444

(1) Merck was a related party until the closing of the Company's public offering on May 14, 2020.

(2) Vaxcyte was a related party until the closing of its initial public offering on June 16, 2020.

The Company's balance of deferred revenue contains the transaction price from collaboration agreements allocated to performance obligations which are partially unsatisfied. The Company expects to recognize approximately \$7.8 million of the deferred revenue over the next twelve months.

The following table presents the changes in the Company's deferred revenue balance from collaboration agreements during the nine months ended September 30, 2021:

	Nine Months Ended September 30, 2021 (in thousands)	
Deferred revenue—December 31, 2020	\$	20,703
Additions to deferred revenue		19,402
Recognition of revenue in current period		(32,156)
Deferred revenue—September 30, 2021	\$	7,949

There have been no material changes to the Company's collaboration agreements in the three and nine months ended September 30, 2021, except as described below.

Collaboration with BMS

BMS 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®. 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").

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. BMS has worldwide development and commercialization rights with respect to the BCMA ADC. The Company will continue to be responsible for clinical supply manufacturing and certain development services for the BCMA ADC and is eligible to receive from BMS aggregate development and regulatory contingent payments of up to \$275.0 million, if approved in multiple indications, and tiered royalties ranging from mid to high single digit percentages on worldwide sales of any resulting commercial products.

As of both September 30, 2021 and December 31, 2020, there was zero balance in deferred revenue related to payments received by the Company under the BMS Agreement.

2018 BMS Master Services Agreement

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.

As of September 30, 2021, and December 31, 2020, there was \$ 1.8 million and \$ 1.2 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Ongoing performance related to unsatisfied performance obligations	\$ –	\$ 1,000	\$ –	\$ 2,974
Research and development services	249	246	762	646
Materials supply	869	5,873	7,022	7,053
Total revenue	<u>\$ 1,118</u>	<u>\$ 7,119</u>	<u>\$ 7,784</u>	<u>\$ 10,673</u>

Collaboration with Merck

2018 Merck Agreement

In July 2018, the Company entered into an agreement (the "2018 Merck Agreement") with Merck to jointly develop up to three research programs focusing on cytokine derivatives for cancer and autoimmune disorders with an initial transaction price of \$60.0 million. Under ASC 606, the Company determined there was a financing component associated with the \$60.0 million upfront payment and has calculated total interest expense of \$ 7.4 million as of September 30, 2021 on the unearned revenue portion beyond one year from the effective date of the agreement, which amount is expected to be recognized as interest expense and revenue over the estimated service period for the first and second target programs.

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. The \$5.0 million was, in prior periods, considered to be a fully constrained variable consideration. Removal of the constraint on this variable consideration resulted in a change to the total transaction price, from \$60.0 million to \$65.0 million. The Company allocated the updated transaction price to all identified performance obligations on the same basis as the initial allocation upon inception of the 2018 Merck Agreement, with any adjustments recorded as a cumulative catch-up in the current period.

In the second quarter of 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. The \$15.0 million was, in prior periods, considered to be a fully constrained variable consideration. Removal of the constraint on this variable consideration resulted in a change to the total transaction price, from \$65.0 million to \$80.0 million. The Company allocated the updated transaction price to all identified performance obligations on the same basis as the initial allocation upon inception of the 2018 Merck Agreement, with any adjustments recorded as a cumulative catch-up in the nine-month period ended September 30, 2021. Based upon the adjusted transaction price, revenue allocated to the access to intellectual property rights was \$9.4 million and incremental revenue of \$ 1.6 million was recognized in the nine-month period ended September 30, 2021 as this performance obligation was previously completed. Revenue allocated to the first and second target programs totaled \$60.6 million, to be recognized on a proportion of performance basis, using the FTE cost as the basis of measurement, with such performance expected to occur over an estimated service period of three years for each target program. Incremental revenue of \$ 9.1 million was recognized in the nine-month period ended September 30, 2021. The Company allocated \$9.1 million of the adjusted transaction price to the material right associated with the contingent third program and incremental revenue of \$3.2 million was recognized in the nine-month period ended September 30, 2021 as this performance obligation was previously completed. As it pertains to the JSC performance obligation, the incremental transaction price allocation resulted in additional revenue of \$0.1 million recognized in the nine-month period ended September 30, 2021. As a result of the change in transaction price, due to the \$ 15.0 million contingent payment earned in the second quarter of 2021, the Company recorded a \$14.0 million cumulative catch-up in revenue in the nine months ended September 30, 2021.

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 to discover and develop novel cytokine derivative therapeutics for cancer and autoimmune disorders. Under the terms of the 2021 Amendment, the Company will receive a payment of \$2.5 million and may receive up to an additional \$ 7.5 million upon the achievement of certain developmental milestones. Pursuant to ASC 606, the Company concluded that the 2021 Amendment constitutes a contract modification which is to be accounted for as a separate contract from the 2018 Merck Agreement. The \$7.5 million is considered to be a fully constrained variable consideration. The amount of \$2.5 million was recorded within the Company's accounts receivable and current deferred revenue as of September 30, 2021.

The Company is eligible to receive aggregate contingent payments of up to approximately \$ 0.5 billion for each of the target programs 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 each of the target programs are developed for non-oncology or a single indication, the Company will be eligible for reduced aggregate milestone 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.

As of September 30, 2021 and December 31, 2020, there was a total of \$ 5.1 million and \$ 18.5 million, respectively, of 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, 2021 and December 31, 2020, 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,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Ongoing performance related to unsatisfied performance obligations	\$ 3,506	\$ 6,907	\$ 30,889	\$ 13,048
Research and development services	419	1,732	2,328	4,245
Financing component on unearned revenue	149	416	561	1,544
Materials supply	2,340	-	4,397	-
Total revenue	\$ 6,414	\$ 9,055	\$ 38,175	\$ 18,837

There was no revenue recognized under the 2021 Amendment in the three-month and nine-month periods ended September 30, 2021.

Collaboration with EMD Serono

EMD Serono Agreements

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. Under the MDA Agreement, a novel bispecific ADC product candidate targeting EGFR and MUC1, known as M1231, is undergoing development.

The Company is eligible to receive up to \$ 52.5 million for M1231 under the MDA Agreement, primarily from pre-commercial contingent payments. Relatedly, the Company earned a \$2.0 million contingent payment in the second quarter of 2021 related to a patient enrollment achievement in the Phase 1 dose escalation portion of a study of M1231. In August 2020, the Company earned a \$1.0 million clinical supply milestone payment under the MDA Agreement. In

September 2019, the Company earned a \$ 1.5 million contingent payment under the MDA Agreement upon designation by EMD Serono of a specific bispecific antibody drug conjugate as a clinical development candidate with their approval to advance it to IND-enabling studies. In addition, the Company is eligible to receive tiered royalties ranging from low-to-mid single digit percentages, along with certain additional one-time royalties, on worldwide sales of any commercial products that may result from the MDA Agreement.

As of both September 30, 2021 and December 31, 2020, there was no deferred revenue related to payments received by the Company under the MDA Agreement.

2019 EMD Serono Supply Agreement

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.

As of both September 30, 2021 and December 31, 2020, there was \$1.0 million of deferred revenue related to payments received by the Company under 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,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Contingent payment earned	\$ —	\$ 1,000	\$ 2,000	\$ 1,000
Research and development services	214	265	503	1,088
Materials supply	35	242	341	2,568
Total revenue	\$ 249	\$ 1,507	\$ 2,844	\$ 4,656

Vaxcyte Supply Agreement

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

During 2020, upon Vaxcyte’s request and their agreement to reimburse the related costs, the Company entered into agreements with third-party contract manufacturers (“CMOs”) to conduct process transfers to allow for such CMOs to manufacture and supply extract and custom reagents for Vaxcyte. The agreed-upon reimbursements by Vaxcyte of the costs associated with such arrangements, principally for pass-through costs from the CMOs, were accounted for by the Company as a reduction to research and development expense.

Revenues under the Vaxcyte Supply Agreement were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Research and development services	\$ 247	\$ —	\$ 716	\$ —
Materials supply	489	142	1,707	278
Total revenue	\$ 736	\$ 142	\$ 2,423	\$ 278

6. Loan and Security Agreement

The Company entered into loan and security agreements with Oxford Finance LLC (“Oxford”) and Silicon Valley Bank (“SVB”) in both August 2017 and February 2020. 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, 2020, or as further described below, for additional information.

In connection with entering into the loan and security agreement in February 2020, the Company issued to the lenders warrants exercisable for 81,257 shares of the Company’s common stock (the “2020 Warrants”). The 2020 Warrants are exercisable in whole or in part, immediately, and have a per share exercise price of \$9.23, which is the closing price of the Company’s common stock reported on the Nasdaq Global Market on the day prior to the effective date of the February 2020 loan and security agreement. The 2020 Warrants will terminate on the earlier of February 28, 2030 or the closing of certain merger or consolidation transactions. The estimated fair value upon issuance of the Warrants of \$0.6 million was recorded as a debt discount on the associated borrowings on the Company’s balance sheet. The debt discount is being amortized to interest expense over the expected repayment period of the loan using the effective-interest method.

As of September 30, 2021, the Company has classified \$ 6.3 million of the outstanding debt balance as current and \$ 18.7 million as non-current, which reflects the scheduled repayment terms under the February 2020 loan and security agreement.

As of both September 30, 2021 and December 31, 2020, accrued interest expense was \$ 0.2 million.

During the three and nine months ended September 30, 2021, the Company recorded interest expense related to loans outstanding of \$ 0.7 million and \$1.9 million, respectively, with average interest rates of 8.07% in both periods, and interest related to the accretion of debt discount of \$ 0.1 million and \$0.4 million, respectively. During the three and nine months ended September 30, 2020, the Company recorded interest expense related to loans outstanding of \$0.7 million and \$1.7 million, respectively, with average interest rates of 8.07% and 8.08%, respectively, and interest related to the accretion of debt discount of \$ 0.1 million and \$0.3 million, respectively.

