

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from _____ to

Commission File Number 001-39756

Silverback Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

500 Fairview Ave N, Suite 600
Seattle, Washington

(Address of principal executive offices)

81-1489190

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

98109

(Zip Code)

Registrant's telephone number, including area code: (206) 456-2900

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	SBTX	The Nasdaq Stock Market LLC

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

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

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

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

As of November 8, 2021 there were 35,076,083 shares of registrant's common stock, \$0.0001 par value per share, outstanding.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

	<u>Page</u>
PART I	<u>FINANCIAL INFORMATION</u>
Item 1.	Financial Statements (Unaudited)
	Condensed Balance Sheets
	Condensed Statements of Operations and Comprehensive Loss
	Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
	Condensed Statements of Cash Flows
	Notes to Unaudited Condensed Financial Statements
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations
Item 3.	Quantitative and Qualitative Disclosures About Market Risk
Item 4.	Controls and Procedures
PART II	<u>OTHER INFORMATION</u>
Item 1.	Legal Proceedings
Item 1A.	Risk Factors
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds
Item 3.	Defaults Upon Senior Securities
Item 4.	Mine Safety Disclosures
Item 5.	Other Information
Item 6.	Exhibits

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this “Quarterly Report”) contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our plans to research, develop, and commercialize SBT6050 and any future product candidates;
- our ability to obtain and maintain regulatory approval of product candidates arising from our ImmunoTAC technology platform, including SBT6050, in any of the indications for which we plan to develop them;
- our ability to obtain funding for our operations, including funding necessary to commence and complete the clinical trials, conduct additional manufacturing, and conduct preclinical studies of any of our product candidates, including SBT6050;
- the success, cost, and timing of our research and development activities, including our ongoing and planned clinical trials and preclinical studies;
- the size of the markets for our product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our product candidates;
- the rate and degree of market acceptance of our product candidates;
- our ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party service providers, including our contract research organizations, suppliers, and manufacturers;
- the safety, efficacy, and market success of competing therapies that are or become available;
- our ability to attract and retain key scientific and management personnel;
- our ability to attract and retain collaborators with development, regulatory and commercialization expertise;
- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing upon the intellectual property rights of others;
- the impact of the COVID-19 pandemic on our business and operations; and
- other risks and uncertainties, including those described under Part II, Item 1A, “Risk Factors” of this Quarterly Report.

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A, “Risk Factors” of this Quarterly Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Unless the context otherwise indicates, references in this Quarterly Report to the terms “Silverback”, “the Company”, “we”, “our” and “us” refer to Silverback Therapeutics, Inc., and references to our “common stock” refers to our voting common stock.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

An investment in shares of our common stock involves a high degree of risk. Below is a list of the more significant risks associated with our business. This summary does not address all of the risks that we face. Additional discussion of the risks listed in this summary, as well as other risks that we face, are set forth under Part II, Item 1A, "Risk Factors" in this Quarterly Report. Some of the material risks associated with our business include the following:

- We have a limited operating history, have incurred net losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, may not be able to sustain it.
- The COVID-19 pandemic could continue to adversely impact our business, including our ongoing and planned clinical trials, supply chain, and business development activities.
- Preclinical and clinical development is a lengthy, expensive, and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance into clinical trials, including SBT6050, may not achieve favorable results in later clinical trials, if any, or receive marketing approval.
- Serious adverse events of our product candidates have been observed in our clinical trials, and other serious adverse events, undesirable side effects, or unexpected properties may be observed during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.
- The market opportunities for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.
- Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.
- If we are required by the U.S. Food and Drug Administration (FDA) to obtain approval of a companion diagnostic in connection with approval of any of our product candidates, and we do not obtain or face delays in obtaining FDA approval of a diagnostic device or test, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.
- Even if we obtain regulatory approval for our product candidates, they will remain subject to ongoing regulatory oversight. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.
- We contract with third parties for the manufacture and supply of certain of our product candidates for use in preclinical testing and clinical trials and will rely on third parties for commercial supply, which supply may become limited or interrupted at any time or may not be of satisfactory quality and quantity.
- Any approved products may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, healthcare payors, and others in the medical community necessary for commercial success.
- If the market opportunities for any of our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.
- If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.
- We may not realize the benefits of any acquisitions, in-license, or strategic alliances that we enter into.
- We may rely on trade secret and proprietary know-how, which can be difficult to trace and enforce, and if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.
- If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.

