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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

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	**47-0926186**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
310 Utah Avenue, Suite 150 South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 392-8412

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 ☒

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	STRO	Nasdaq Global Market

As of May 10, 2019, the registrant had 22,925,441 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)

	March 31, 2019 (Unaudited)	December 31, 2018 (See Note 2)
Assets		
Current assets:		
Cash and cash equivalents	$ 26,616	$ 125,298
Marketable securities—current	143,953	79,194
Accounts receivable, net (including amounts from related parties of $1,188 and $959 as of March 31, 2019 and December 31, 2018, respectively)	3,338	2,489
Prepaid expenses and other current assets	2,628	2,965
Total current assets	176,535	209,946
Property and equipment, net	9,926	10,934
Marketable securities, non—current	13,747	-
Other long-term assets	2,235	2,244
Restricted cash	15	15
Total assets	$ 202,458	$ 223,139
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,395	$ 3,061
Accrued compensation	2,502	6,217
Deferred revenue—current	19,024	21,574
Debt—current	5,766	4,724
Other current liabilities	443	847
Total current liabilities	31,130	36,423
Deferred revenue, non—current	31,520	44,599
Deferred rent	469	476
Debt—non-current	8,500	10,000
Other noncurrent liabilities	121	102
Total liabilities	71,740	91,600
Stockholders' equity:		
Common stock, $0.001 par value — 300,000,000 shares authorized as of March 31, 2019 and December 31, 2018; 22,925,441 and 22,848,184 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	23	23
Additional paid-in-capital	284,890	281,891
Accumulated other comprehensive gain (loss)	56	(47)
Accumulated deficit	(154,251)	(150,328)
Total stockholders' equity	130,718	131,539
Total liabilities and stockholders' equity	$ 202,458	$ 223,139

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 March 31,	
	2019	2018
	(dollars in thousands)	
Revenues (including amounts from related parties of $4,916 during the three months ended March 31, 2019, and $4,084 during the three months ended March 31, 2018)	$ 8,629	$ 5,793
Operating expenses		
Research and development	15,180	13,082
General and administrative	7,715	4,414
Total operating expenses	22,895	17,496
Loss from operations	(14,266)	(11,703)
Interest income	1,176	40
Interest and other expense, net	(1,160)	(383)
Net loss	$ (14,250)	$ (12,046)
Net loss per share, attributable to common stockholders, basic and diluted	$ (0.62)	$ (25.75)
Weighted-average shares used in computing net loss per share attributable to common stockholders	22,865,075	467,719

See accompanying notes to unaudited interim condensed financial statements.

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

	Three Months Ended March 31,	
	2019	**2018**
Net loss	$ (14,250)	$ (12,046)
Other comprehensive income (net of tax):		
Unrealized gain on available-for-sale securities	103	—
Comprehensive loss	$ (14,147)	$ (12,046)

See accompanying notes to unaudited interim condensed financial statements.

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

For the three months ended March 31, 2019

	Common Stock		Additional Paid-In-	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	(Deficit) Equity
Balances at December 31, 2018	22,848,184	$ 23	$ 281,891	$ (47)	$ (150,328)	$ 131,539
Exercise of common stock options and common stock warrants for cash	8,347	—	42	—	—	42
Issuance of common stock under Employee Stock Purchase Plan	68,910	—	671	—	—	671
Stock-based compensation expense	—	—	2,286	—	—	2,286
Net unrealized loss on available-for- sale securities	—	—	—	103	—	103
Adoption of new accounting standards					10,327	10,327
Net loss	—	—	—	—	(14,250)	(14,250)
Balances at March 31, 2019	22,925,441	$ 23	$ 284,890	$ 56	$ (154,251)	$ 130,718

For the three months ended March 31, 2018

	Redeemable Convertible Preferred Stock		Common Stock		Note Receivable from	Additional Paid-In-	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Stockholder	Capital	Loss	Deficit	(Deficit) Equity
Balances at December 31, 2017	173,750,421	$ 102,505	465,330	$ —	$ (208)	$ 6,218	$ —	$ (115,011)	$ (109,001)
Exercise of common stock options and common stock warrants for cash	—	—	6,619	—	—	38	—	—	38
Stock-based compensation expense	—	—	—	—	—	249	—	—	249
Vesting of early exercised shares	—	—	—	—	—	14	—	—	14
Net loss	—	—	—	—	—	—	—	(12,046)	(12,046)
Balances at March 31, 2018	173,750,421	$ 102,505	471,949	$ —	$ (208)	$ 6,519	$ —	$ (127,057)	$ (120,746)

See accompanying notes to unaudited interim condensed financial statements.

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

	Three Months Ended March 31,	
	2019	**2018**
Operating activities		
Net loss	$ (14,250)	$ (12,046)
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,137	1,162
Accretion of discount on marketable securities	(600)	–
Stock-based compensation	2,286	264
Reduction of the liability attributable to a research, development and commercialization agreement	(127)	–
Accretion of debt discount	42	38
Revaluation of SutroVax option liability	14	–
Other	17	35
Changes in operating assets and liabilities:		
Accounts receivable	(849)	(2,531)
Prepaid expenses and other assets	336	(130)
Accounts payable	476	(189)
Accrued compensation	(3,715)	980
Other liabilities	397	44
Deferred rent	(7)	21
Deferred revenue	(5,302)	(2,658)
Net cash used in operating activities	(20,145)	(15,010)
Investing activities		
Purchases of marketable securities	(119,053)	–
Maturities of marketable securities	37,750	–
Sales of marketable securities	3,500	–
Purchases of property and equipment	(276)	(364)
Net cash used in investing activities	(78,079)	(364)
Financing activities		
Payment of deferred offering costs	–	(52)
Payment of debt	(500)	–
Proceeds from exercise of common stock options	42	38
Net cash used in by financing activities	(458)	(14)
Net decrease in cash, cash equivalents and restricted cash	(98,682)	(15,388)
Cash, cash equivalents and restricted cash at beginning of period	125,313	22,035
Cash, cash equivalents and restricted cash at end of period	$ 26,631	$ 6,647
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 330	$ 300
Supplemental disclosure of non-cash investing and financing information:		
Vesting of early exercised shares	$ –	$ 14
Purchase of property and equipment included in accounts payable	63	5
Deferred initial public offering costs included in accounts payable	–	53
Embedded interest associated with program fees	$ 860	$ –

See accompanying 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 for cancer and autoimmune disorders. The Company was incorporated on April 21, 2003, and was formerly known as Fundamental Applied Biology, Inc. The Company 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 March 31, 2019, there was an accumulated deficit of $154.3 million. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities and costs to operate as a public company.

As of March 31, 2019, the Company had unrestricted cash, cash equivalents and marketable securities of $184.3 million, which are available to fund future operations. The Company will need to raise additional capital to support the completion of its research and development activities and its operations.

The Company believes that its unrestricted cash, cash equivalents and marketable securities as of March 31, 2019 will be sufficient for the Company to continue as a going concern for at least one year from the issuance date of its unaudited interim condensed financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). 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 balance sheets and the amount 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 multiple element arrangements, stock-based compensation expense, fair value of redeemable convertible preferred stock warrant liabilities (prior to closing of the Company's IPO), income taxes and certain accrued liabilities. Actual results could differ from such estimates or assumptions.

Unaudited Interim Condensed Financial Statements

The interim condensed balance sheet as of March 31, 2019, the condensed statements of operations and comprehensive loss for the three months ended March 31, 2019 and 2018, the condensed statements of stockholders' (deficit) equity for the three months ended March 31, 2019 and 2018 and the condensed statements of cash flows for the three months ended March 31, 2019 and 2018, are unaudited. The unaudited interim condensed financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's financial position as of March 31, 2019, its results of operations and comprehensive loss for the three months ended March 31, 2019 and 2018, the changes in stockholders' (deficit) equity for the three months ended March 31, 2019 and 2018 and cash flows for the three months ended March 31, 2019 and 2018. The financial data and the other financial information contained in these notes to the condensed financial statements related to the three-month periods are also unaudited. The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other future annual or interim period. The condensed balance sheet as of December 31, 2018 included herein was derived from the audited financial statements as of that date. The condensed financial statements 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, 2018.

Adoption of New Accounting Principles

Revenue Recognition

On January 1, 2019, the Company adopted Accounting Standards Update (ASU) No. 2014-09 (Topic 606), Revenue from Contracts with Customers ("ASC 606"). ASC 606 supersedes the guidance in ASC 605, Revenue Recognition. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

In the adoption of ASC 606, the Company used the practical expedients to analyze only those contracts that were still active contracts as of January 1, 2019 and evaluated those contracts based on the cumulative contract modifications through that date. The Company does not believe that the use of the practical expedients has or will have a material impact on its transition adjustment or its prospective accounting. The Company adopted ASC 606 on a modified retrospective basis under which it recognized the cumulative effect of adoption of $10.3 million as a transition adjustment to reduce opening accumulated deficit; therefore, the periods prior to the adoption date of ASC 606 have not been restated. If the Company had continued to use ASC 605 during 2019, revenue would have been $7.6 million in the three months ended March 31, 2019, as compared to the $8.6 million reported.