7. Commitments and Contingencies

In June 2021, the Company entered into a third amendment (the “Third Amendment”) to its manufacturing facility lease, dated May 18, 2011, as amended, by and between Alemany Plaza LLC, located in San Carlos, California (the “San Carlos Lease”), as an extension to the term of the San Carlos Lease for a period of five years (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, the Company entered into a first amendment (the “First Amendment”) to its manufacturing support facility lease, dated May 4, 2015, as amended, by and between 870 Industrial Road LLC, located in San Carlos, California (the “Industrial Lease”), as an extension to the term of the Industrial Lease for a period of five years (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, the Company entered into a sublease agreement (the “Sublease”) with Five Prime Therapeutics, Inc. (the “Sublessor”), for approximately 115,466 square feet, located in South San Francisco, California (the “Premises”). The Company expects to use the Premises as its new corporate headquarters and to conduct (or expand) research and development activities. The commencement date for the first 85,755 square feet of the Premises (“Initial Premises”) per sublease was in July 2021, at which time the Company commenced making monthly payments under the Sublease, with occupancy of such space commencing in August 2021. The Company was provided early access to the Sublease commencing 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 (the “Landlord”). The commencement date for the remaining 29,711 square feet of the Premises (the “Expansion Premises”) is expected to be 24 months following the commencement date on the Initial Premises, although the Company has the right to accelerate the commencement date on the Expansion Premises to an earlier date upon six months’ prior written notice to the Sublessor. 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, 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 the Company of base rent abatement to be provided by Sublessor, subject to certain terms contained in the Sublease. The Sublease contains customary provisions requiring the Company to pay its 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 the Company fails to remedy a breach of certain of its obligations within specified time periods. Additionally, the Company posted a security deposit of \$ 0.9 million, which is reflected as restricted cash in non-current assets on the Company's balance sheet as of September 30, 2021 and December 31, 2020.

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 condensed statements of operations, were as follows (in thousands):

	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
Operating lease cost	\$ 2,266	\$ 6,396
Short-term lease cost	22	73
Variable lease cost	754	1,513
Total lease costs	<u>\$ 3,042</u>	<u>\$ 7,982</u>

During the nine months ended September 30, 2021, the Company recorded operating lease expense of \$ 6.4 million and paid \$ 4.0 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, 2021, the weighted-average remaining lease term was 5.9 years and the weighted-average discount rate used to determine the operating lease liability was 10.8%.

As of September 30, 2021, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Year Ending December 31,	Amount
	(in thousands)
Remaining in 2021	\$ 2,142
2022 (1)	1,643
2023	8,002
2024	9,219
2025	9,533
Thereafter	17,282
Total lease payments	<u>47,821</u>
Less: imputed interest	<u>(14,303)</u>
Operating lease liabilities	33,518
Less: current portion	<u>(1,445)</u>
Total lease liabilities, non-current	<u>\$ 32,073</u>

(1) Includes approximately \$5.2 million in potential financial benefit to the Company of base rent abatement to be provided by sublessor for months 7 – 18 of the sublease period, subject to certain terms contained in the Sublease.

Under the historical guidance of ASC 840, the deferred rent balance on December 31, 2020 totaled \$ 1.3 million and our future minimum lease payments for our operating leases on December 31, 2020 were as follows (in thousands):

Year Ending December 31,	Amount	
	(in thousands)	
2021	\$	5,742
2022 (1)		5,183
2023		6,310
2024		7,476
2025 and thereafter		24,034
Total future minimum lease payments	\$	48,745

- (1) Excludes approximately \$5.2 million in potential financial benefit to the Company of base rent abatement to be provided by sublessor for months 7 – 18 of the sublease period, subject to certain terms contained in the Sublease.

Rent expense was \$0.9 million and \$2.7 million for the three and nine months ended September 30, 2020, respectively.

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 balance sheets, statements of operations, or 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. Related-Party Transactions

Upon the Company's public offering on May 14, 2020, Merck's ownership of the Company's outstanding equity interest decreased to less than 10%. As a result, starting May 14, 2020, the Company ceased to reflect balances and transactions associated with Merck as being with a related party in its financial statements. Transactions with Merck for the three and nine months ended September 30, 2021 and 2020 are described in Note 5.

As discussed in Note 2, Vaxcyte closed its IPO of its common stock on June 16, 2020, resulting in the Company's ownership of Vaxcyte's outstanding equity interest being less than 4.0%. As a result, starting on June 16, 2020, the Company ceased to reflect any balances and transactions associated with Vaxcyte as being with a related party in its financial statements. Transactions with Vaxcyte for the three and nine months ended September 30, 2021 and 2020 are described in Note 5.

9. 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, 2021	December 31, 2020
Common stock options issued and outstanding	6,533,772	5,439,295
Restricted common stock units issued and outstanding	2,262,776	666,375
Remaining shares reserved for issuance under 2004 and 2018 Equity Incentive Plan	1,681,651	1,710,824
Shares reserved for issuance under 2018 Employee Stock Purchase Plan	673,251	361,539
Warrants to purchase common stock	153,070	153,070
Total	<u>11,304,520</u>	<u>8,331,103</u>

Preferred Stock

As of September 30, 2021 and December 31, 2020, 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, 2021 and December 31, 2020.

Warrants

In August 2017, the Company issued warrants to Oxford and SVB to purchase an aggregate of 682,230 shares of Series D-2 redeemable convertible preferred stock at an exercise price of \$0.6596 per share in connection with the issuance of the August 2017 Loan. If there was a subsequent convertible preferred stock or other senior equity securities financing with a per share price less than the Series D-2 redeemable convertible preferred per share price, then the warrant would automatically convert to a warrant to purchase such class of shares, based on the per share price of such equity. Given that the price per share of the Series E redeemable convertible preferred stock was less than the price per share of the Series D-2 redeemable convertible preferred stock, the 2017 Warrant converted into a warrant to purchase a total of 1,682,871 shares of Series E redeemable convertible preferred stock at an exercise price of \$0.2674 per share. The warrant is exercisable from the original date of issuance and has a 10-year term.

The Company adjusted the warrant liability for changes in fair value until the completion of its IPO on October 1, 2018, at which time certain convertible preferred stock warrants were converted into warrants for the purchase of common stock and the related convertible preferred stock warrant liability was reclassified to additional paid-in capital and others expired. On October 1, 2018, 1,232,220 shares of the Series C redeemable convertible preferred warrants were canceled, and the remaining 687,928 shares were converted on a 1-for-0.0370 basis to warrants to purchase 25,454 shares of common stock. All Series E redeemable convertible preferred warrants were converted on a 1-for-0.0275 basis to warrants to purchase 46,359 shares of common stock.

In February 2020, in connection with entering into a loan and security agreement, the Company issued to Oxford and SVB the 2020 Warrants, which are exercisable for 54,171 shares and 27,086 shares, respectively, of the Company's common stock. The 2020 Warrants are exercisable in whole or in part, immediately, and have a per share exercise price of \$9.23, which is the closing price of the Company's common stock reported on the Nasdaq Global Market on the day prior to the effective date of the February 2020 loan and security agreement. The 2020 Warrants will terminate on the earlier of February 28, 2030 or the closing of certain merger or consolidation transactions.

10. Equity Incentive Plans, Employee Stock Purchase Plan and Stock-Based Compensation

2004 Equity Incentive Plan, 2018 Equity Incentive Plan and 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 2,287,605 shares on January 1, 2021.

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.

As of September 30, 2021, the Company had a total of 1,681,651 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	Weighted-Average Remaining Contract Term (Years)	Aggregate Intrinsic Value (in thousands)
Stock options outstanding at December 31, 2020	5,439,295	\$ 11.93	7.75	\$ 53,202
Granted	1,383,950	\$ 20.40		
Exercised	(185,974)	\$ 10.60		
Canceled and forfeited	(103,499)	\$ 10.58		
Stock options outstanding at September 30, 2021	6,533,772	\$ 13.78	7.65	\$ 35,715
Stock options exercisable at September 30, 2021	3,523,838	\$ 12.73	6.80	\$ 21,959

The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying stock option awards and the estimated fair value of the Company's common stock on the date of exercise. For the three and nine months ended September 30, 2021, the aggregate intrinsic value of stock options exercised was \$0.1 million and \$2.3 million, respectively, determined at the date of the option exercise. For the three and nine months ended September 30, 2020, the aggregate intrinsic value of stock options exercised was \$48,000 and \$0.1 million, respectively, determined at the date of the option exercise.

Employee Stock Options Valuation

For determining stock-based compensation expense, the fair-value-based measurement of each employee stock option was estimated as of the date of grant using the Black-Scholes option-pricing model with assumptions as follows:

	Nine Months Ended September 30,	
	2021	2020
Expected term (in years)	5.3-6.1	5.1-7.0
Expected volatility	81.6%-84.9%	73.2%-84.2%
Risk-free interest rate	0.6%-1.1%	0.2%-1.6%
Expected dividend	—	—

Using the Black-Scholes option-valuation model, the weighted-average estimated grant-date fair value of employee stock options granted during the three and nine months ended September 30, 2021 was \$13.21 and \$14.35 per share, respectively, and during the three and nine months ended September 30, 2020 was \$5.69 and \$5.09 per share, respectively.

Restricted Stock Units

During the nine months ended September 30, 2021, the Company granted 1,913,750 shares of restricted common stock units (“RSUs”) to certain employees. These RSUs vest annually and 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, 2021 is as follows:

	Number of shares	Weighted Average Grant-Date Fair Value
Non-vested December 31, 2020	666,375	\$ 9.83
Granted	1,913,750	\$ 20.56
Vested and released	(232,474)	\$ 11.06
Canceled and forfeited	(84,875)	\$ 17.07
Non-vested September 30, 2021	<u>2,262,776</u>	\$ 18.50

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 457,521 shares on January 1, 2021. 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.

The fair value of the ESPP shares is estimated using the Black-Scholes option pricing model. For the nine months ended September 30, 2021 and 2020, the fair value of ESPP shares was estimated using the following assumptions:

	Nine Months Ended September 30,	
	2021	2020
Expected term (in years)	0.5	0.5
Expected volatility	65.9-111.4%	94.1 %
Risk-free interest rate	0.1 %	0.4 %
Expected dividend	—	—

As of September 30, 2021, 473,740 shares had been purchased and 673,251 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,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Research and development expense:	\$ 1,933	\$ 761	\$ 4,882	\$ 1,972
General and administrative expense:	\$ 4,562	2,351	11,472	6,858
Total	\$ 6,495	\$ 3,112	\$ 16,354	\$ 8,830

As of September 30, 2021, unrecognized stock-based compensation expense related to the unvested stock options and RSUs granted was \$28.1 million and \$36.6 million, respectively. The remaining unrecognized compensation cost is expected to be recognized over a weighted-average period of 2.6 years and 3.4 years, respectively. As of September 30, 2021, there was \$0.3 million of unrecognized stock-based compensation expense related to the ESPP.