- We face substantial competition, which may result in others discovering, developing, or commercializing products more quickly or marketing them more successfully than us.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- The price of our common stock is subject to volatility related or unrelated to our operations.
- We are currently party to an in-license agreement under which we were granted rights to manufacture certain components of our product candidates. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these technologies or both, which would adversely affect our business and prospects.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

Silverback Therapeutics, Inc.
Condensed Balance Sheets
(in thousands, except share and par value data)

	September 30, 2021 <u>(unaudited)</u>	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 300,660	\$ 386,569
Prepaid expenses and other current assets	4,695	4,087
Total current assets	305,355	390,656
Investments	39,938	—
Restricted cash	350	350
Right-of-use asset	5,011	2,180
Property and equipment, net	1,907	1,618
Total assets	<u>\$ 352,561</u>	<u>\$ 394,804</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,720	\$ 2,583
Accrued expenses	12,537	5,278
Term loan payable, net	—	844
Current portion of lease liability	1,090	896
Total current liabilities	15,347	9,601
Lease liability, net of current portion	5,080	2,326
Total liabilities	<u>20,427</u>	<u>11,927</u>
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred Stock, \$0.0001 par value per share; 10,000,000 shares authorized at September 30, 2021 and December 31, 2020; no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, \$0.0001 par value per share; 200,000,000 shares authorized at September 30, 2021 and December 31, 2020, 35,067,751 and 34,801,537 shares issued and 35,037,136 and 34,701,274 shares outstanding at September 30, 2021 and December 31, 2020, respectively	4	3
Additional paid-in capital	494,916	479,608
Accumulated other comprehensive loss	(34)	—
Accumulated deficit	(162,752)	(96,734)
Total stockholders' equity	<u>332,134</u>	<u>382,877</u>
Total liabilities, and stockholders' equity	<u>\$ 352,561</u>	<u>\$ 394,804</u>

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

Silverback Therapeutics, Inc.

Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 15,641	\$ 6,200	45,630	\$ 15,740
General and administrative	7,040	1,912	20,447	4,077
Total operating expenses	22,681	8,112	66,077	19,817
Loss from operations	(22,681)	(8,112)	(66,077)	(19,817)
Interest income (expense), net	26	(4)	59	(45)
Net loss	\$ (22,655)	\$ (8,116)	(66,018)	\$ (19,862)
Unrealized loss on available-for-sale securities	(34)	—	(34)	—
Comprehensive loss attributable to common stockholders	\$ (22,689)	\$ (8,116)	(66,052)	\$ (19,862)
Net loss per share applicable to common stockholders, basic and diluted	\$ (0.65)	\$ (11.97)	\$ (1.89)	\$ (29.53)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	35,001,466	678,048	34,884,656	672,531

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

Silverback Therapeutics, Inc.
Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)
(unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2020	—	\$ —	34,701,274	\$ 3	\$ 479,608	\$ —	\$ (96,734)	\$ 382,877
Exercise of common stock options and vesting of early exercised common stock options	—	—	125,930	—	254	—	—	254
Stock-based compensation	—	—	—	—	4,285	—	—	4,285
Net loss and comprehensive loss	—	—	—	—	—	—	(18,867)	(18,867)
Balance as of March 31, 2021	—	\$ —	34,827,204	\$ 3	\$ 484,147	\$ —	\$ (115,601)	\$ 368,549
Exercise of common stock options, shares issued under the employee stock purchase plan, and vesting of early exercised common stock options	—	—	135,881	1	866	—	—	867
Stock-based compensation	—	—	—	—	4,730	—	—	4,730
Net loss and comprehensive loss	—	—	—	—	—	—	(24,496)	(24,496)
Balance as of June 30, 2021	—	\$ —	34,963,085	\$ 4	\$ 489,743	\$ —	\$ (140,097)	\$ 349,650
Exercise of common stock options and vesting of early exercised common stock options	—	—	74,051	—	154	—	—	154
Stock-based compensation	—	—	—	—	5,019	—	—	5,019
Net loss and comprehensive loss	—	—	—	—	—	(34)	(22,655)	(22,689)
Balance as of September 30, 2021	—	\$ —	35,037,136	\$ 4	\$ 494,916	\$ (34)	\$ (162,752)	\$ 332,134