The impact of the adoption of Topic 606 on select unaudited condensed balance sheet as of January 1, 2019 was as follows (in thousands):

	December 31, 2018	Adjustments Due to the Adoption of Topic 606	January 1, 2019
Condensed Balance Sheet Data			
Accounts receivable, net	$ 2,489	$ –	$ 2,489
Total current assets	209,946	–	209,946
Deferred revenue, current	21,574	(2,124)	19,450
Deferred revenue, non-current	44,599	(8,203)	36,396
Total liabilities	91,600	(10,327)	81,273
Accumulated deficit	(150,328)	10,327	(140,001)

The impact of the adoption of ASC 606 on select unaudited condensed balance sheet and condensed statement of operations line items as of and for the three months ended March 31, 2019 were as follows:

	As of and for the three months ended March 31, 2019 (in thousands)		
	As reported	Adjustments Increase / (Decrease)	Balances without the Adoption of Topic 606
Condensed Balance Sheet Data			
Deferred revenue, current	19,024	(3,171)	22,195
Deferred revenue, non-current	31,520	(7,309)	38,829
Total liabilities	71,740	(10,480)	82,220
Accumulated deficit	(154,251)	10,480	(164,731)
Condensed Statement of Operations data			
Revenues	8,629	1,013	7,616
Interest and other expense, net	(1,160)	860	(300)
Net loss	(14,250)	(153)	(14,403)

Nonemployee Share-Based Payment

In June 2018, the FASB issued ASU 2018-07 (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by

aligning it with the accounting for share-based payments to employees, with certain exceptions. Some of the areas of simplification apply only to nonpublic entities. The Company adopted this guidance on January 1, 2019. The adoption of this guidance did not have a material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13 (Topic 820), Fair Value Measurement: Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement, reducing certain disclosures concerning the fair value hierarchy. The guidance is effective for the Company in annual periods beginning after December 15, 2019, and interim periods within those annual periods. The Company does not expect the adoption of this guidance to have a material impact on the Company's condensed financial statements.

In June 2016, the FASB issued ASU 2016-13 (Topic 326), Financial Instruments Credit Losses, which requires consideration of a broader range of reasonable and supportable information to developing credit loss estimates. The guidance is effective for the fiscal year beginning January 1, 2020, including interim periods within that fiscal year. The Company does not expect the adoption of this guidance to have a material impact on the Company's condensed consolidated financial statements.

Leases

In February 2016, the FASB issued ASU 2016-02 (Topic 842), Leases ("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. For public entities, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. The guidance is effective for nonpublic business entities for fiscal years and interim periods beginning after December 15, 2019, with early adoption permitted. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, ASC842 will be effective for the Company from January 1, 2020. Originally, entities were required to adopt ASC 842 using a modified retrospective transition method. However, in July 2018, the FASB issued ASU 2018-11 (Topic 842), Leases: Targeted Improvements, which provides entities with an additional transition method. Under ASU 2018-11, entities have the option of initially applying ASC 842 at the adoption date, rather than at the beginning of the earliest period presented, and recognizing the cumulative effect of applying the new standard as an adjustment to beginning retained earnings in the year of adoption while continuing to present all prior periods under previous lease accounting guidance. The Company expects to elect this transition method at the adoption date of January 1, 2020. The Company is currently evaluating the impact of adopting this guidance on the Company's financial statements. The Company currently expects that its operating lease commitments will be subject to the new standard and recognized as right-of-use assets and operating lease liabilities upon adoption of this standard, which will increase the total assets and total liabilities that it reports relative to such amounts prior to adoption.

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.

	March 31,	
	2019	2018
	(in thousands)	
Cash and cash equivalents	$ 26,616	$ 6,632
Restricted cash	15	15
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	$ 26,631	$ 6,647

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 minimizes 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 recognizes revenue when its customers obtain control of the promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services.

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's 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.

For arrangements that include multiple performance obligations, the Company allocates the transaction price to the identified performance obligations based on the standalone selling price ("SSP") of each distinct performance obligation. In instances where SSP is not directly observable, the Company develops assumptions that require judgment to determine the SSP for each performance obligation identified in the contract. These key assumptions may include full-time equivalent ("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 Sales: 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.

The Company's revenue recognition policies under ASC 605 are described in the Annual Report on Form 10-K for the year ended December 31, 2018.

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:

	March 31, 2019			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets:				
Money market funds	$ 26,721	$ 26,721	$ –	$ –
Commercial paper	55,085	–	55,085	–
Corporate debt securities	38,998	–	38,998	–
Asset-backed securities	30,862	–	30,862	–
U.S. government agency securities	32,755	–	32,755	–
Total	$ 184,421	$ 26,721	$ 157,700	–

	December 31, 2018			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets:				
Money market funds	$ 116,202	$ 116,202	$ –	$ –
Commercial paper	26,625	–	26,625	–
Corporate debt securities	11,774	–	11,774	–
Asset-backed securities	16,899	–	16,899	–
U.S. government agency securities	23,896	–	23,896	–
Total	$ 195,396	$ 116,202	$ 79,194	$ –

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 composed of money market funds.

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 U.S. government agency 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. Level 3 liabilities that were measured at estimated fair value on a recurring basis consisted of the redeemable convertible preferred stock warrant liability (prior to closing of the Company's IPO).

Upon closing of the IPO on October 1, 2018, all of the outstanding redeemable convertible preferred stock warrants either expired or were converted into common stock warrants, which resulted in the reclassification of the redeemable convertible preferred stock warrant liability to other income and additional paid-in-capital.

4. Cash Equivalents and Marketable Securities

Cash equivalents and marketable securities consisted of the following:

	March 31, 2019		
	Amortized Cost Basis	Unrealized Gains	Fair Value
	(in thousands)		
Money market funds	$ 26,721	$ –	$ 26,721
Commercial paper	55,085	–	55,085
Corporate debt securities	38,977	21	38,998
Asset-based securities	30,842	20	30,862
U.S. government agencies	32,740	15	32,755
Total	184,365	56	184,421
Less amounts classified as cash equivalents	(26,721)	–	(26,721)
Total marketable securities	$ 157,644	$ 56	$ 157,700

	December 31, 2018		
	Amortized Cost Basis	Unrealized Losses	Fair Value
	(in thousands)		
Money market funds	$ 116,202	$ –	$ 116,202
Commercial paper	26,625	–	26,625
Corporate debt securities	11,795	(21)	11,774
Asset-based securities	16,920	(21)	16,899
U.S. government agencies	23,901	(5)	23,896
Total	195,443	(47)	195,396
Less amounts classified as cash equivalents	(116,202)	–	(116,202)
Total marketable securities	$ 79,241	$ (47)	$ 79,194

As of March 31, 2019, $13.7 million of marketable securities had maturities of more than one year and are classified as long-term assets. As of December 31, 2018, no marketable securities had maturities of more than one year.

5. Collaboration and License Agreements and Supply Agreements

The Company has entered into collaboration and license agreements with various pharmaceutical and biotechnology companies. As described in Note 2, on January 1, 2019, the Company adopted ASC 606, Revenue from Contracts with Customers, which supersedes the guidance in ASC 605, Revenue Recognition. The Company recognized revenue under ASC 606 for the three months ended March 31, 2019 and under ASC 605 for the three months ended March 31, 2018. In accordance with the collaboration agreements, the Company recognized revenue as follows:

	Three Months Ended March 31,	
	2019	2018
	(dollars in thousands)	
Celgene Corporation (“Celgene”) (1)	$ 1,575	$ 4,084
Merck Sharp & Dohme Corporation (“Merck”)—related party	4,635	-
Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name “EMD Serono”)	2,138	1,709
SutroVax—related party	281	-
Total revenue	$ 8,629	$ 5,793

(1) Celgene was a related party during the three months ended March 31, 2018 as it held more than 10% of the Company’s common stock for the periods presented until the IPO closed on October 1, 2018.

The following table presents the changes in the Company’s deferred revenue balance from collaboration agreements during the three months ended March 31, 2019:

	Three Months Ended March 31, 2019
	(in thousands)
Deferred revenue—December 31, 2018	$ 66,173
Transition adjustment related to adoption of ASC 606	(10,327)
Recognition of revenue in current period	(5,302)
Deferred revenue—March 31, 2019	$ 50,544

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 $19.0 million of deferred revenue over the next twelve months.

There have been no material changes to the Company’s collaboration agreements in the three months ended March 31, 2019, except as described below.

Celgene Agreement

In September 2014, the Company signed a Collaboration and License Agreement with Celgene 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™.

Upon signing the Celgene Agreement, the Company received an upfront, nonrefundable payment totaling $83.1 million.