As of September 30, 2020, unrecognized stock-based compensation expense related to the unvested stock options and RSUs granted was \$ 18.5 million and \$5.4 million, respectively. The remaining unrecognized compensation cost is expected to be recognized over a weighted-average period of 2.4 years and 2.7 years, respectively. As of September 30, 2020, there was \$0.3 million of unrecognized stock-based compensation expense related to the ESPP.

Non-Employee Stock-Based Compensation Expense

The fair value of options granted to non-employees was estimated using the Black-Scholes method. The stock-based compensation expense related to non-employees for the three and nine months ended September 30, 2021 and 2020 was immaterial.

Call Option Plan

In February 2017, the Company adopted a Call Option Plan to grant selected employees, officers, directors and consultants (collectively, the "Participants") options to purchase shares of the common stock of Vaxcyte. As of September 30, 2021, the Company has reserved 266,724 shares of Vaxcyte common stock for issuance under the program, under which call options covering 248,944 and 17,780 shares were granted in February 2017 and August 2019, respectively. The call options granted in February 2017 vested 25% on each of January 1, 2017, 2018, 2019, and 2020, and expire one year from the vesting date. The call options granted in August 2019 vest 25% on each of January 1, 2019, 2020, 2021, and 2022, and expire one year from the vesting date.

A summary of the status of the call options as of September 30, 2021 and December 31, 2020 is as follows:

	September 30, 2021 Shares	December 31, 2020 Shares
Options vested and exercised	257,834	257,834
Options vested and outstanding	4,445	-
Options unvested and outstanding	4,445	8,890
Total options granted	<u>266,724</u>	<u>266,724</u>

The amounts recognized as compensation expense related to the Call Option Plan for the three and nine months ended September 30, 2021 were \$32,000 and \$78,000, respectively. The amounts recognized as compensation expense related to the Call Option Plan for the three and nine months ended September 30, 2020 were \$90,000 and \$0.2 million, respectively.

The amounts recognized as other expense or income related to the remeasurement of the vested call options for the three and nine months ended September 30, 2021 were \$13,000 of other expense and \$ 5,000 of other income, respectively. The amounts recognized as other expense related to the remeasurement of the vested call options for the three and nine months ended September 30, 2020 were \$1.1 million and \$3.1 million, respectively. As of September 30, 2021 and December 31, 2020, the liability attributable to the Call Option Plan was \$182,000 and \$109,000, respectively.

11. Net (Loss) Income Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands, except share and per share amounts)			
Numerator:				
Net (loss) income, basic and diluted	\$ (30,902)	\$ 17,139	\$ (67,413)	\$ 27,416
Denominator:				
Weighted-average shares used to compute basic EPS	46,162,544	36,887,266	46,060,010	29,994,917
Dilutive effect of common stock options	-	828,623	-	228,557
Dilutive effect of restricted stock units	-	159,788	-	120,649
Dilutive effect of warrants to purchase common stock	-	1,875	-	5,733
Weighted-average shares used to compute diluted EPS	46,162,544	37,877,552	46,060,010	30,349,856
Net (loss) income per share:				
Basic	\$ (0.67)	\$ 0.46	\$ (1.46)	\$ 0.91
Diluted	<u>\$ (0.67)</u>	<u>\$ 0.45</u>	<u>\$ (1.46)</u>	<u>\$ 0.90</u>

The following common stock equivalents were excluded from the computation of diluted net loss per share for the periods ended September 30, 2021, because including them would have been antidilutive:

	As of September 30, 2021
Common stock options issued and outstanding	6,533,772
Restricted stock units issued and outstanding	2,262,776
Warrants to purchase common stock	153,070
Employee stock purchase plan	6,663
Total	<u>8,956,281</u>

12. Subsequent Event

On October 9, 2021, the Company entered into an option agreement with BioNova Pharmaceuticals Limited (“BioNova”) (the “BioNova Option Agreement”), to confer BioNova the option to obtain exclusive rights to develop and commercialize STRO-001 in the People’s Republic of China, Taiwan, Hong Kong, and Macau (“Greater China”). BioNova will pursue the clinical development, regulatory approval, and commercialization of STRO-001 in multiple indications, including non-Hodgkin’s lymphoma, multiple myeloma, and leukemia in the licensed territory. The Company will retain development and commercial rights of STRO-001 globally outside of Greater China, including the United States.

Under the BioNova Option Agreement, BioNova will pay to the Company an initial licensing option payment of \$ 4 million, with potential payments totaling up to \$200 million related to option exercise, development, regulatory, and commercial milestones. The Company will provide STRO-001 to BioNova under appropriate clinical and commercial supply service agreements. Upon commercialization, the Company is eligible to receive tiered royalties ranging from low- to mid-teen percentages based on annual net sales of STRO-001 in Greater China for at least ten years following the first commercial sale of STRO-001 in Greater China.

BioNova has the right to terminate the BioNova Option Agreement for convenience or other reasons specified in the BioNova Option Agreement, upon prior written notice.

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, 2020. 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. These forward-looking statements may include, but are not limited to, statements related to our expectations regarding the potential impacts of the COVID-19 pandemic on our business, financial condition, and results of operations, our future results of operations and financial position, business strategy, market size, potential growth opportunities, preclinical and clinical development activities, efficacy and safety profile of our product candidates, use of net proceeds from our public offerings, our ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical studies and clinical trials, commercial collaborations with third parties and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates. 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 drug discovery, development and manufacturing company focused on deploying our proprietary integrated cell-free protein synthesis platform, XpressCF[®], to create a broad variety of optimally designed, next-generation protein therapeutics, initially for cancer and autoimmune disorders. We aim to design therapeutics using the most relevant and potent modalities, including cytokine-based therapeutics, immuno-oncology, or I/O agents, antibody-drug conjugates, or ADCs, and bispecific antibodies that are directed primarily against clinically validated targets where the current standard of care is suboptimal. We believe our platform allows us to accelerate the discovery and development of potential first-in-class and 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 using our XpressCF[®] Platform to create 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 compliant manufacturing facility. We have the ability to manufacture our cell-free extract that supports our production of proteins on a large scale using a semi-continuous fermentation process. Our two most advanced product candidates are wholly owned: STRO-001, an ADC directed against CD74, for patients with multiple myeloma and non-Hodgkin's lymphoma, or NHL, and STRO-002, an ADC directed against folate receptor-alpha, or FolR α , for patients with ovarian and endometrial cancers.

We are developing 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+[™] Platform. The Phase 1 trial for STRO-001 is an open-label study that is 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, determine the recommended Phase 2 dose and interval and evaluate preliminary anti-tumor activity. The secondary objectives are to characterize the human pharmacokinetics of STRO-001 and additional safety, tolerability and efficacy measures.

STRO-002 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+[™] Platform. Our Phase 1 trial for STRO-002 is an open-label study evaluating STRO-002 as a monotherapy for patients with ovarian and endometrial cancers. The trial is being conducted in two-parts, dose escalation and dose expansion. The primary objectives of the STRO-002 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.

Based on our proprietary XpressCF® platform, we have also entered into multi-target, product-focused collaborations with leaders in the field of oncology, including a cytokine derivatives collaboration with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, or Merck; a B Cell Maturation Antigen, or BCMA, ADC collaboration with Celgene Corporation, or Celgene, a wholly owned subsidiary of Bristol-Myers Squibb Company, New York, NY, or BMS; and a MUC1-EGFR ADC collaboration with Merck KGaA, Darmstadt Germany (operating in the United States and Canada under the name “EMD Serono”).

Our two most advanced product candidates are wholly owned: STRO-001, an ADC directed against CD74, for patients with multiple myeloma and non-Hodgkin lymphoma, or NHL, and STRO-002, an ADC directed against folate receptor-alpha, or FolR α , for patients with ovarian and endometrial cancers. STRO-001 is currently enrolling patients in a Phase 1 trial, with updated data reported in December 2020. Based on such reported data, STRO-001 has been generally well-tolerated and, unlike certain other ADCs, no ocular toxicity signals have been observed, with no patients receiving prophylactic corticosteroid eye drops. Dose escalation in the STRO-001 Phase 1 trial is continuing, and the maximum tolerated dose has not yet been reached, with the last reported doses of 5.0 mg/kg in the multiple myeloma cohort and 4.2 mg/kg in the NHL cohort. The FDA has granted Orphan Drug Designation for STRO-001 for the treatment of multiple myeloma.

Our second candidate, STRO-002, is currently enrolling patients in the dose expansion cohort of a Phase 1 trial focused on ovarian and endometrial cancers, with updated data from the dose-escalation portion of the trial most recently reported in May 2021. As of April 23, 2021, the dose-escalation cohort of the Phase 1 trial had enrolled 39 ovarian cancer patients and included 34 patients treated with clinically active dose levels at 2.9 mg/kg or higher, of which 31 patients had at least one post-baseline scan and were evaluable for RECIST responses.

The dose escalation portion of the STRO-002 Phase 1 trial has been fully enrolled and the dose expansion portion of the trial is ongoing to assess the efficacy, safety and tolerability of STRO-002 at dose levels of 4.3 and 5.2 mg/kg. For the dose-expansion portion, we dosed the first patient in January 2021, and have achieved our targeted enrollment of 40 patients. We expect to report initial dose-expansion data in the second half of 2021. Additionally, an expansion cohort for FolR α -selected endometrial cancer has been initiated and is enrolling patients, and initiation of a combination cohort with bevacizumab in ovarian cancer is planned for the second half of 2021.

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 Celgene (now BMS), Merck and EMD Serono, the issuance and sale of redeemable convertible preferred stock, our initial public offering, or IPO, follow-on public offerings of common stock, and debt proceeds.

We have no products approved for commercial sale and have not generated any revenue from commercial product sales. We had a net loss of \$67.4 million for the nine months ended September 30, 2021. We had a loss from operations of \$46.2 million and net income of \$27.4 million, due principally to an unrealized gain of \$78.6 million related to our holdings of Vaxcyte common stock, for the nine months ended September 30, 2020. 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, 2021, we had an accumulated deficit of \$295.3 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, marketing, manufacturing and distribution. We expect our operating expenses to significantly increase as we continue 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. 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.