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

Silverback Therapeutics, Inc.
Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)
(unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2019	15,714,283	\$ 53,174	664,431	\$ —	\$ 5,010	\$ —	\$ (63,787)	\$ (58,777)
Issuance of Series B redeemable convertible preferred stock for cash, net of \$76 in issuance costs (Note 7)	10,027,666	21,458	—	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock upon conversion of convertible notes	4,673,388	10,095	—	—	—	—	—	—
Exercise of common stock options and vesting of early exercised common stock options	—	—	5,350	—	6	—	—	6
Stock-based compensation	—	—	—	—	47	—	—	47
Net loss and comprehensive loss	—	—	—	—	—	—	(5,279)	(5,279)
Balance as of March 31, 2020	<u>30,415,337</u>	<u>\$ 84,727</u>	<u>669,781</u>	<u>\$ —</u>	<u>\$ 5,063</u>	<u>\$ —</u>	<u>\$ (69,066)</u>	<u>\$ (64,003)</u>
Proceeds received in advance of issuance of Series B redeemable convertible preferred stock (Note 7)	—	12,048	—	—	—	—	—	—
Exercise of common stock options and vesting of early exercised common stock options	—	—	1,843	—	2	—	—	2
Stock-based compensation	—	—	—	—	128	—	—	128
Net Loss and comprehensive income	—	—	—	—	—	—	(6,467)	(6,467)
Balance as of June 30, 2020	<u>30,415,337</u>	<u>\$ 96,775</u>	<u>671,624</u>	<u>\$ —</u>	<u>\$ 5,193</u>	<u>\$ —</u>	<u>\$ (75,533)</u>	<u>\$ (70,340)</u>
Issuance of Series B convertible preferred stock for cash (Note 7)	21,732,862	34,895	—	—	—	—	—	—
Issuance of Series C convertible preferred stock for cash, net of \$53 in issuance cost (Note 7)	24,926,685	84,897	—	—	—	—	—	—
Exercise of common stock options and vesting of early exercised common stock options	—	—	12,754	—	16	—	—	16
Stock-based compensation	—	—	—	—	191	—	—	191
Net loss and comprehensive loss	—	—	—	—	—	—	(8,116)	(8,116)
Balance as of September 30, 2020	<u>77,074,884</u>	<u>\$ 216,567</u>	<u>684,378</u>	<u>\$ —</u>	<u>\$ 5,400</u>	<u>\$ —</u>	<u>\$ (83,649)</u>	<u>\$ (78,249)</u>

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

Silverback Therapeutics, Inc.
Condensed Statements of Cash Flows
(in thousands)
(unaudited)

	For the Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (66,018)	\$ (19,862)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	596	448
Stock-based compensation	14,034	366
Non-cash lease expense	903	797
Amortization of debt issuance costs	2	28
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(608)	(313)
Accounts payable and accrued expenses	6,422	(914)
Lease liability	(786)	(650)
Net cash used in operating activities	(45,455)	(20,100)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(39,971)	—
Purchase of property and equipment	(822)	(670)
Net cash used in investing activities	(40,793)	(670)
Cash flows from financing activities:		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	153,401
Principal payments on term loan payable	(846)	(467)
Proceeds from exercise of common stock options and employee stock purchase plan	1,185	177
Net cash provided by financing activities	339	153,111
Change in cash, cash equivalents, and restricted cash	(85,909)	132,341
Cash, cash equivalents, and restricted cash at beginning of period	386,919	10,526
Cash, cash equivalents, and restricted cash at end of period	\$ 301,010	\$ 142,867
Supplemental disclosure of cash flow information:		
Right-of-use assets and lease liabilities recognized	\$ 3,733	\$ —
Deferred offering costs included in accounts payable and accrued liabilities	\$ —	\$ 1,020
Issuance of Series B redeemable convertible preferred stock upon conversion of convertible notes	\$ —	\$ 10,095

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

Silverback Therapeutics, Inc.
Notes to Unaudited Condensed Financial Statements

1. Nature of Business

Silverback Therapeutics, Inc. (“Silverback” or “the Company”) is a clinical-stage biopharmaceutical company focused on leveraging its proprietary ImmunoTAC technology platform to develop systemically delivered and tissue targeted therapeutics for the treatment of cancer, chronic viral infections, and other serious diseases. The Company’s platform enables it to strategically pair proprietary linker-payloads that modulate key disease-modifying pathways with monoclonal antibodies directed at specific disease sites. The Company was formed in Seattle, Washington and incorporated in the state of Delaware on January 4, 2016.