In March 2015, the Company received a $15.0 million contingent payment ("March 2015 payment") from Celgene that provided Celgene a right to access certain of the Company's technology for use in conjunction with certain Celgene intellectual property. In June 2016, the Company received a $25.0 million milestone ("June 2016 payment") upon completion of certain preclinical activities. Additionally, in June 2016, the Company earned a $10.0 million substantive milestone for certain manufacturing accomplishments.

In August 2017, the Company entered into an amended and restated collaboration and license agreement with Celgene to refocus the collaboration on four programs that are advancing through preclinical development, including an ADC program targeting B cell maturation antigen ("BCMA ADC").

In August 2017, the Company received an option fee payment of $12.5 million. In September 2017, the Company earned a $10.0 million milestone for certain manufacturing accomplishments, which payment was received from Celgene in October 2017. In December 2018, the Company earned a $10.0 million milestone for certain manufacturing accomplishments, which payment was received from Celgene in the same month.

The Company has received and will be eligible to receive financial support for research and development services assigned to the Company by Celgene, based on an agreed-upon level of FTE personnel effort and related reimbursement rate, which will be recognized as revenue as the related reimbursable activities approved by Celgene and the Company are performed by the Company.

Under the terms of the Celgene Agreement, the Company is entitled to earn development and regulatory contingent payments for each of the four programs under the collaboration, and royalties on sales of any commercial products that may result from the Celgene Agreement. For licensed products for which Celgene holds worldwide rights, the Company is eligible to receive contingent development and regulatory payments and tiered royalties. Additionally, for licensed products for which Celgene holds ex-U.S. rights, the Company will also be eligible to receive contingent development and regulatory payments and tiered royalties. The contingent payments under the Celgene Agreement are not considered to be substantive milestones because the receipt of such payments is based solely on the performance of Celgene.

Celgene may terminate the Celgene Agreement at any time with 120 days' prior written notice. Either the Company or Celgene has the right to terminate the Celgene Agreement based on the other party's uncured material breach, challenge of the validity and enforceability of intellectual property, or bankruptcy.

In accounting for this arrangement under ASC 606, applying the practical expedients, the Celgene Agreement was treated as a single arrangement that had been modified in 2017.

Given the modification of the Celgene Agreement in 2017, the Company determined that the remaining deferred revenue balance of $8.2 million as of the date of the modification, related to certain prior Celgene payments to the Company, together with the $12.5 million option fee payment received in August 2017, would comprise the transaction price of $20.7 million to be allocated on a relative basis among the Company's performance obligations based on the Company's best estimate of each SSP or fair value. The Company identified the three performance obligations relating to the Celgene Agreement as: (1) access by Celgene to worldwide development and commercialization rights on the first collaboration program to achieve investigational new drug ("IND") clearance; (2) the Company's estimated future services on the collaboration Joint Steering Committee ("JSC"); and (3) Celgene's use of certain technology and the option to acquire worldwide development and commercialization rights to a second collaboration program.

Based on its estimated SSP, relative to the total estimated SSP values of all identified performance obligations, the portion of the transaction price allocated to the first performance obligation was $8.2 million, which performance obligation was satisfied as of the modification date of the Celgene Agreement, as the BCMA ADC program was the most advanced of the four collaboration programs and estimated by the Company to be the one for which Celgene would first achieve IND clearance and gain worldwide development and commercialization rights. The second and third performance obligations identified above were unsatisfied as of the modification date of the Celgene Agreement. The Company determined the portion of the transaction price to be allocated to the JSC performance obligation was $0.2 million. Revenue related to such performance obligation will be recognized by the Company over the estimated period during which it will perform its JSC services. The Company determined that the portion of the transaction price to be allocated to the third performance obligation, which provided Celgene with an option to acquire worldwide development and commercialization rights to a

second collaboration program, was $12.3 million. Revenue related to such performance obligation will be recognized over the period from August 2017 through September 2020, the estimated term of the use of the technology.

Upon the adoption of ASC 606 on January 1, 2019, the Company recorded a $4.5 million adjustment to decrease its deferred revenue for performance obligations that were satisfied in prior periods, with the corresponding adjustment being a reduction to the Company's accumulated deficit. For the three months ended March 31, 2019, the Company recognized approximately $1.1 million of revenue under ASC 606.

As of March 31, 2019 and December 31, 2018, there was $5.9 million and $11.4 million, respectively, of deferred revenue related to payments received by the Company under the Celgene Agreements.

2018 Celgene Master Services Agreement

In March 2018, the Company entered into a Master Development and Clinical Manufacturing Services Agreement (the "2018 Celgene Master Services Agreement") with Celgene, wherein Celgene requested the Company to provide development, manufacturing and supply chain management services, including clinical product supply. The consideration for the services is based on an agreed-upon level of FTE personnel effort and related reimbursement rate in addition to agreed-upon pricing for the clinical product supply.

Upon adoption of ASC 606 on January 1, 2019, this was deemed a modification of the arrangement and the consideration terms were at fair value and materials are to be provided on an as agreed upon basis. Accordingly the Company will recognize revenue upon the performance of such services.

For the three months ended March 31, 2019 and 2018, the Company earned $0.5 million and $1.9 million, respectively, under the 2018 Celgene Master Services Agreement.

2018 Merck Agreement – Related Party

In July 2018, the Company entered into an Exclusive Patent License and Research Collaboration Agreement (the "2018 Merck Agreement") with Merck, a related party of the Company, to jointly develop up to three research programs focusing on cytokine derivatives for cancer and autoimmune disorders.

Under the 2018 Merck Agreement, the Company received from Merck a non-refundable, non-creditable, upfront payment of $60.0 million in August 2018 for access to the Company's technology and the identification and preclinical research and development of two target programs, with an option for Merck to engage the Company to continue these activities for a third program upon the payment of an additional amount. Under ASC 606, the Company identified the five performance obligations under the 2018 Merck Agreement as: (1) access to certain intellectual property rights; (2) performance of services related to the first target program; (3) performance of services related to the second target program; (4) the Company's estimated future services on the collaboration JSC; and (5) a material right pertaining to the performance of services related to a contingent third target program upon the payment of an additional amount. The transaction price of $60.0 million was allocated among the performance obligations using the Company's best estimate of SSP for each of the associated performance obligations. Based on its estimated SSP, relative to the estimated total SSP values of all identified performance obligations, the portion of the transaction price allocated to the first performance obligation was $7.3 million. It was determined that such performance obligation was satisfied as of the effective date of the 2018 Merck Agreement, and accordingly revenue associated with this performance obligation would, pursuant to ASC 606, have been recorded on the effective date of the Merck Agreement. Revenue allocated to the first and second target programs, which totaled $47.1 million is being 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. As it pertains to the JSC performance obligation, the revenue allocated to such performance obligation was $0.7 million, which is being recognized as revenue on a proportion of performance basis using FTE cost as the basis, and such effort is expected to be incurred on a relatively consistent basis throughout the term of the 2018 Merck Agreement. The Company allocated $4.9 million of the transaction price to the material right associated with the contingent third program. Recognition of the $4.9 million as revenue will begin upon commencement of the third program or upon the determination that the contingent third target program is no longer a performance obligation.

Additionally, under ASC 606, the Company determined there was a financing component associated with the $60.0 million upfront payment, and has calculated total interest of $7.6 million on the unearned revenue portion beyond one year from the effective date of the agreement, which amount is expected to be recognized as revenue over the estimated service period for the first and second target programs .

For the three months ended March 31, 2019, the Company recognized $3.0 million of revenue associated with the $60.0 million upfront payment, $0.9 million related to the interest component described above, and $0.8 million for FTE funding provided by Merck.

Upon adoption of ASC 606 on January 1, 2019, the Company recorded a $6.3 million adjustment to decrease its deferred revenue for performance obligations that were satisfied in prior periods, with the corresponding adjustment being a reduction to the Company's accumulated deficit.

As of March 31, 2019 and December 31, 2018, there was $43.7 million and $53.0 million, respectively, of deferred revenue related to the transaction price under the 2018 Merck Agreement. As of both March 31, 2019 and December 31, 2018, the Company had a $0.9 million receivable from Merck related to the 2018 Merck Agreement, which is included in accounts receivable on the balance sheet.

The Company is also eligible to receive aggregate milestone payments of up to $1.6 billion, assuming the development and sale of all therapeutic candidates 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.

Merck may terminate the 2018 Merck Agreement at any time with 60 days' prior written notice. Either the Company or Merck has the right to terminate the 2018 Merck Agreement based on the other party's uncured material breach or bankruptcy.

During 2018, Merck purchased 74,794,315 shares of the Company's Series E redeemable convertible preferred stock at a price per share of $0.2674, resulting in gross proceeds of $20.0 million. In a private placement concurrent with the Company's IPO, which was completed on October 1, 2018, Merck purchased 666,666 shares of common stock at a price per share of $15.00, resulting in proceeds of approximately $10.0 million. As a result of the investments in the Company's equity, Merck is a related party.