Impacts of the COVID-19 Pandemic

The extent of the impact of COVID-19 on our operational and financial performance will depend on certain developments, including the duration and spread of the pandemic, impacts on our clinical studies, employee or industry events, and effects on our collaboration partners, suppliers, service providers and manufacturers, all of which are uncertain and cannot be predicted. The COVID-19 pandemic and its adverse effects have become more prevalent in the locations where we, our CROs, suppliers or third-party business partners conduct business. We are experiencing the impact of the COVID-19 pandemic on our business through delays in the availability of materials routinely used in biologic therapeutic development and manufacturing, which has the potential to cause delays in our research, development and/or manufacturing activities, but overall patient enrollment and treatment remains on track. We may experience more pronounced and significant disruptions in our operations, liquidity, supply chain, facilities, and clinical trials in the future as well. With respect to our clinical trials, we have experienced minor delays in enrollment and occasional delays in data entry by trial sites, but overall enrollment and treatment remains on track. We may in the future experience more significant delays in enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis that could materially adversely impact our business, results of operations, revenue earned from our collaboration partners, and overall financial performance in future periods. Specifically, we may experience impact from changes in how we and companies worldwide conduct business due to the COVID-19 pandemic, including but not limited to restrictions on travel and in-person meetings, the speed and breadth of mass vaccinations for COVID-19 and the efficacy of such vaccines, delays in site activations and enrollment of clinical trials, prioritization of hospital resources toward pandemic effort, delays in review by the FDA and comparable foreign regulatory agencies, and disruptions in our supply chain for our product candidates. As of the filing date of this Form 10-Q, the extent to which the COVID-19 pandemic may impact our financial condition, results of operations or guidance is uncertain. The effect of the COVID-19 pandemic will not be fully reflected in our results of operations and overall financial performance until future periods. See the section titled "Risk Factors" for further discussion of the possible impact of the ongoing COVID-19 pandemic on our business.

Financial Operations Overview

Revenue

We have no 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 and EMD Serono, and to a lesser extent, from manufacturing, supply and services and products we provide to the above collaborators and to Vaxcyte.

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.

Please see further discussion on the revenue recognition treatment of performance obligations under Critical Accounting Policies and Estimates.

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. Non-refundable advance payments for services that will be used or rendered for future research and development activities are recorded as prepaid expenses and recognized as expenses as the related services are performed.

We expect our research and development expenses to increase in the future as we 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 and research and development facilities 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 periods indicated. 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,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Internal costs:				
Research and drug discovery	\$ 6,708	\$ 4,688	\$ 19,409	\$ 13,664
Process and product development	4,470	2,652	11,201	7,916
Manufacturing	7,579	6,084	23,313	17,446
Clinical development	1,709	673	3,662	1,831
Total internal costs	20,466	14,097	57,585	40,857
External Program Costs:				
Research and drug discovery	379	288	1,069	871
Toxicology and translational science	357	31	963	642
Process and product development	104	117	286	283
Manufacturing	3,249	3,023	7,718	6,822
Clinical development	2,047	1,805	6,852	4,748
Total external program costs	6,136	5,264	16,888	13,366
Total research and development expenses	\$ 26,602	\$ 19,361	\$ 74,473	\$ 54,223

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 additional 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. We also expect to increase the size of our administrative function to support the anticipated growth of our business, and as we continue to advance our product candidates into and through the clinic, we expect the growth of our business to require increased general and administrative expenses.

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.

Interest and Other Expense, Net

Interest expense includes interest incurred on our debt and amortization of debt issuance costs. Additionally, we identified a financing component under the Merck 2018 Agreement and recorded interest expense associated with the upfront payment. Other income (expense) in the three months ended September 30, 2021 and 2020 includes changes in values attributable to the arrangement with the Call Option Plan as defined in the notes to our financial statements included elsewhere in this report.

Comparison of the Three Months Ended September 30, 2021 and 2020

	Three Months Ended September 30,			Change (%)
	2021	2020	Change	
	(in thousands)			
Revenues	\$ 8,517	\$ 17,823	\$ (9,306)	(52)%
Operating expenses				
Research and development	26,602	19,361	7,241	37%
General and administrative	16,589	9,079	7,510	83%
Total operating expenses	43,191	28,440	14,751	52%
Loss from operations	(34,674)	(10,617)	(24,057)	227%
Interest income	109	295	(186)	(63)%
Unrealized gain on equity securities	4,483	29,778	(25,295)	(85)%
Interest and other expense, net	(820)	(2,317)	1,497	(65)%
Net (loss) income	<u>\$ (30,902)</u>	<u>\$ 17,139</u>	<u>\$ (48,041)</u>	<u>(280)%</u>

Revenue

We have recognized revenue as follows during the periods indicated:

	Three Months Ended September 30,			Change (%)
	2021	2020	Change	
	(in thousands)			
Bristol Myers Squibb Company ("BMS")	\$ 1,118	\$ 7,119	\$ (6,001)	(84)%
Merck Sharp & Dohme Corporation ("Merck") (1)	6,414	9,055	(2,641)	(29)%
Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name "EMD Serono")	249	1,507	(1,258)	(83)%
Vaxcyte (2)	736	142	594	418%
Total revenue	<u>\$ 8,517</u>	<u>\$ 17,823</u>	<u>\$ (9,306)</u>	<u>(52)%</u>

(1) Merck was a related party until the closing of our public offering on May 14, 2020.

(2) Vaxcyte was a related party until the closing of its initial public offering on June 16, 2020.

Total revenue decreased by \$9.3 million, or 52%, during the three months ended September 30, 2021 compared to the three months ended September 30, 2020. This was due to a decrease of \$6.0 million from BMS, which reflects a \$5.0 million decrease in contract research and manufacturing activities supporting clinical trial supply and a \$1.0 million decrease due to the completion in September 2020 of revenue recognition of the transaction price under the BMS Agreement. Further, there was a decrease of \$2.6 million from Merck, which was comprised of a \$3.7 million decrease in the ongoing performance of research and development services on the first collaboration program which was fully recognized in July 2021, and a \$1.3 million decrease in research and development services, partially offset by a \$2.4 million increase in manufacturing activities supporting clinical trial supply. EMD Serono revenue decreased by \$1.3 million, which reflects a \$1.0 million contingent payment earned in the third quarter of 2020, with such decrease being partially offset by a \$0.6 million increase in Vaxcyte revenue.

Research and Development Expense

Research and development expense increased by \$7.2 million, or 37%, during the three months ended September 30, 2021 compared to the three months ended September 30, 2020. The increase was due primarily to increases of \$3.3 million in personnel-related expenses from higher headcount, \$1.3 million in laboratory supplies, clinical trial costs and production materials-related expenses, \$0.5 million in consulting and outside services, and \$2.1 million in facility-related expenses.

General and Administrative Expense

General and administrative expense increased by \$7.5 million, or 83%, during the three months ended September 30, 2021 compared to the three months ended September 30, 2020. The increase was due primarily to increases of \$3.7 million in personnel-related expenses from higher headcount, \$1.8 million in insurance and external services, \$1.6 million in facility-related expenses and \$0.4 million in equipment and office related expenses.

Interest Income

Interest income decreased by \$0.2 million during the three months ended September 30, 2021 compared to the three months ended September 30, 2020, due primarily to a decrease in the amortization of premiums on investments.

Unrealized Gain on Equity Securities

Unrealized gain on equity securities was \$4.5 million during the three months ended September 30, 2021, as compared to \$29.7 million for the three months ended September 30, 2020. 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.

Interest and Other Expense, Net

Interest and other expense, net, decreased by \$1.5 million during the three months ended September 30, 2021 compared to the three months ended September 30, 2020, due primarily to a \$1.2 million decrease related to the remeasurement of the vested call options under the Call Option Plan and a \$0.3 million decrease in interest expense associated with the financing component related to the 2018 Merck Agreement.

Comparison of the Nine Months Ended September 30, 2021 and 2020

	Nine Months Ended September 30,			Change (%)
	2021	2020	Change	
	(in thousands)			
Revenues	\$ 51,226	\$ 34,444	\$ 16,782	49%
Operating expenses				
Research and development	74,473	54,223	20,250	37%
General administrative	40,241	26,435	13,806	52%
Total operating expenses	114,714	80,658	34,056	42%
Loss from operations	(63,488)	(46,214)	(17,274)	37%
Interest income	481	1,320	(839)	(64)%
Unrealized (loss) gain on equity securities	(1,881)	78,638	(80,519)	(102)%
Interest and other expense, net	(2,525)	(6,328)	3,803	(60)%
Net (loss) income	\$ (67,413)	\$ 27,416	\$ (94,829)	(346)%

Revenue

We have recognized revenue as follows during the periods indicated:

	Nine Months Ended September 30,			Change (%)
	2021	2020	Change	
	(in thousands)			
Bristol Myers Squibb Company	\$ 7,784	\$ 10,673	\$ (2,889)	(27)%
Merck Sharp & Dohme Corporation (1)	38,175	18,837	19,338	103%
Merck KGaA, Darmstadt, Germany	2,844	4,656	(1,812)	(39)%
Vaxcyte (2)	2,423	278	2,145	772%
Total revenue	\$ 51,226	\$ 34,444	\$ 16,782	49%

(1) Merck was a related party until the closing of our public offering on May 14, 2020.

(2) Vaxcyte was a related party until the closing of its initial public offering on June 16, 2020.

Total revenue increased by \$16.8 million, or 49%, during the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020. This was due primarily to an increase of \$19.3 million from Merck, primarily related to revenue from ongoing performance of research and development services, of which \$5.9 million was associated with the contingent third program that was fully recognized upon the determination that the related performance obligation had terminated during the first quarter of 2021, \$14.0 million was a cumulative catch-up in revenue as a result of the change in transaction price, due to a \$15.0 million contingent payment earned in the second quarter of 2021 for the initiation of the first IND-enabling toxicology study under the first program in the collaboration, and a \$4.4 million increase in materials supply. Revenue from Vaxcyte under our supply agreement increased by \$2.1 million as well. Partially offsetting these increases were a \$2.0 million decrease in the ongoing performance of research and development services due to the performance obligation pertaining to the first collaboration program, which was fully recognized in July 2021. This was offset by a decrease of \$1.9 million in research and development services and a decrease of \$1.0 million related to the financing component associated with the upfront payment. In addition, there was a decrease of \$2.9 million from BMS which was primarily due to the completion in September 2020 of revenue recognition of the transaction price under the BMS Agreement, and a decrease of \$1.8 million in EMD Serono revenue.