EMD Serono Agreement

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

Upon signing the Collaboration Agreement, the Company received an upfront, nonrefundable, non-creditable payment totaling $10.0 million. Upon signing the MDA Agreement, the Company received an additional upfront, nonrefundable payment totaling $10.0 million and will receive financial support for research and development services to be provided by the Company, based on an agreed-upon level of FTE personnel effort and related reimbursement rate.

The Company is eligible to receive up to $52.5 million for each product developed under the MDA Agreement, primarily from pre-commercial contingent payments. 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. The MDA Agreement term expires on a product-by-product and country-by-country basis. Upon expiration, EMD Serono will have a fully paid-up, royalty-free, perpetual, and irrevocable non-exclusive license, with the right to grant sublicenses, under certain Company intellectual property rights. EMD Serono may terminate the MDA Agreement at any time with 90 days' prior written notice or upon the inability of the Company to provide EMD Serono access to a specified number of cancer drug targets. Either the Company or EMD Serono has the right to terminate the MDA Agreement based on the other party's uncured material breach or bankruptcy.

Upon adoption of ASC 606 on January 1, 2019, the Company identified a single performance obligation under the MDA Agreement, which consists of the technology license, research and development activities and JSC participation over the estimated period of the agreement, as each are interrelated and not distinct within the overall context of the agreement. The transaction price of $20.0 million is being recognized on a proportion of performance basis, using the FTE cost as the basis of measurement, with such performance expected to occur over the estimated service period of the agreement, from June 2014 through May 2019.

The Company recorded a $0.6 million adjustment to increase its deferred revenue for performance obligations that were unsatisfied in prior periods, with the corresponding adjustment being an increase to the Company's accumulated deficit.

As of March 31, 2019 and December 31, 2018, there was $0.9 million and $1.7 million, respectively, of deferred revenue related to payments received by the Company under the MDA Agreement. As of March 31, 2019 and December 31, 2018, the Company had $1.5 million and $0.9 million, respectively, of receivables from EMD Serono related to the MDA Agreement, which are included in accounts receivable on the balance sheet.

SutroVax, Inc. Supply Agreement – Related Party

In May 2018, the Company entered into a Supply Agreement (the "Supply Agreement") with SutroVax, Inc., ("SutroVax"), wherein SutroVax engaged the Company to supply extracts and custom reagents, as requested by SutroVax. The pricing is based on an agreed upon cost plus arrangement. For the three months ended March 31, 2019, the Company recognized $0.3 million under the Supply Agreement. As of March 31, 2019 and December 31, 2018, the Company had $0.3 million and $49,000 in receivables, respectively, from SutroVax related to the Supply Agreement, which is included in accounts receivable on the balance sheet.

Upon adoption of ASC 606 on January 1, 2019, as the Company has a right to consideration from SutroVax in an amount that corresponds directly with the value of the Company's supplied extracts and custom reagents, the Company's sales of extracts and custom reagents in discrete unit form are recognized as revenue at the time when such supplies are shipped to SutroVax, in line with the practical expedient in ASC 606-10-55-18.

The Company has not received any returns to date and believes that returns of its products will continue to be minimal. As such, the Company does not record any reserve for the returns but will continue to evaluate the need for a reserve each reporting period.

The Leukemia & Lymphoma Society, Inc.

In August 2018, the Company entered into a Research, Development and Commercialization Agreement (the "LLS Agreement") with The Leukemia & Lymphoma Society ("LLS"), under which LLS has agreed to contribute up to $6.0 million in clinical development funding for STRO-001, the Company's CD74-targeting ADC to treat relapsed and/or refractory multiple myeloma and non-Hodgkin lymphoma. The funding will be provided in installments based upon the achievement of funding milestones, with any excess funding above actual expenditures refundable to LLS. The initial payment of $0.5 million was received by the Company upon execution of the LLS Agreement. As of March 31, 2019, the Company had received total payments from LLS of $1.0 million, of which this full amount was reflected as an offset against other income (expense). In consideration for the funding to the Company under the LLS Agreement, the Company may be required in the future to make payments to LLS, contingent upon reaching certain pre-specified late-stage clinical development, regulatory and commercialization milestones and should the Company enter into certain transactions relating to STRO-001 with a third party, which payments in the aggregate could total up to a maximum $19.5 million, assuming receipt by the Company from LLS of the entire $6.0 million in clinical development funding for STRO-001. As of March 31, 2019, no events have occurred that would require such payments to LLS. The LLS Agreement terminates upon the earlier of (a) fulfillment of all payment obligations by both parties or (b) 12 years after the effective date. LLS may terminate the LLS Agreement at any time with 60 days' prior written notice. Either the Company or LLS has the right to terminate the LLS Agreement based on the other party's uncured material breach.

The Company concluded that the contingent payments were an embedded derivative and recorded a related liability. As of March 31, 2019, and December 31, 2018, the Company recorded $0.1 million as other noncurrent liabilities, with the corresponding amount recorded in the statement of operations as other income (expense), net. The value of the embedded derivative was estimated, at each reporting period, based on the probability-adjusted and discounted value of future payments.

6. Loan and Security Agreement

In August 2017, the Company entered into a loan and security agreement with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB") under which it borrowed $15.0 million (the "August 2017 Loan"). The loan is due in 30 monthly installments from March 2019 through its repayment in August 2021, with interest-only monthly payments until March 2019. The Company commenced repayment of the loan in March 2019.

The August 2017 Loan is secured by all assets of the Company, excluding intellectual property and certain other assets. The August 2017 Loan contains customary affirmative and restrictive covenants, including with respect to fundamental transactions, the incurrence of additional indebtedness, grant liens, pay any dividend or make any distributions to the Company's holders, make investments, merge or consolidate with any other person, or engage in transactions with its affiliates, but does not include any financial covenants. The loan agreement provides that an event of default will occur if, among other triggers, any circumstances occur that could reasonably be expected to result in a material adverse effect on the Company's business, operations or condition, or on its ability to perform its obligations under the loan. The loan agreement also includes customary representations and warranties, other events of default and termination provisions.

As of March 31, 2019, the Company has classified $5.8 million of the outstanding debt balance as current and $8.5 million as non-current, which reflects the scheduled repayment terms under the August 2017 Loan.

The interest charges on the loan are based on a floating rate that equals the greater of 7.39% or the sum of the 30-day U.S. Dollar London Interbank Offered Rate ("LIBOR") plus 6.40%. For the three months ended March 2019, the average interest rate was 8. 90%. In addition, the Company will make a final payment equal to 3.83% of the original principal amount of the loan, or $0.6 million, which is being accrued over the term of the loan using the effective-interest method. As of March 31, 2019, total interest expense accrued was $ 0.3 million.

In connection with the August 2017 Loan, the Company issued to Oxford and SVB a warrant to purchase the Company's Series D-2 redeemable convertible preferred stock (the "2017 Warrant"). The 2017 Warrants were later converted into warrants to purchase Series E redeemable convertible preferred stock in May and July 2018, and upon the Company's IPO on October 1, 2018, all Series E redeemable convertible preferred stock warrants were converted to warrants to purchase 46,359 shares of common stock. The estimated fair value upon issuance of the 2017 Warrant of $0.3 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 repayment period of the loan using the effective-interest method.

During the three months ended March 31, 2019 and 2018, the Company recorded interest expense related to this loan of $0.4 million and $0.4 million, respectively, and interest related to the accretion of debt discount of $42,000 and $38,000, respectively.

7. Related-Party Transactions

Upon the Company's IPO, Celgene's ownership of the Company's outstanding equity interest decreased to less than 10%. As a result, starting October 1, 2018, the Company ceased to reflect balances and transactions associated with Celgene as a related party in its financial statements. Transactions with Celgene for the three months ended March 31, 2019 and 2018, respectively, are described in Note 5.

Related party transactions with Merck, which owned 11.9% of the Company's outstanding equity interest both as of March 31, 2019 and December 31, 2018, are described in Note 5.

Three directors of the Company have performed consulting services for the Company, which consulting services were terminated prior to the Company's IPO in September 2018. During the three months ended March 31, 2019, the Company made no payment to these three directors relating to consulting services. During the three months ended March 31, 2018, the Company paid $15,000, $7,500 and $7,500, respectively, to these three directors relating to their consulting services.

Investment in SutroVax, Inc. ("SutroVax")

In December 2013, the Company and Johnson & Johnson Innovation, through the Johnson & Johnson Development Corporation, provided initial co-funding for a new company, SutroVax. SutroVax leverages the Company's proprietary integrated cell-free protein synthesis platform, XpressCF™, to develop novel vaccines for a broad range of disease targets. The Company had $0.3 million and $49,000 in receivables due from SutroVax as of March 31, 2019 and December 31, 2018, respectively, which were included in accounts receivable on the condensed balance sheet.

As of both March 31, 2019 and December 31, 2018, the Company held a 5.6% common stock ownership interest in SutroVax, respectively, on a fully-diluted basis, with a carrying value of $0 and was accounted for under the cost method.