Research and Development Expense

Research and development expense increased by \$20.3 million, or 37%, during the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020. The increase was due primarily to increases of \$8.0 million in personnel-related expenses from higher headcount, \$4.6 million in laboratory supplies and production materials-related expenses, \$4.2 million in facility-related expenses, \$1.8 million in clinical trial costs, \$1.5 million in consulting and outside services, and \$0.2 million in equipment-related expenses.

General and Administrative Expense

General and administrative expense increased by \$13.8 million, or 52% during the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020. The increase was due primarily to increases of \$7.8 million in personnel-related expenses from higher headcount, \$2.7 million in facility-related expenses, \$2.5 million in insurance and external services, and \$0.8 million in equipment-related expenses.

Interest Income

Interest income decreased by \$0.8 million during the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020, due primarily to a \$1.6 million decrease in the amortization of premiums on investments, partially offset by an increase of \$0.8 million from higher average investment balances in 2021.

Unrealized (Loss) Gain on Equity Securities

Unrealized (loss) on equity securities was \$1.9 million during the nine months ended September 30, 2021, as compared to an unrealized gain of \$78.6 million for the nine months ended September 30, 2020. The unrealized (loss) gain on equity securities in each period was entirely due to the remeasurement of the estimated fair value of our investment in Vaxcyte common stock.

Interest and Other Expense, Net

Interest and other expense, net, decreased by \$3.8 million during the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020, due primarily to a \$3.1 million decrease in other expenses related to the remeasurement of the vested call options under the Call Option Plan and a \$1.0 million decrease in interest expense associated with the financing component related to the 2018 Merck Agreement, partially offset by a \$0.3 million increase in interest expense related to our outstanding debt.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have incurred significant net operating 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 and debt. As of September 30, 2021, we had cash, cash equivalents and marketable securities of \$254.2 million, equity securities of \$39.8 million, outstanding debt of \$25.0 million and an accumulated deficit of \$295.3 million.

2021 Contingent Payment from Merck

In the second quarter of 2021, we earned and received a \$15.0 million contingent payment from Merck for the initiation of an IND enabling toxicology study for the first program in its collaboration to develop novel cytokine derivative therapeutics for cancer and autoimmune disorders.

2020 Public Offerings

On May 14, 2020, we closed a public offering of 12,650,000 shares of our common stock at a public offering price of \$7.75 per share, which included the exercise in full of the underwriters' option to purchase 1,650,000 shares of common stock. Our net proceeds from this offering, after deducting underwriting discounts and commissions and other offering expenses, was approximately \$91.4 million.

On December 11, 2020, we closed a public offering of 6,900,000 shares of our common stock at a public offering price of \$21.00 per share, which included the exercise in full of the underwriters' option to purchase 900,000 shares of common stock. Our net proceeds from this offering, after deducting underwriting discounts and commissions and other offering expenses, was approximately \$135.8 million.

At-The-Market Sales

During the year ended December 31, 2020, we sold an aggregate of 2,614,286 shares of our common stock through our At-the-Market ATM facility, or ATM Facility, pursuant to a sales agreement dated October 4, 2019 with Cowen and Company, LLC, as sales agent. The gross proceeds from these sales were approximately \$24.6 million, before deducting fees of approximately \$0.8 million, resulting in net proceeds of approximately \$23.8 million. During the nine months ended September 30, 2021, we did not sell any shares under an ATM facility.

Vaxcyte, Inc. Equity Ownership

In June 2020, Vaxcyte closed an initial public offering of its common stock at a price per share of \$16.00. The Vaxcyte common stock held by us 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, adjusted for a discount for lack of marketability due to the presence of a lock-up agreement during certain periods in 2020, with any unrealized gains and losses recorded in our statements of operations. The lock-up agreement expired in December 2020. As of September 30, 2021, we held 1,567,324 shares of Vaxcyte common stock with an estimated fair value of \$39.8 million.

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 (the "Third Amendment") to our manufacturing facility lease, dated May 18, 2011, as amended, by and between Alemany Plaza LLC, located at San Carlos, California (the "San Carlos Lease"), as an extension to the term of the San Carlos Lease for a period of five years (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 (the "First Amendment") to our manufacturing facility lease, dated May 4, 2015, as amended, by and between 870 Industrial Road LLC, located at San Carlos, California (the "Industrial Lease"), as an extension to the term of the Industrial Lease for a period of five years (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 with Five Prime Therapeutics, Inc. located in South San Francisco, California. Please see Note 7 to our condensed financial statements.

The following table summarizes our contractual obligations as of September 30, 2021:

	Payments due in the year				Total
	2021	2022-2023	2024-2026	Beyond 2026	
	(in thousands)				
Contractual obligations:					
Debt, principal	\$ -	\$ 21,875	\$ 3,125	\$ -	\$ 25,000
Debt, interest	510	2,603	44	-	3,157
Operating lease obligations	855	3,336	4,524	-	8,715
Sublease obligation (1)	1,286	6,310	23,221	8,289	39,106
Total contractual obligations	<u>\$ 2,651</u>	<u>\$ 34,124</u>	<u>\$ 30,914</u>	<u>\$ 8,289</u>	<u>\$ 75,978</u>

(1) Includes approximately \$5.2 million in potential financial benefit to us of base rent abatement to be provided by sublessor for months 7 – 18 of the sublease period, subject to certain terms contained in the Sublease.

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, 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,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	\$ (60,099)	\$ (48,923)
Net cash used in investing activities	(118,096)	(15,203)
Net cash provided by financing activities	2,750	124,393
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (175,445)</u>	<u>\$ 60,267</u>

Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2021 was \$60.1 million. Our net loss of \$67.4 million included \$1.9 million of unrealized loss on equity securities as a result of the remeasurement of the estimated fair value of our investment in Vaxcyte common stock, non-cash charges of \$16.4 million for stock-based compensation, \$3.5 million for depreciation and amortization, \$3.8 million for noncash lease expenses, \$2.0 million for the amortization of premium on our marketable securities and \$0.5 million in other non-cash charges. Cash used in operating activities also reflected a net decrease in operating assets and liabilities of \$20.8 million, due to an a decrease of \$12.8 million in our deferred revenue balance from revenue recognized under our collaboration agreements, an increase of \$6.8 million in accounts receivable from our collaborators, an increase of \$4.5 million in prepaid expenses and other assets, an increase of \$5.1 million in accounts payable and other liabilities due to timing of payments, partially offset by a decrease of \$1.5 million in our operating lease liability and a decrease of \$0.3 million in accrued compensation expense.

Cash used in operating activities for the nine months ended September 30, 2020 was \$48.9 million. Our net income of \$27.4 million included \$78.6 million of unrealized gain on equity securities as a result of the remeasurement of the estimated fair value of our investment in Vaxcyte common stock, and was partially offset by non-cash charges of \$8.8 million for stock-based compensation, \$3.1 million for depreciation and amortization, \$3.2 million for the remeasurement of the vested options under the Call Option Plan, \$0.3 million for the amortization of premium on our marketable securities, and \$0.3 million for financing costs related to the public offering. Cash used in operating activities also reflected a net decrease in operating assets and liabilities of \$13.7 million, comprised of a decrease of \$1.6 million in accounts payable and other liabilities due to timing of payments, a decrease of \$11.6 million in our deferred revenue balance from revenue recognized under our collaboration agreements, an increase of \$1.2 million in accounts receivable from our collaborators, and a \$0.8 million decrease in prepaid expenses and other assets.

Cash Flows from Investing Activities

Cash used in investing activities of \$118.1 million for the nine months ended September 30, 2021 was primarily related to purchases of marketable securities of \$226.1 million and purchases of property and equipment of \$12.8 million, principally for leasehold improvements to the premises under the Sublease, offset partially by maturities and sales of marketable securities of \$120.8 million.

Cash used in investing activities of \$15.2 million for the nine months ended September 30, 2020 was primarily related to purchases of marketable securities of \$114.0 million and purchases of property and equipment of \$5.5 million, principally to support laboratory and manufacturing activities, offset partially by maturities and sales of marketable securities of \$104.3 million.

Cash Flows from Financing Activities

Cash provided by financing activities of \$2.8 million for the nine months ended September 30, 2021 was primarily related to \$2.0 million of proceeds received from the exercise of common stock options, and \$1.8 million of net proceeds received from participants in our employee equity plans, partially offset by a \$1.0 million tax payment related to the net shares settlement of vested restricted stock units.

Cash provided by financing activities of \$124.4 million for the nine months ended September 30, 2020 was primarily related to \$91.4 million of net proceeds from the issuance of common stock from our public offering, \$16.8 million of net proceeds from the sales of common stock pursuant to our ATM, \$25.0 million of gross proceeds from our debt refinancing, and \$1.1 million of proceeds received from participants of our employee stock purchase plan and from the exercise of common stock options, partially offset by a \$10.0 million repayment of the August 2017 Loan.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements, as defined under SEC rules.

JOBS Act Accounting Election

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies.

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

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenues of at least \$1.07 billion, (ii) the date in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th and (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period. As the market value of our common stock that was held by non-affiliates exceeded \$700 million as of June 30, 2021, we will be classified as a large accelerated filer and cease being an emerging growth company as of December 31, 2021.

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 U.S. GAAP. 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 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, 2020.

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 \$254.2 million and \$326.5 million as of September 30, 2021 and December 31, 2020, respectively, which consisted primarily of money market funds, commercial paper, corporate debt securities, asset-based securities, U.S. government 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 \$39.8 million as of September 30, 2021, 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, 2021 would decrease the fair value by \$4.0 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, 2021 and December 31, 2020, we had \$25.0 million and \$24.5 million, respectively, in debt outstanding, net of debt discount. Our debt with Oxford and SVB bears 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%. This debt matures on March 1, 2024 and will be 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, 2021, 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, 2021, 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, 2021 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

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 annual report, 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:

- The COVID-19 pandemic is impacting the availability of routine materials for our business, which has caused us to spend significant effort in sourcing alternatives and otherwise modifying our activities, and it may have even more pronounced and significant impact on our activities in the future.
- 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 timely funding, may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations.
- Our product candidates are in early stages of development and may fail 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[®] Platform and, in particular, our proprietary product candidates, STRO-001 and STRO-002.
- If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.
- 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[®] Platform 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. 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.

- 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
- 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.

Risks Related to Our Business

The COVID-19 pandemic is having an impact on our business, which has caused us to spend significant effort in sourcing alternatives and otherwise modifying our activities.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. A pandemic, including COVID-19, or other public health epidemic poses the risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities in whole or in part for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. In response to the spread of COVID-19, we modified operations in our executive offices with our administrative employees primarily continuing their work outside of those offices, restricted on-site research, development and manufacturing staff to only those required to execute their job responsibilities on-site for prioritized activities, limited the number and proximity of staff in any given laboratory or in our manufacturing facility (except as necessary for particular activities), and implemented multiple work place safety, social distancing and disinfection protocols. Following the guidance of the CDC, OSHA, and applicable state regulations and orders, we have relaxed these safeguards and largely have returned to on-site work. We continue to closely monitor the state of the ongoing pandemic and the guidance provided by applicable governmental authorities and will modify our policies accordingly.

We continue to experience the impact of the COVID-19 pandemic on our business, including delays in the availability of materials routinely used in biologic therapeutic development and manufacturing, which may cause delays in our research, development and/or manufacturing activities, but overall patient enrollment and treatment remains on track. Most notably, certain consumables used in our development and manufacturing processes have been allocated, based on the Defense Priorities and Allocations System, or DPAS, rules currently in effect, first to production of COVID-19 therapeutic and prophylactic products and then next to production of approved products, with production of products under clinical investigation taking last priority. For example, we have not been able to procure certain filters used for GMP manufacture of our and our partners' product candidates in the time frame we were expecting, placing the timeline for manufacture of such product candidates at risk. Further, routine materials such as disposable bags, filters, and chromatography resins have become limited in supply and placed the timeline for development of the process to manufacture another one of our partners' projects at risk. We are attempting to mitigate these risks by ordering sufficient materials to provide a safety stock in reserve and by sourcing some of these materials from our partners' safety stock. We are also exploring developing new manufacturing processes to replace certain materials subject to reallocation under DPAS with equivalent materials that are not subject to reallocation. If these efforts are unsuccessful, or consumable shortages become more pronounced as the pandemic continues, we may experience delays in discovery, development and/or manufacture of our or our partners' products, which could delay our clinical and non-clinical programs. As such, these impacts and any potential future impacts from the COVID-19 pandemic may adversely affect our or our partners' research, development and/or manufacturing activities, which could negatively impact our business, financial condition, and operations.

As a result of the COVID-19 pandemic, or similar pandemics, we may experience disruptions that could severely impact our business, clinical trials and preclinical studies, including:

- additional delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- changes in protocol-specified procedures that lead to missing data (e.g., reduced or postponed patient visits, missed lab tests and scans, and patient discontinuation);

- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine, losing insurance coverage or not accepting home health visits;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical assessments at pre-specified timepoints during the trial and clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the U.S. Food and Drug Administration and comparable foreign regulatory agencies, which may impact approval timelines;
- delays or disruptions in non-clinical experiments and investigational new drug application-enabling good laboratory practice standard toxicology studies;
- limitations on employee resources that would otherwise be focused on the conduct of our research, preclinical studies, clinical trials and manufacturing operations, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions;
- interruption of, or delays in receiving, supplies of our product candidates or precursor molecules or other raw materials and the manufacture or shipment of both drug substance and finished drug product for our product candidates from either us or contract manufacturing organizations due to staffing shortages, production slowdowns, stoppages and disruptions in delivery systems or reallocation of global manufacturing resources to therapeutic or prophylactic treatments for COVID-19 resulting in reduced manufacturing capacity or shortages of raw materials; and
- reduced ability to engage with the medical and investor communities, including due to the cancellation of conferences scheduled throughout the year.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

In addition, the trading prices for our common stock and other biopharmaceutical companies, as well as the broader equity and debt markets, have been highly volatile as a result of the COVID-19 pandemic and the resulting impact on economic activity. As a result, we may face difficulties raising capital when needed, and any such sales may be on unfavorable terms to us.

The COVID-19 pandemic continues to evolve. The extent to which the outbreak may impact our business, clinical trials, research activities, preclinical studies and manufacturing activities will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of COVID-19, the duration of the pandemic, the speed and breadth of mass vaccinations for COVID-19 and the efficacy of such vaccines, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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 enrolled a limited number of patients in our initial clinical trials, have no products approved for commercial sale, have not generated any revenue from commercial product sales and, as of September 30, 2021, had an accumulated deficit of \$295.3 million. For the nine months ended September 30, 2021 and the year ended December 31, 2020, our net loss was \$67.4 million and \$32.1 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. The net loss for the nine months ended September 30, 2021 included the impact of the non-operating, unrealized loss of \$1.9 million related to our holdings of Vaxcyte common stock. The net loss for the year ended December 31, 2020 included the impact of the non-operating, unrealized gain of \$41.5 million related to our holdings of Vaxcyte common stock. 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. 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. 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 commercializing 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.

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 and to manufacture and market products, if any, which are approved for commercial sale. In addition, we expect 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 STRO-001 and STRO-002, and the development of our in-house manufacturing capabilities. Clinical trials for our product candidates will require substantial funds to complete. As of September 30, 2021, we had \$254.2 million in cash, cash equivalents and marketable securities. We expect to incur substantial expenditures in the foreseeable future as we seek to advance STRO-001 and STRO-002 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 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 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 and enforcing patent and other intellectual property claims;
- the costs of manufacturing our product candidates and those of our collaborators using our proprietary XpressCF[®] Platform;
- 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; and
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates and satisfy our obligations as a public company.

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 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 agreements, the sale of equity securities and debt financing. 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, 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. Additional funds may not be available to us on acceptable terms or at all. Subject to limited exceptions, the Loan and Security Agreement we entered into with Oxford and SVB in February 2020, under which we borrowed \$25.0 million, prohibits us from incurring indebtedness without the prior written consent of Oxford or 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 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 early stages of development. In particular, our product candidates, STRO-001 is in the dose escalation phase and STRO-002 is in the dose expansion phase of their respective Phase 1 clinical trials. Also, enrollment began in the second half of 2019 for patients in the Phase 1 clinical trial for CC-99712, a BCMA ADC candidate resulting from our BMS collaboration; and a Phase 1 clinical trial was initiated in the first quarter of 2021 for M1231, a MUC1-EGFR bispecific ADC resulting from our EMD Serono collaboration. 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® Platform;
- delays in submitting investigational new drug applications, or 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 trials;
- harmful side effects or inability of our product candidates to meet efficacy endpoints during clinical trials;
- 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; or
- 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[®] Platform and, in particular, our proprietary product candidates, STRO-001 and STRO-002. 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[®] Platform and our proprietary product candidates, STRO-001 and STRO-002. 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 STRO-001 and STRO-002. 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 STRO-001 and STRO-002 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;

- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates and their components;
- enforcing and defending our intellectual property rights and claims;
- 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; and
- maintaining an acceptable safety profile of our product candidates through clinical trials and following regulatory 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 folate receptor-alpha, or FolR α targeting antibody-drug conjugate, or ADC, using conventional technology that results in a heterogeneous ADC mixture. We have compared STRO-002 to this benchmark molecule in multiple preclinical models. We believe the results of these tests help us understand how the therapeutic index of STRO-002 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 announce and expect, 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 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.

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 are developing a pipeline of product candidates using our proprietary XpressCF[®] Platform. 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[®] Platform is ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our XpressCF[®] Platform is both preliminary and limited.

To date, we have tested our first clinical stage product candidates, STRO-001 and STRO-002, our partner BMS has tested CC-99712, and our partner EMD has tested M1231 in a limited number of clinical trial patients. We may ultimately discover that our XpressCF[®] Platform and any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness. XpressCF[®] 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[®] Platform. 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[®] Platform may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. Although our XpressCF[®] Platform 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 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 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 presented updated data from the dose escalation portion of our STRO-002 Phase 1 trial in May 2021. Based on data from the trial through April 23, 2021, STRO-002 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 treatment-emergent adverse events 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.

If product candidates based on our XpressCF[®] Platform 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 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 interim 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. 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.

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® Platform, which is a new technology. 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.

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® Platform. 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® Platform and resulting product candidates.

Since 2014, we have entered into collaborations with Merck Sharp & Dohme Corp., 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), and BioNova Pharmaceuticals Limited (BioNova) to develop or commercialize certain cancer and other therapeutics. 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® Platform 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 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 Phase 1 clinical trial use of our product candidates STRO-001 and STRO-002 and our partner BMS's CC-99712 product candidate, and our partner EMD Serono's M1231 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 the 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.

Our existing collaborations with Merck, BMS, EMD Serono and BioNova are important to our business. If our collaborators cease development efforts under our existing or future collaboration agreements, 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. Substantially all of our revenue to date has been derived from our existing collaboration agreements with Merck, BMS and EMD Serono, and a significant portion of our future revenue and cash resources is expected to be derived from these agreements 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, 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, Celgene, now BMS, was advancing four preclinical collaboration programs, one of which is CC-99712, an ADC targeting B-cell maturation antigen, or BCMA, for the treatment of multiple myeloma. BMS has worldwide development and commercialization rights with respect to this BCMA ADC, for which the FDA cleared the IND application, and a Phase 1 clinical trial has commenced enrolling patients. However, in 2019, Celgene, now BMS, decided to not exercise the option to acquire U.S. clinical development and commercialization rights to a second collaboration program and subsequently allowed the ex-U.S. rights to three additional collaboration programs (BCMA-CD3, PD1-LAG3, and PD1-TIM3) to revert to us at no cost to us. Therefore, we now solely hold worldwide rights to the three programs. EMD Serono has advanced a collaboration program, M1231, a MUC1-EGFR bispecific ADC, into a Phase 1 clinical trial in the first quarter of 2021. EMD Serono has worldwide rights to M1231 and sole discretion in the clinical development and commercialization of this product. 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. In addition, any dispute or litigation proceedings we may have with our collaborators in the future could delay development programs, create uncertainty as to ownership of intellectual property rights, distract management from other business activities and generate substantial expense.

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 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. 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. 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 linker-warhead with the antibody component of our STRO-001 and STRO-002 product candidates. 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 the cooperation of an existing or future collaborator;
- 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. 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 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 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.

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 is 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.

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.

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.

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, prospects, financial condition and results of operations.

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® Platform 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® Platform. STRO-001 and STRO-002 are our most advanced clinical stage programs 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.