SutroVax qualifies as a variable interest entity. However, the Company maintains only shared power to direct the activities that most significantly impact the performance of SutroVax. Therefore, the Company is not considered the primary beneficiary and consolidation is not required.

See Note 5, SutroVax, Inc. Supply Agreement for discussion of the supply arrangement entered into with SutroVax in May 2018 and related revenue recognized for the three months ended March 31, 2019.

8. Stockholders' Equity (Deficit)

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 had reserved common stock, on an if-converted basis, for issuance as follows:

	March 31, 2019	December 31, 2018
Common stock options issued and outstanding	3,874,914	3,111,718
Common stock awards issued and outstanding	464,900	311,240
Remaining shares reserved for issuance under 2004 and 2018 Equity Incentive Plan	2,742,059	2,525,610
Shares reserved for issuance under 2018 Employee Stock Purchase Plan	389,571	230,000
Warrants to purchase common stock	71,813	71,813
Total	7,543,257	6,250,381

Preferred Stock

Effective October 30, 2018, the Company had 10,000,000 shares of preferred stock authorized with a par value of $0.001. No shares of preferred stock were outstanding as of March 31, 2019.

Warrants

During the period from 2008 to 2012, the Company issued various warrants for the purchase of redeemable convertible preferred stock in connection with debt financings and the issuance of redeemable convertible preferred stock.

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 described above 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 to warrants to purchase common stock on a 1-for-0.0370 basis. All Series E redeemable convertible preferred warrants were converted to warrants to purchase common stock on a 1-for-0.0275 basis.

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

2004 Equity Incentive Plan and 2018 Equity Incentive 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 has 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, 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 1,142,409 shares on January 1, 2019. As of March 31, 2019, the Company had 2,742,059 shares available for grant under the 2018 Plan.

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

	Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contract Term (Years)	Aggregate Intrinsic Value
Balances at December 31, 2018	3,111,718	$ 13.74	8.76	$ 1,088
Granted	777,350	$ 10.50		
Exercised	(8,347)	$ 5.08		
Canceled	(5,807)	$ 14.93		
Balances at March 31, 2019	3,874,914	$ 13.11	8.77	$ 2,450

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 months ended March 31, 2019, the aggregate intrinsic value of stock options exercised was $46,116, determined at the date of the option exercise. For the three months ended March 31, 2018, the aggregate intrinsic value of stock options exercised was $60,000, 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:

	Three Months Ended March 31,	
	2019	2018
Expected term (in years)	5.05-7.01	5.97-6.08
Expected volatility	72.89%-74.89%	58.00 %
Risk-free interest rate	2.40%-2.55%	2.72%-2.73%
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 months ended March 31, 2019 was $5.86 per share and during the three months ended March 31, 2018, was $8.39 per share. The total fair value of options vested during the three months ended March 31, 2019 was $1.7 million, and for the three months ended March 31, 2018 was $0.2 million.

Restricted Stock Units

During the three months ended March 31, 2019, the Company granted 154,900 shares of restricted common stock, or RSUs, to certain employees. These RSUs will become fully vested over four years in March 2023. As of March 31, 2019, no RSUs had vested.

A summary of the status and activity of non-vested RSUs at March 31, 2019 is as follows:

	Number of shares	Weighted Average Grant-Date Fair Value
Non-vested December 31,2018	311,240	$ 15.20
Granted	154,900	$ 11.45
Canceled	(1,240)	$ 14.14
Non-vested March 31,2019	464,900	$ 13.82

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, the day that the Form S-1 related to the IPO was declared effective, 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 increase automatically on January 1st of each of the first ten calendar years after the effective date by the number of shares equal to the lesser of 1% of the total outstanding shares of the Company's common stock as of the immediately preceding December 31 (rounded to the nearest whole share) or a number of shares as may be determined by the Company's board of directors. As a result, common stock reserved for issuance under the ESPP was increased by 228,481 shares on January 1, 2019. 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 initial ESPP purchase date by the Company's eligible employees was March 15, 2019.

The fair value of the ESPP shares is estimated using the Black-Scholes option pricing model. For the three months ended March 31, 2019, the fair value of ESPP shares was estimated using the following assumptions:

	Three Months Ended March 31, 2019
Expected term (in years)	0.5
Expected volatility	74.89 %
Risk-free interest rate	2.44 %
Expected dividend	–

As of March 31, 2019, 68,910 shares purchase had been made and 389,571 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.

For the three months ended March 31, 2019 and 2018, the Company recorded $1.7 million and $0.2 million, respectively, of stock-based compensation expense related to the stock options granted under the Company's Equity Incentive Plans, $0.5 million and none, respectively, of stock-based compensation expense related to the RSUs and $0.1 million and none, respectively, of stock-based compensation expense related to the ESPP.

As of March 31, 2019, unrecognized stock-based compensation expense related to the unvested stock options and RSUs granted was $22.5 million and $5.5 million, respectively. The remaining unrecognized compensation cost is expected to be recognized over a weighted-average period of 3.4 years and 2.7 years, respectively. As of March 31, 2019, there is no unrecognized stock-based compensation expense related to the ESPP.

Total stock-based compensation expense recognized was as follows:

	Three Months Ended March 31,	
	2019	2018
Research and development	$ 411	$ 48
General and administrative	1,875	201
Total	$ 2,286	$ 249

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 months ended March 31, 2019 and 2018 was immaterial.

2017 Call Option Plan

In February 2017, the Company adopted a 2017 Call Option Plan to grant selected employees, officers, directors and consultants (collectively, the "Participants") options to purchase shares of the common stock of SutroVax, an unconsolidated investee of the Company. The Company has reserved 450,000 shares of SutroVax common stock as of

March 31, 2019 for issuance under the program. The call options vest 25% on each of January 1, 2017, 2018, 2019, and 2020, and expire one year from the vesting date.

Using the Black-Scholes option-valuation model, the call options are measured at fair value on grant date and at each reporting period prior to their vesting, with cost recognized over the requisite service period as compensation cost. Any changes in the fair value subsequent to the vesting date are recognized in other income (expense), net in the statement of operations. Call options covering 420,000 shares have been granted with an exercise price of $0.76 per share. As of March 31, 2019, 315,000 of such options had vested, 210,000 were exercised and 105,000 were outstanding and unvested. As of December 31, 2018, 210,000 of such options had vested and were exercised and 210,000 were outstanding and unvested.

The amounts recognized as compensation expense related to the 2017 Call Option Plan for the three months ended March 31, 2019 and 2018, respectively, were $18,000 and $15,000.

The amounts recognized as other income (expense) related to the 2017 Call Option Plan for the three months ended March 31, 2019 and 2018, respectively, were $4,000 and zero.

10. Net Loss Per Share

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

	Three Months Ended March 31,	
	2019	**2018**
Numerator:		
Net loss, basic and diluted	$ (14,250)	$ (12,046)
Net loss	$ (14,250)	$ (12,046)
Denominator:		
Shares issued in computing net loss per share, basic and diluted	22,865,075	467,719
Net loss per share, basic and diluted	$ (0.62)	$ (25.75)

The following common stock equivalents were excluded from the computation of diluted net loss per share for the three months ended March 31, 2019 and 2018, because including them would have been antidilutive:

	As of March 31,	
	2019	**2018**
Redeemable convertible preferred stock	–	5,063,404
Common stock options and awards issued and outstanding	4,339,814	820,875
Warrants to purchase redeemable convertible preferred stock	–	93,527
Warrants to purchase common stock	71,813	1,099
Total	4,411,627	5,978,905

11. Subsequent Events

As related to the Celgene Agreement discussed in Note 5, Celgene was advancing four preclinical collaboration programs, one of which is an ADC targeting B-cell maturation antigen ("BCMA") for the treatment of multiple myeloma. Celgene has worldwide development and commercialization rights with respect to this BCMA ADC.

The U.S. Food and Drug Administration recently cleared the IND application for the BCMA ADC, which was discovered and manufactured by the Company and which is the first collaboration program IND. The Company will continue to be responsible for clinical supply manufacturing and certain development services for this BCMA ADC and is eligible to receive from Celgene 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.

With respect to the remaining three collaboration programs (BCMA-CD3, PD1-LAG3 and PD1-TIM3), Celgene has decided to not retain the option to acquire U.S. clinical development and commercialization rights to a second

collaboration program. Celgene is therefore not paying the Company the $12.5 million option maintenance fee due on IND clearance for the first collaboration program, described above. Consequently, the U.S. clinical development and commercialization rights to the other three collaboration programs remain owned by the Company, without any further option to Celgene. For any products resulting from these three programs, Celgene will own ex-U.S. development and commercialization rights and will be obligated to pay the Company development and regulatory contingent payments and tiered royalties ranging from mid to high single digit percentages.

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, 2018. 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 regarding 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 offering, 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 and site-specific conjugation 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 targets, 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 lymphoma, or NHL, and STRO-002, an ADC directed against folate receptor-alpha, or FolRα, for patients with ovarian and endometrial cancers. STRO-001 is currently enrolling patients in a Phase 1 trial, with initial safety data expected in mid-2019 and initial efficacy data expected by year end 2019. In October 2018, we were granted Orphan Drug Designation by the U.S. Food and Drug Administration, or FDA, for STRO-001 for the treatment of multiple myeloma. We began enrolling patients in a STRO-002 Phase 1 trial focused on ovarian and endometrial cancers in March 2019, with initial safety data expected by year end 2019. We have also entered into multi-target, product-focused collaborations with leaders in the field of oncology, i ncluding a cytokine derivatives collaboration with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, or Merck, an ADC targeting B-cell maturation antigen, or BCMA, and an immuno-oncology directed alliance with Celgene Corporation, or Celgene, and an oncology-focused collaboration with Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name "EMD Serono").

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 Merck, Celgene and EMD Serono, the issuance and sale of redeemable convertible preferred stock, our initial public offering, or IPO, of common stock and debt proceeds.

On October 1, 2018, we closed our IPO and issued and sold an aggregate of 5,667,000 shares of common stock at a price of $15.00 per share for gross proceeds of approximately $85.0 million. We received net proceeds from the IPO of approximately $74.4 million, after underwriting discounts, commissions and offering expenses. In addition to the shares of common stock sold in the IPO, we concurrently sold in a private placement to Merck, 666,666 shares of common stock at the IPO offering price of $15.00 per share, for proceeds of approximately $10.0 million.

We have no products approved for commercial sale and have not generated any revenue from commercial product sales. We had a net loss of $14.3 million and $12.0 million for the three months ended March 31, 2019 and 2018, respectively. Although we had net income for the year ended December 31, 2016 of $1.7 million, we cannot assure you that we will ever have net income again or that we will generate positive cash flow from operating activities. As of March 31, 2019, we had an accumulated deficit of $154.3 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, receipt and revenue recognition of upfront, milestones and other collaboration agreement payments.

Recent Developments

As previously disclosed under the amended and restated collaboration and license agreement with Celgene, or Celgene Agreement, Celgene was advancing four preclinical collaboration programs, one of which is an ADC targeting BCMA, for the treatment of multiple myeloma. Pursuant to the Celgene Agreement, Celgene has worldwide development and commercialization rights with respect to this BCMA ADC.

The FDA recently cleared the investigational new drug, or IND, application for the BCMA ADC, which was discovered and manufactured by us and which is the first collaboration program IND. We will continue to be responsible for clinical supply manufacturing and certain development services for this BCMA ADC and are entitled to development and regulatory contingent payments and tiered royalties from Celgene for this BCMA ADC.

With respect to the remaining three collaboration programs (BCMA-CD3, PD1-LAG3 and PD1-TIM3), Celgene has decided to not retain the option to acquire U.S. clinical development and commercialization rights to a second collaboration program. Celgene is therefore not paying us the $12.5 million option maintenance fee due on IND clearance for the first collaboration program, described above. Consequently, the U.S. clinical development and commercialization rights to the other three collaboration programs remain owned by us, without any further option to Celgene. For any products resulting from these three programs, Celgene will own ex-U.S. development and commercialization rights and will be obligated to pay us development and regulatory contingent payments and tiered royalties ranging from mid to high single digit percentage.

Financial Operations Overview

Total 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 Celgene, Merck and EMD Serono, and to a lesser extent, from manufacturing, supply and services and products we provide to Celgene and SutroVax, Inc., or SutroVax.

As described in Note 2 to our Condensed Financial Statements, on January 1, 2019, we adopted ASC 606, Revenue from Contracts with Customers. ASC 606 supersedes the guidance in ASC 605, Revenue Recognition. We adopted ASC 606 on a modified retrospective basis under which we recognized the $10.3 million cumulative effect of adoption as a reduction to the opening accumulated deficit balance. Revenue for the three months ended March 31,2018 was recorded under ASC 605, while revenue for the three months ended March 31, 2019 was recorded under ASC 606. If we had continued to use ASC 605 during 2019, revenue would have been $7.6 million in the three months ended March 31, 2019, as compared to the $8.6 million actually recorded for the period.

Collaboration revenue

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 our 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.

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.

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. We use 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 us over the estimated service performance period.

License Grants: For collaboration arrangements that include a grant of a license to our intellectual property, we consider whether the license grant is distinct from the other performance obligations included in the arrangement. For licenses that are distinct, we recognize revenues from nonrefundable, upfront payments and other consideration allocated to the license when the license term has begun and we have 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, we assess 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, we re-evaluate 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 us upon the initiation of a clinical study or filing for or receipt of regulatory approval, we review the relevant facts and circumstances to determine when we should update the transaction price, which may occur before the triggering event. When we update the transaction price for milestone and contingent payments, we allocate 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. Our collaborators generally pay milestones and contingent payments subsequent to achievement of the triggering event.

Research and development services: For amounts allocated to our research and development obligations in a collaboration arrangement, we recognize 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 Sales: We provide materials and reagents, clinical materials and services to certain of our 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 us.

Our revenue recognition policies under ASC 605 are described in our Annual Report on Form 10-K for the year ended December 31, 2018.

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 facility and capabilities. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time consuming. The actual probability of success for our product candidates may be affected by a variety of factors including: the safety and efficacy of our product candidates, early clinical data, investment in our clinical programs, the ability of collaborators to successfully develop our licensed product candidates, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates.

The following table summarizes our research and development expenses incurred during the 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 services, and other consulting costs.

	Three Months Ended March 31,	
	2019	**2018**
Internal costs:		
Research and drug discovery	$ 4,445	$ 3,677
Process and product development	2,421	2,038
Manufacturing	4,900	3,996
Clinical development	430	291
Total internal costs	12,196	10,002
External Program Costs:		
Research and drug discovery	225	235
Toxicology and translational science	480	509
Process and product development	89	89
Manufacturing	913	1,521
Clinical development	1,277	726
Total external program costs	2,984	3,080
Total research and development expenses	$ 15,180	$ 13,082

General and Administrative

Our general and administrative expenses consist primarily of personnel costs, expenses for outside professional services, including legal, human resource, 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.

Interest Income

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

Interest Expense and Other Expense, Net

Interest expense includes interest incurred on our debt and amortization of debt issuance costs. Additionally, under ASC 606, the Company identified a financing component under the Merck 2018 Agreement and recorded interest expense associated with the upfront payment.

Other expense, net in the three months ended March 31, 2019 primarily includes increases from the remeasurement of our derivative liability. In the three months ended March 31, 2018, the remeasurement of our liabilities related to our redeemable convertible preferred stock warrants was zero. We adjusted the liability for changes in estimated fair value until the earlier of the exercise of the warrants, expiration of the warrants, or conversion of the redeemable convertible preferred stock warrants upon the completion of our IPO, into common stock warrants. With the completion of our IPO on October 1, 2018, the redeemable convertible preferred stock warrant liability was reclassified to additional paid-in-capital and we will no longer record any related periodic fair value adjustments.

Comparison of the Three Months Ended March 31, 2019 and 2018

	Three Months Ended March 31,			Change
	2019	2018	Change	(%)
	(dollars in thousands)			
Revenues (including amounts from related parties of $4,916 during the three months ended March 31, 2019, and $4,084 during the three months ended March 31, 2018)	$ 8,629	$ 5,793	$ 2,836	49%
Operating expenses				
Research and development	15,180	13,082	2,098	16%
General and administrative	7,715	4,414	3,301	75%
Total operating expenses	22,895	17,496	5,399	31%
Loss from operations	(14,266)	(11,703)	(2,563)	22%
Interest income	1,176	40	1,136	*
Interest and other expense, net	(1,160)	(383)	(777)	*
Net loss	$ (14,250)	$ (12,046)	$ (2,204)	18%

* Percentage not meaningful

Revenue

We have recognized revenue as follows during the periods indicated:

	Three Months Ended March 31,			Change
	2019	2018	Change	(%)
	(dollars in thousands)			
Celgene Corporation (“Celgene”) (1)	$ 1,575	$ 4,084	$ (2,509)	(61)%
Merck Sharp & Dohme Corporation (“Merck”)—related party	4,635	-	4,635	*
Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name “EMD Serono”)	2,138	1,709	429	25%
SutroVax—related party	281	-	281	*
Total revenue	$ 8,629	$ 5,793	$ 2,836	49%

(1) Celgene was a related party during the three months ended March 31, 2018 as it held more than 10% of our common stock for the periods presented until the closing of our IPO on October 1, 2018.

* Percentage not meaningful

Under ASC 606, total revenue increased by $2.8 million, or 49%, during the three months ended March 31, 2019 compared to the three months ended March 31, 2018, due primarily to the inception of the 2018 Merck Agreement which added revenue of $4.6 million, of which $0.5 million represents additional revenue earned under ASC 606, along with a $0.9 million increase in revenue related to the financing component to the upfront payment. Further, supply and other revenue from SutroVax increased by $0.3 million, and due to the adoption of ASC 606, the Company recorded an additional $0.3 million in license fee and research development services from EMD Serono. This was offset by a $2.5 million decrease in option fees, research and development services, and clinical materials and services from Celgene, of which $0.7 million was due to the change from ASC 605 to ASC 606 .