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, 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 non-Hodgkin lymphoma 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. Similarly, as we are developing STRO-002 for a potential indication in patients with elevated FcγR2b expression levels, we may be required to obtain FDA approval or clearance of a companion diagnostic, concurrent with approval of STRO-002, to test for elevated FcγR2b 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 also entered into an agreement to develop diagnostic assays suitable for use as a companion diagnostic for STRO-002. 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. In addition, our partner BMS may be required to develop and obtain regulatory clearance for a companion diagnostic to assess BCMA expression in patients in connection with their development of CC-99712. Similarly, our partner EMD Serono may be required to develop and obtain regulatory clearance for companion diagnostics to assess MUC1 and EGFR expression in patients in connection with their development of M1231.

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® Platform, 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 better funded biopharmaceutical, biotechnological and therapeutics companies, including companies focused on cancer immunotherapies, such as AstraZeneca PLC, BMS, GlaxoSmithKline PLC, Merck, Novartis AG, Pfizer Inc., or Pfizer, Roche Holding Ltd, Sanofi S.A., AbbVie Inc. and companies focused on ADCs, such as Pfizer, GlaxoSmithKline PLC, Daiichi Sankyo Company, Limited, ImmunoGen, Inc., Seagen, Inc., Genentech, Inc., or Genentech, Gilead Sciences Inc., Eisai Co., Ltd., Mersana Therapeutics, Inc., and ADC Therapeutics SA, as well as numerous small companies. Moreover, we also compete with current and future therapeutics developed at universities and other research institutions.

We are aware of several companies that are developing ADCs, cytokine derivatives, bispecific antibodies and cancer immunotherapies. 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 drugs and therapeutics range from monoclonal antibodies such as Genentech's Herceptin; ADCs, such as Genentech's Kadcyla; to immune checkpoint inhibitors such as BMS's Opdivo; 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. With respect to B cell-based malignancies, such as multiple myeloma, the most common treatments are chemotherapeutic compounds, radiation therapy, stem cell transplantation, corticosteroids, immunomodulating agents, and targeted therapy. 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.

Our success largely depends on the continued service of key management, advisors and other specialized personnel, including William J. Newell, our chief executive officer, Edward Albini, our chief financial officer, Trevor J. Hallam, Ph.D., our chief scientific officer, Arturo Molina, M.D., our chief medical officer and Shabbir T. Anik, Ph.D., our chief technical operations officer. 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® 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, 2021, we had 218 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 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 and results of operations.

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 and maintain 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, store and transmit large amounts of confidential information, including intellectual property, proprietary business information health information, and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, 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 network security problems, bugs, viruses, worms, phishing attempts, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures 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, and although believe that these attempts were detected and neutralized prior to any significant impact to our business and we have implemented additional measures to prevent such attacks, 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, although we have not been informed of any resulting breach to our data. 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. 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. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including 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, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. 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. For example, the California Consumer Privacy Act of 2018, or the CCPA, imposes a private right of action for security breaches that could lead to some form of remedy including regulatory scrutiny, fines, private right of action settlements, and other consequences. We would also be exposed to a risk of loss or litigation and potential liability, which could materially 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 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.

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 we entered into in February 2020 with Oxford and SVB 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. 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, the risk of accidental 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, 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 or other natural disasters 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. 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. In addition, it is uncertain if and to what extent various states will conform to the 2017 Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, 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.

We plan to use our current year operating losses to offset taxable income from any revenue generated from operations, including revenue from corporate collaborations. To the extent that our taxable income exceeds any current year operating losses, we plan to use our net operating loss carryforwards to offset income that would otherwise be taxable. 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 generated in tax years beginning after December 31, 2020, is limited to 80% of taxable income. Net operating losses generated in taxable years beginning after December 31, 2017 and beginning on or prior to December 31, 2020 may be carried back up to five years. Net operating losses arising in taxable years beginning after December 31, 2020 may not be carried back under current law. It is uncertain if and to what extent various states will conform to the 2017 Tax Act or the CARES Act.

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 may have experienced other ownership changes in the past, and may 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, 2021, we held Vaxcyte common stock with a fair value of \$39.8 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 the COVID-19 pandemic. 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 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 and enforce patent 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 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 may not be able to apply for patents on certain aspects of our product candidates in a timely fashion or at all. Further, we 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 will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. 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. 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 do not 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.

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® Platform. 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, Russia, 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.

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.

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.

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. 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 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 2023, which has claims relating to methods of treating CD74-positive multiple myeloma with an ADC targeting CD74. As another example, we are aware of another 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. If any of these patents are valid and not yet expired when, and if, we receive marketing approval for STRO-001, 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 STRO-001. 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® Platform 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® Platform 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 technology 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 technology, 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, technology 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.

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.

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.

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 STRO-002 Phase 1 trial focused on ovarian and endometrial cancers in March 2019. 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 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;
- 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; 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. 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, plan 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 expense. 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. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and biologics and to spur innovation, but its ultimate implementation is unclear. 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, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and, subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We 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. The ACA, among other things, (i) subjected therapeutic biologics to potential competition by lower-cost biosimilars by creating a licensure framework for follow-on biologic products, (ii) proscribed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted or injected, (iii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) established annual fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics, (v) established a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts (now 70%) off negotiated prices of applicable brand drugs and therapeutic biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs and therapeutic biologics to be covered under Medicare Part D, (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability, (vii) expanded the entities eligible for discounts under the Public Health program (viii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research and (ix) established a Center for

Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

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." In November 2020, the U.S. Supreme Court held oral arguments on the Fifth Circuit U.S. Court of Appeals decision that held that the individual mandate is unconstitutional. In June 2021, the Supreme Court remanded the case with instructions to dismiss for lack of standing. However, the Supreme Court did not decide the ultimate issue of the validity of the individual mandate. Thus, there may be other efforts to challenge the individual mandate or to challenge, repeal or replace the ACA. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business 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 eliminates 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, including the BBA, will remain in effect through 2029 unless additional Congressional action is taken. The CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. The Consolidated Appropriations Act, 2021 extended the suspension of the 2% Medicare sequester through December 31, 2021. 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 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. At the federal level, the former presidential administration's budget proposal for fiscal year 2021 included a \$135 billion allowance to support legislative proposals seeking to reduce drug process, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower cost generic and biosimilar drugs. In particular, on July 24, 2020 and September 13, 2020, the former presidential administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. The FDA also 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 CMS also issued an interim final rule implementing former presidential administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. 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. It is unclear to what extent these new regulations 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. 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 I 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, as well as 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) 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; effective January 1, 2022, transfers of value to physician assistants, nurse practitioners or clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives must also be reported;
- 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; 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.

Changes in privacy laws, regulations and standards may cause our business to suffer.

We are, and may increasingly become, subject to various laws and regulations, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate. Personal privacy and data security have become significant issues in the United States, Europe and in many other jurisdictions. The regulatory framework for privacy and security issues worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. The CCPA came into effect on January 1, 2020 and became enforceable by the California Attorney General on July 1, 2020, along with related regulations which came into force on August 14, 2020. Additionally, although not effective until January 1, 2023, the California Privacy Rights Act, or the CPRA, which expands upon the CCPA, was passed in the recent election on November 3, 2020. The CCPA has created new individual privacy rights and places increased privacy and security obligations on entities handling personal information. The CPRA significantly modifies the CCPA, including by expanding consumers' rights with respect to certain personal information and creating a new state agency to oversee implementation and enforcement efforts. The CCPA and CPRA may significantly impact our business activities and require substantial compliance costs that adversely affect our business, operating results, prospects and financial condition. Industry organizations also regularly adopt and advocate for new standards in this area. In the United States, these include rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. State laws are changing rapidly and there is discussion in the U.S. of a new comprehensive federal data privacy law to which we would become subject if it is enacted. Additionally, the CCPA has prompted a number of proposals for new federal and state-level privacy legislation, such as in Nevada, Virginia, New Hampshire, Illinois and Nebraska. Such new privacy laws add additional complexity, requirements, restrictions and potential legal risk, require additional investment in resources for compliance programs, and could impact business strategies and the availability of previously useful data.

Internationally, many jurisdictions in which we operate have established their own data security and privacy legal framework with which we or our customers must comply. For example, the EU's General Data Protection Regulation, or GDPR, which became effective in May 2018, greatly increased the European Commission's jurisdictional reach of its laws and adds a broad array of requirements for handling personal information, including, for example, requirements to establish a legal basis for processing, higher standards for obtaining consent from individuals to process their personal information, more robust disclosures to individuals and a strengthened individual data rights regime, requirements to implement safeguards to protect the security and confidentiality of personal information that requires the adoption of administrative, physical and technical safeguards, shortened timelines for data breach notifications to appropriate data protection authorities or data subjects, limitations on retention and secondary use of information, increased requirements pertaining to health data and additional requirements that we impose certain contractual obligations on third-party processors in connection with the processing of the personal information. The GDPR, together with national legislation, regulations and guidelines of the EU member states governing the processing of personal information, impose strict obligations and restrictions on the ability to collect, use, retain, protect, disclose, transfer and otherwise process personal

information. In particular, the GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal information relates, the transfer of personal information out of the European Economic Area, security breach notifications and the security and confidentiality of personal information. The GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater, and other administrative penalties. Additionally, the United Kingdom, or UK, implemented the Data Protection Act effective in May 2018 and statutorily amended in 2019, that substantially implements the GDPR and contains provisions, including UK-specific derogations, for how GDPR is applied in the UK. From the beginning of 2021 (when the transitional period following Brexit expires), we will have to continue to comply with the GDPR and also the Data Protection Act, with each regime having the ability to fine up to the greater of €20 million (£17 million) or 4% of global turnover. The costs of compliance with, and other burdens imposed by, such laws and regulations that are applicable to our business operations may limit the use and adoption of our services, reduce overall demand for them. Changes in these legislations may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment in resources for compliance programs, could impact strategies and availability of previously useful data, and could result in increased compliance costs and/or changes in business practices and policies.

Additionally, on July 16, 2020, the Court of Justice of the European Union, or the Court of Justice, invalidated the European Union-United States, or EU-U.S., Privacy Shield on the grounds that the EU-U.S. Privacy Shield failed to offer adequate protections to EU personal information transferred to the United States. While the Court of Justice upheld the use of other data transfer mechanisms, such as the Standard Contractual Clauses, the decision has led to some uncertainty regarding the use of such mechanisms for data transfers to the United States, and the court made clear that reliance on Standard Contractual Clauses alone may not necessarily be sufficient in all circumstances. The use of Standard Contractual Clauses for the transfer of personal information specifically to the United States also remains under review by a number of European data protection supervisory authorities. For example, German and Irish supervisory authorities have indicated that the Standard Contractual Clauses alone provide inadequate protection for EU-U.S. data transfers. Use of the data transfer mechanisms must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals. The European Data Protection Board, or the EDPB, issued additional guidance regarding the Court of Justice's decision on November 11, 2020 which imposes higher burdens on the use of data transfer mechanisms, such as the Standard Contractual Clauses, for cross-border data transfers.

To comply with this guidance, we may need to implement additional safeguards to further enhance the security of data transferred out of the European Economic Area, which could increase our compliance costs, expose us to further regulatory scrutiny and liability, and adversely affect our business. Further, the European Commission published new versions of the Standard Contractual Clauses in June 2021. Additionally, other countries (e.g., Australia and Japan) have adopted certain legal requirements for cross-border transfers of personal information. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. Further, since the transition period for Brexit ended December 31, 2020, there remains some uncertainty regarding cross-border data transfers from the European Economic Area to the UK. The EU issued two adequacy decisions for such transfers in late June 2021. Some countries also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of delivering our products and services. If we are required to implement additional measures to transfer data from the European Economic Area, this could increase our compliance costs, and could adversely affect our business, financial condition and results of operations.

In many jurisdictions, enforcement actions and consequences for noncompliance are also rising. In addition to government regulation, privacy advocates and industry groups may propose new and different self-regulatory standards that either legally or contractually applies to us. Any inability to adequately address privacy and security concerns, even if unfounded, or comply with applicable privacy and data security laws, regulations and policies, could result in additional cost and liability to us, damage our reputation, and adversely affect our business. Additionally, 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 process 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 do not have a marketing or sales 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. We have only recently initiated our first clinical trials for our first two product candidates. 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 STRO-002, it may not lead to a faster development or regulatory review or approval process.

We have been granted a Fast Track Designation for STRO-002. 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 STRO-002, 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 STRO-002 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, 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. 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 opportunities for grant funding toward clinical trial costs, 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.

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[®] Platform, 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;
- 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.

General Risk Factors

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;
- 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;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters, epidemics, pandemics or contagious diseases, and other calamities;
- 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.

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.

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.

We are an “emerging growth company” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports, registration statements and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously.

We expect to remain an emerging growth company until December 31, 2021. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an “emerging growth company” or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

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

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are required to comply with the SEC's rules that implement Section 404(a) of the Sarbanes-Oxley Act, and are therefore required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Pursuant to Section 404(a), we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To comply with the applicable provisions of Section 404 for this filing, we engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have dedicated internal resources; engaged outside consultants and adopted a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on the Nasdaq Global Market.

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 and Use of Proceeds.

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
10.1	2021 Equity Inducement Plan Document	S-8	333-258603	8/9/2021	99.1	
10.2	Second Amendment to the Exclusive Patent License and Research Collaboration Agreement					X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					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, 2021, 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.

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.

SUTRO BIOPHARMA, INC.

Date: November 9, 2021

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

Date: November 9, 2021

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

**Second Amendment to the
Exclusive Patent License and Research Collaboration Agreement**

This Second Amendment to the Exclusive Patent License and Research Collaboration Agreement between the Parties, effective as of July 23, 2018, and as subsequently amended by Amendment #1, effective as of August 26, 2020 (the "**Agreement**"), is entered into and effective as of the date of last signature below ("**Amendment #2**") by and between SUTRO BIOPHARMA, INC., a corporation organized and existing under the laws of Delaware ("**Sutro**"), and MERCK SHARP & DOHME CORP., a corporation organized and existing under the laws of the State of New Jersey ("**Merck**").

WHEREAS, the Parties desire to amend the Agreement to (i) extend the Research Program Term for the First Research Program in order for the Parties to research and conduct certain preclinical activities for Additional Molecules (as defined below) and (ii) agree to certain additional milestone payments related to PCC Approval by such Additional Molecule, all as more fully set forth below;

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, the Parties agree as follows:

1. Expansion of First Research Program. Section 2.1.1 of the Agreement is amended by adding the following sentences to the end thereof:

“The Parties wish to expand the Research Plan for the First Research Program to enable continued research and preclinical activities to support certain cytokine derivative molecules, including SP10784 ("**Additional Molecules**"); each such molecule an "**Additional Molecule**". The high-level activities to be undertaken by the Parties during the Extended Research Program Term (as defined below) for the Additional Molecules are set forth in the amended Research Plan for the First Research Program which is attached hereto as Schedule 2.1, Part A. Sutro and Merck agree that the Joint Research Committee shall review the Research Plan activities for the Additional Molecules and determine when such Research Plan activities are completed pursuant to Section 2.4.2 of the Agreement.

2.1.1.1 PCC Nomination. Upon completion of the Research Plan activities for the Additional Molecules, the Joint Research Committee shall make a recommendation as to whether an Additional Molecule should be further advanced as a Preclinical Candidate ("**PCC**") and presented for PCC nomination to Merck's internal governance committee. In the event the JRC makes such recommendation to advance the Additional Molecule as a PCC, Merck shall promptly present such Additional Molecule to its internal governance committee for approval ("**PCC Nomination**").

2.1.1.2 PCC Approval. Upon approval by Merck's internal governance committee of the PCC Nomination for an Additional Molecule ("**PCC Approval**"), Sutro and Merck shall commence the activities required to support process development lock ("**Process Development Lock**"). The activities required for Process Development Lock for the Additional Molecule are set forth in the amendment to the Research Plan for the First Research Program which is

attached here to as Schedule 2.1, Part B. The Joint Research Committee, in consultation with the Joint Chemistry, Manufacturing and Controls Committee, shall review the process development activities to be conducted under the amended Research Plan and determine when Process Development Lock has been achieved.”

2. Extension of First Research Program Term. Section 2.1.5.1 of the Agreement is amended by adding the following sentences to the end thereof:

“Notwithstanding the foregoing and the first extension of the First Research Program Term as set forth in the letter agreement, dated March 9, 2020, between the Parties, the Research Program Term for the First Research Program shall be extended until March 31, 2022 and up to sixty (60) days thereafter in the event the Joint Research Committee requires additional time to make a PCC recommendation for the Additional Molecule pursuant to Section 2.1.1.1 and/or to enable PCC Approval by Merck pursuant to Section 2.1.1.2 (“**Extended Research Program Term**”). Further, upon the achievement of PCC Approval by the Additional Molecule, the Research Program Term for the First Research Program shall be automatically extended from March 31, 2022 or such date up to sixty (60) days thereafter, until the earlier of (i) achievement of Process Development Lock by the Additional Molecule as determined by the Joint Research Committee and (ii) December 31, 2023 (“**Subsequent Extended Research Program Term**”).”

3. Payments. Section 7.3.1 of the Agreement is hereby deleted and replaced with the following 7.3.1 and 7.3.1.1:

“7.3.1 One-Time Research Milestones on a per Research Program basis. The one-time research milestone payments set forth in the table below shall be made for each Research Program under this Agreement. In addition, the Parties understand and agree that, prior to the effective date of Amendment #2 to this Agreement, Merck timely paid the one-time research milestone payments below for the First Research Program and that further one-time research milestone payments below shall only be made for other applicable Research Programs under this Agreement.

Milestone Event	Payment to Sutro
1. Upon written notice by Merck pursuant to Section 2.1.5.3 to extend the Research Program Term of a given Research Program for an additional year.	US\$ [*/] Million
2. Initiation of the first IND Enabling Toxicology Study for the first Compound resulting from a given Research Program.	US\$ [*/] Million

7.3.1.1 Milestone Payments for the Extended Research Program Term.

- a. Extended Research Program Term Payment. In accordance with Section 2.1.5.3 and the terms of the Agreement, Merck shall pay to Sutro a one-time, non-refundable, non-creditable payment for the Extended Research Program Term in the

amount of US\$ [*/] within thirty (30) days after the Effective Date of this Amendment #2.

- b. PCC Approval Payments. With respect to the First Research Program, upon achievement of PCC Approval by the Additional Molecule, Merck shall pay to Sutro a one-time, non-refundable, non-creditable payment in the amount of US\$ [*/]. Further, upon achievement of Process Development Lock by the Additional Molecule, Merck shall pay to Sutro a one-time, non-refundable, non-creditable payment in the amount of US\$ [*/]. Written notification of PCC Approval and Process Development Lock and payment of such milestones shall be made by Merck in accordance with the terms set forth in Section 7.3.5. Notwithstanding the obligations set forth in Section 2.1.5.3, the Parties agree that Merck shall not be required to make any additional payments to Sutro in the event there is no PCC Approval of the Additional Molecule.
- c. FTE Payments. During the Extended Research Program Term and Subsequent Extended Research Program Term (if applicable), Merck shall pay Sutro for the FTEs and material pass-through costs required to carry out the First Research Program activities as set forth in the Research Plan pursuant to Section 2.3 of the Agreement.”

4. Except as expressly amended hereby, all of the terms and conditions of the Agreement remain in full force and effect. Terms not defined in this Amendment #2 shall have the meaning given such definitions in the Agreement.

[remainder of this page intentionally left blank]

IN WITNESS WHEREOF, the Parties hereto have executed this Amendment #2 as of the date of last signature below.

MERCK SHARP & DOHME CORP.

By:

Name: Sunil A. Patel

Title: SVP, Corporate Development and BD&L

Date: September 28, 2021

SUTRO BIOPHARMA, INC..

By:

Name:

Title:

Date:

AMENDMENT TO THE RESEARCH PLAN FOR FIRST RESEARCH PROGRAM (SCHEDULE 2.1)

[]*

**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 9, 2021

/s/ William J. Newell

William J. Newell
Chief Executive Officer
(Principal Executive Officer)

**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 9, 2021

/s/ Edward C. Albini

Edward C. Albini

Chief Financial Officer

(Principal Accounting Officer and Principal Financial Officer)

**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, 2021 (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 9, 2021

/s/ William J. Newell

William J. Newell

Chief Executive Officer

(Principal Executive Officer)

**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, 2021 (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 9, 2021

/s/ Edward C. Albini

Edward C. Albini

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)