Research and Development Expense

Research and development expense increased by $2.1 million, or 16%, during the three months ended March 31, 2019 compared to the three months ended March 31, 2018. The increase was due primarily to increases of $1.5 million in compensation-related expenses due to higher headcount and $1.0 million in preclinical research and clinical development expenses, of which $0.5 million was related to external clinical trial services for STRO-001 and STRO-002.

General and Administrative Expense

General and administrative expense increased by $3.3 million, or 75%, during the three months ended March 31, 2019 compared to the three months ended March 31, 2018. The increase was due primarily to increases of $2.4 million in personnel-related expenses, $0.5 million in legal, insurance and external audit fees, and $0.2 million in licenses and other fees associated with being a public company.

Interest Income

Interest income increased by $1.1 million during the three months ended March 31, 2019 compared to the three months ended March 31, 2018, due primarily to a higher cash balance resulting from the proceeds from the Series E financing, the upfront payment received under the 2018 Merck Agreement, and combined net proceeds from the completion of our IPO and the private placement of common stock to Merck.

Interest Expense and Other Expense, Net

Interest expense and other expense, net increased by $0.8 million during the three months ended March 31, 2019 compared to the three months ended March 31, 2018, due primarily to interest expense associated with a financing component under ASC 606 related to the 2018 Merck Agreement.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have incurred net losses, except for 2016, and negative cash flows from operations. Prior to our IPO, our operations have been financed primarily by payments received from our collaborators, net proceeds from the sale and issuance of our preferred stock, and debt proceeds. As of March 31, 2019, we had $184.3 million in cash, cash equivalents and marketable securities, and outstanding debt of $14.3 million, which is net of $0.2 million unamortized debt discount, and an accumulated deficit of $154.3 million.

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 preclinical 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. Because of 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:

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Cash used in operating activities	$ (20,145)	$ (15,010)
Cash used in investing activities	(78,079)	(364)
Cash used in financing activities	(458)	(14)
Decrease in cash and cash equivalents	$ (98,682)	$ (15,388)

Cash Flows from Operating Activities

Cash used in operating activities for the three months ended March 31, 2019 was $20.1 million. Our net loss of $14.3 million was decreased by non-cash charges of $2.3 million for stock-based compensation and $1.1 million for depreciation and amortization, which were offset partially by a $0.6 million increase in the accretion of discount on our marketable securities and a $0.1 million reduction of the liability attributable to the arrangement with The Leukemia & Lymphoma Society. Cash used in operating activities also reflected a net decrease in operating assets and liabilities of $8.7 million, due to a decrease in our deferred revenue balance of $5.3 million from revenue recognized under our collaboration agreements, a decrease of $3.7 million in accrued compensation expense primarily due to bonuses paid in connection with certain goal achievements, and an increase in accounts receivable of $0.8 million from higher research and development services revenues from our collaborators. This was offset partially by a decrease in $0.3 million in prepaid expenses and other current assets, a $0.5 million increase in accounts payable due to timing of payments, and a 0.4 million increase in other liabilities of which $0.3 million was contributions received from participants of our employee stock purchase plan offset against $0.7 million in purchases made from our employee stock purchase plan.

Cash used in operating activities for the three months ended March 31, 2018 was $15.0 million. Our net loss of $12.0 million was decreased by non-cash charges of $1.2 million for depreciation and amortization and $0.3 million for stock-based compensation. Cash used in operating activities reflected a net decrease in operating assets and liabilities of $4.5 million, primarily due to a decrease in our deferred revenue balance of $2.7 million from the recognition of revenue from our collaboration agreements, an increase in accounts receivables of $2.5 million due to higher research and development services revenues from our collaborators, and a decrease in accounts payable of $0.2 million due to timing of payments. This was offset partially by an increase in $0.1 million in prepaid expenses and other current assets primarily due to payments made to contract research organizations related to STRO-001, and an increase of $1.0 million in accrued bonus compensation driven primarily by higher headcount.

Cash Flows from Investing Activities

Cash used in investing activities of $78.1 million for the three months ended March 31, 2019 was primarily related to purchases of marketable securities of $119.1 million and purchases of property and equipment of $0.3 million, principally for laboratory and manufacturing equipment, offset partially by maturities and sales of marketable securities of $41.3 million.

Cash used in investing activities of $0.4 million for the three months ended March 31, 2018 was primarily related to purchases of property and equipment, principally for laboratory and manufacturing equipment and leasehold improvements.

Cash Flows from Financing Activities

Cash used in financing activities of $0.5 million for the three months ended March 31, 2019 was related to commencement of the repayment of the August 2017 Loan in March 2019.

Cash used in financing activities of $14,000 for the three months ended March 31, 2018 was primarily related to the $52,000 payment of deferred offering costs in connection with our IPO, offset by proceeds of $38,000 from the issuances of common stock from the exercise of stock options.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements, as defined under SEC rules. While we have an investment classified as variable interest entity, its purpose is not to provide off-balance sheet financing.

Critical Accounting Policies and Estimates

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

We believe that the assumptions and estimates associated with revenue recognition, research and development expenditures, stock-based compensation and redeemable convertible preferred stock warrants have the most significant impact on our condensed financial statements. Therefore, we consider these to be our critical accounting policies and estimates.

Other than as the result of the adoption of the new revenue recognition guidance under ASC 606 as described in Note 2, Adoption of New Accounting Principles, to our Condensed Financial Statements, 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, 2018.

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 (1) the last day of our first fiscal year (a) in which we have total annual gross revenues of at least $1.07 billion, or (b) 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, (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period and (3) December 31, 2023.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitati ve 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 $184.3 million and $204.5 million as of March 31, 2019 and December 31, 2018, respectively, which consisted of money market funds, commercial paper, corporate debt securities, asset-based securities and U.S. government agency securities. Such interest earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant.

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 interest rates during any of the periods presented would not have had a material impact on our financial statements. We do not believe that our cash, cash equivalents or marketable securities have a significant risk of default or illiquidity.

As of March 31, 2019, and December 31, 2018, we had $14.3 million and $14.7 million, respectively, in debt outstanding, net of debt discount. Our debt with Oxford and SVB bears interest at a floating rate that equals the greater of 7.39% or the sum of the 30-day U.S. Dollar LIBOR plus 6.40% and has a maturity date of August 1, 2021. 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. Cont rols and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosures controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of March 31, 2019. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2019, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

Management determined that, as of March 31, 2019, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1 . Legal Proceedings.

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

Item 1A. Risk Factors.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this quarterly report, 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.

Risks Related to Our Business

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

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

To date, we have enrolled a limited number of patients in our initial clinical trials, evaluating the safety of our first and second clinical stage product candidates, STRO-001 and STRO-002, have no products approved for commercial sale, have not generated any revenue from commercial product sales and, as of March 31, 2019, had an accumulated deficit of 154.3 million. For the three months ended March 31, 2019 and the year ended December 31, 2018, our net loss was $14.3 million and $35.3 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. 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 product candidates STRO-001, our initial clinical program, and STRO-002, our second clinical program, and the development of our in-house manufacturing capabilities. Clinical trials for our product candidates will require substantial funds to complete. As of March 31, 2019, we had $184.3 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 facility 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, or the Loan and Security Agreement, we entered into with Oxford and SVB in August 2017 under which we borrowed $15.0 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 most advanced product candidate, STRO-001, is in the initial stages of dose escalation in clinical trial patients. We began enrolling patients in a STRO-002 Phase 1 trial in March 2019. 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 U.S. Food and Drug Administration, or 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 transfer successfully 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;
- 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 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 lead 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 lead 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 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.

Additionally, we have created a benchmark folate receptor-alpha, or FolRα 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. However, we cannot be certain that our benchmark molecule is the same as the molecule we are attempting to recreate, and the results of the tests comparing our benchmark molecule to STRO-002 may be different than the actual results of a head-to-head test of STRO-002 against a competitor molecule. Additional preclinical and clinical testing will be needed to evaluate the therapeutic index of STRO-002 and to understand its 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, as a result, 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, 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. As a result, 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 cl eavable 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. 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., Kenilworth, NJ, USA, or Merck, Celgene Corporation, or Celgene, and Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name “EMD Serono”) to develop 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. For example, in January 2019, Bristol-Myers

Squibb announced the entry into a definitive agreement to acquire Celgene, with the intent of creating a leading focused specialty biopharma company. Celgene and Bristol-Myers Squibb stockholders voted to approve the combination of the two companies in April 2019 . The transaction is expected to complete in the third quarter of 2019, subject to customary closing conditions and regulatory approvals. 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, 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, Celgene and EMD Serono 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 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, Celgene 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 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 was advancing four preclinical collaboration programs, one of which is an ADC targeting B-cell maturation antigen, or BCMA, for the treatment of multiple myeloma. Celgene has worldwide development and commercialization rights with respect to this BCMA ADC, for which the FDA recently cleared the IND application. Celgene has decided to not retain the option to acquire U.S. clinical development and commercialization rights to a second collaboration program. Celgene is therefore not paying us the $12.5 million option maintenance fee due on IND clearance for the first collaboration program, described above. 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 coll aborations 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. 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.

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 or unstable political environments. If we or our contract manufacturers were to encounter any of these difficulties, 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 and timely availability of raw materials. 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 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 FolRα 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 FolRα expression. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on third parties to perform these functions. We do not currently have any agreement in place with any third party to develop or commercialize companion diagnostics for any of our product candidates. 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.

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, Bristol-Myers Squibb Company, or BMS, GlaxoSmithKline PLC, Merck & Co., Inc., or Merck, Novartis AG, Pfizer Inc., or Pfizer, Roche Holding Ltd, Sanofi S.A and companies focused on ADCs, such as Pfizer, ImmunoGen, Inc., or Immunogen, Seattle Genetics, Inc., or Seattle Genetics, and Genentech, Inc., or Genentech, 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 lead 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 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. 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 and immunomodulating agents. 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 have significantly greater financial, technical, manufacturing, marketing, sales and supply 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 March 31, 2019, we had 154 full-time employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in product development and have just begun our first clinical trials for our first two product candidates. 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 no sales, marketing or 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 inter national 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 or 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 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 or 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 noncompli ance 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.

We depend on our information technology systems, and any failure of these systems, or those of our CROs or other contractors or consultants we may utilize, could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, 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 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, 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 confi dential 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, 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 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 Te chnology 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, which could materially adversely affect our business, 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 and certain other assets. 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 August 1, 2021 maturity date, at which time all amounts borrowed will be due and payable.

The Loan and Security Agreement contains customary affirmative and negative covenants, indemnification provisions and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain certain intellectual property rights. The negative covenants include, among others, restrictions on transferring or licensing our assets, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on our assets, in each case subject to customary exceptions. If we default under the Loan and Security Agreement, the lenders will be able to declare all obligations immediately due and payable and take control of our collateral, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. 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 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 counties of San Francisco and 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, medical epidemic, 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 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 or other event 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.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage points change (by value) in the ownership of its equity over a rolling three-year period), the corporation’s ability to use its pre-change net operating loss, or NOL, carryforwards and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. We have experienced such ownership changes in the past and may experience such ownership changes in the future, some of which are outside our control.

As of December 31, 2018, we had federal NOL carryforwards of approximately $114.0 million, and our ability to utilize those NOL carryforwards could be limited by an “ownership change” as described above, which could result in increased tax liability to our company.

On December 22, 2017, the current U.S. presidential administration, signed into law the Tax Cuts and Jobs Act of 2017, or the Tax Reform Act. The legislation significantly changes U.S. tax law by, among other things, lowering the corporate income tax rates. The Tax Reform Act permanently reduces the U.S. corporate income tax rate from a maximum of 35% to a flat 21% rate, effective January 1, 2018. Additionally, the Tax Reform Act will no longer allow deductions for compensation in excess of $1.0 million for certain employees, even if paid as commissions or performance-based compensation. We may be subject to these limitations as provided for under Section 162(m) of the Code in the future. The Tax Reform Act also limits the amount taxpayers are able to deduct for federal NOL carryforwards generated in taxable years beginning after December 31, 2017 to 80% of the taxpayer’s taxable income. The law also generally repeals all carrybacks. However, any NOLs generated in taxable years after December 31, 2017 can be carried forward indefinitely. Losses arising in taxable years beginning before December 31, 2017 may still be carried back two years and are subject to their current expiration period. As of December 31, 2018, we had approximately $88.7 million of federal NOLs that were generated prior to 2018, which will expire at various dates beginning in 2032, if not used to reduce income taxes payable in the future. Federal NOLs generated by us subsequent to 2017 may only offset 80% of taxable income.

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 m odified retrospective method. This will impact the comparability of our financial results which might lead investors to draw incorrect conclusions which 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 paten t 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. If valid and not yet expired when, and if, we receive marketing approval for STRO-001, we may need to seek a license to this patent, which may not be available on commercially reasonable terms or at all. Failure to receive a license 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 a nd 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; 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 strategies, 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. For example, certain policies of the current U.S. presidential administration may impact our business and industry. Namely, the current U.S. presidential administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, the current U.S. presidential administration ordered a hiring freeze for all executive departments and agencies, including the FDA, which prohibited the FDA from filling employee vacancies or creating new positions. Under the terms of the executive order, the freeze was to remain in effect until implementation of a plan recommended by the Director for the Office of Management and Budget, or OMB, in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. While the general hiring freeze was lifted on April 12, 2017, the FDA remained under a hiring freeze until May 25, 2017. However, the fiscal 2018 budget proposal for the FDA still calls for overall reductions in the FDA workforce, mostly through attrition. We believe an under-staffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, the current U.S. presidential administration issued an executive order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This executive order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the executive order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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 new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts 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.

The current U.S. presidential administration and U.S. Congress have sought, and we expect they will continue to, seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. Since January 2017, the current U.S. presidential administration has issued two executive orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. For example, on October 12, 2017, the current U.S. presidential administration issued an executive order that expands the use of association health plans and allows anyone to purchase short-term health plans that provide temporary, limited insurance. This executive order also calls for the halt of federal payments to health insurers for cost-sharing reductions previously available to lower-income Americans to afford coverage. There is still uncertainty with respect to the impact this executive order could have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Reform Act, among other things, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, the current U.S. presidential administration signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. 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". More recently, in July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. There is still uncertainty with respect to the impact the current U.S. presidential administration and Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

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 2027 unless additional Congressional action is taken. Moreove r, 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 current U.S. presidential administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, the current U.S. presidential administration laid out the administration's "Blueprint" to reduce the cost of prescription medications while preserving innovation and cures. While the Department of Health and Human Services, or HHS, is soliciting feedback on some of these measures, other actions may be immediately implemented by HHS under existing authority. Although a number of these, and other potential, proposals will require authorization through additional legislation to become effective, Congress and the current U.S. presidential administration have each indicated that it will 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. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or companion diagnostics or additional pricing pressures.

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.

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.

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 obtaini ng 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 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 original branded product is approved 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.

We believe that if any of our product candidates are approved as a biological product under a BLA, it should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA will not consider any of our product candidates to be reference products for competing products, 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. Moreover, the extent to which a 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 boxed 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.

If we decide to pursue a Fast Track Designation by the FDA, it may not lead to a faster development or regulatory review or approval process.

We may seek Fast Track Designation for one or more 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, 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.

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 recent tax reform legislation, which was 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 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;
- 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; and
- changes in general market and economic conditions.

If our quarterly and annual operating results fall below the expectations of investors or securities analysts, th e 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.

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 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” sectio n, 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 before or after the lock-up and other legal restrictions on resale lapse in connection with our IPO, the market price of our common stock could decline significantly. Each of our officers, directors, substantially all of our stockholders and participants in our directed share program entered into lock-up agreements with the underwriters that restricted their ability to sell or transfer their shares. These lock-up agreements pertaining to our IPO expired March 25, 2019. Due to this expiration of the lock-up agreements, a substantial number of shares of common stock recently became eligible for sale in the public market.

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.

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

Based on the beneficial ownership of our common stock as of March 31, 2019, our executive officers, directors and affiliates beneficially owned 38.0% of our outstanding voting stock. As a result, these stockholders, if acting together, could have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors’ perception that conflicts of interest may exist or arise.

We are an "emerging growth company" and we cannot be certain if the reduced reporting requirements applicable to emerging gr owth 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 could be an emerging growth company for up to five years following the completion of the initial public offering, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, or if we have total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. 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.

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. 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 with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

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.

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 not currently required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Pursuant to Section 404, we will be 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 achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt 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.

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.

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

Use of Proceeds

On October 1, 2018, we completed our IPO and sold 5,667,000 shares of common stock at an IPO price of $15.00 per share. The offer and sale of all of the shares in the IPO were registered under the Securities Act pursuant to registration statements on Form S-1 (File Nos. 333-227103 and 333-227548), which was declared effective by the SEC on September 26, 2018.

There has been no material change in the planned use of proceeds from our IPO as described in the Prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on September 27, 2018.

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	Filed/Furnished Herewith
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	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				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: May 15, 2019

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

Date: May 15, 2019

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

Exhibit 31.1

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)) for the registrant and have:

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

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

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

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: May 15, 2019

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

Exhibit 31.2

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)) for the registrant and have:

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

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

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

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: May 15, 2019

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

Exhibit 32.1

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

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 March 31, 2019 (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: May 15, 2019

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

Exhibit 32.2

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

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 March 31, 2019 (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: May 15, 2019

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