Initial Public Offering and Related Transaction

On December 3, 2020, the Company’s registration statement on Form S-1 (File No. 333-250009) for its initial public offering of common stock (“IPO”) was declared effective by the Securities and Exchange Commission (“SEC”). On December 8, 2020, the Company issued and sold 13,225,000 shares of common stock in the IPO at a public offering price of \$21.00 per share, resulting in net proceeds of \$255.3 million after deducting underwriting discounts and commissions and offering expenses paid by the Company.

In connection with the IPO, all 77,074,884 shares of redeemable convertible preferred stock outstanding at the time of the IPO converted into 20,758,098 shares of the Company’s common stock.

Risks and Uncertainties

The Company is subject to a number of inherent risks which include, but are not limited to, the need to obtain adequate additional funding, possible failure of clinical trials or other events demonstrating a lack of clinical safety or efficacy of its product candidates, dependence on key personnel, reliance on third-party service providers for manufacturing drug product and conducting clinical trials, the ability to successfully secure its proprietary technology, and risks related to the regulatory approval and commercialization of a product candidate. Additionally, the development and commercialization of new drug products is highly competitive. Products or technologies developed by competitors may diminish or render obsolete the Company’s existing products under development.

Liquidity and Capital Resources

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred net operating losses since its inception and had an accumulated deficit of \$162.8 million as of September 30, 2021. The Company had cash, cash equivalents, restricted cash, and investments of \$340.9 million as of September 30, 2021 and has not generated positive cash flows from operations. To date, the Company has funded its operations primarily through the issuance of redeemable convertible preferred stock, convertible notes, and the sale of common stock in connection with the IPO. The Company’s currently available cash, cash equivalents, restricted cash, and investments as of September 30, 2021 are sufficient to meet its anticipated cash requirements for the 12 months following the date the financial statements are issued. Management considers that there are no conditions or events, in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern for a period of at least 12 months from the date the financial statements are issued.

Management expects operating losses to continue for the foreseeable future. There can be no assurance that the Company will ever earn revenues or achieve profitability, or if achieved, that they will be sustained on a continuing basis. In addition, the manufacturing, clinical and preclinical development activities as well as the commercialization of the Company’s products, if approved, will require significant additional financing. The Company may be unable to secure such financing when needed, or if available, such financings may be under terms that are unfavorable to the Company or the current stockholders. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce the scope of, or eliminate development programs, which may adversely affect its business and operations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (“ASC”), and Accounting Standards Update (“ASU”), of the Financial Accounting Standards Board (“FASB”).

Unaudited Interim Condensed Financial Statements

The accompanying condensed balance sheet as of September 30, 2021, the condensed statements of operations and comprehensive loss and condensed statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the three and nine months ended September 30, 2021 and 2020, and the condensed statements of cash flows for the nine months ended September 30, 2021 and 2020, are unaudited. The balance sheet as of December 31, 2020 was derived from the audited financial statements as of and for the year ended December 31, 2020. The unaudited interim condensed financial statements have been prepared on a basis consistent with the audited annual financial statements as of and for the year ended December 31, 2020, and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2021, the condensed results of its operations for the three and nine months ended September 30, 2021 and 2020, and its cash flows for the nine months ended September 30, 2021 and 2020. The financial data and other information disclosed in these notes related to the nine months ended September 30, 2021 and 2020 are also unaudited. The condensed results of operations for the three and nine months ended September 30, 2021 are not necessarily indicative of the results to be expected for the full year ending December 31, 2021 or any other period.

Use of Estimates

The preparation of the Company's financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to accruals for research and development expenses, valuation of equity awards, and valuation allowances for deferred tax assets. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates.

The full extent to which the coronavirus ("COVID-19") pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including expenses, clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international markets. The Company has considered potential impacts arising from the COVID-19 pandemic and is not presently aware of any events or circumstances that would require the Company to update its estimates, judgments or revise the carrying value of its assets or liabilities.

Fair Value of Financial Instruments

Cash and cash equivalents, restricted cash, and investments are carried at fair value. Accounts payable and accrued expenses are carried at cost, which approximates fair value given their short-term nature. The term loan payable is carried at cost, which approximates fair value as its effective interest rate approximates current market rates.

Cash and Cash Equivalents

Cash equivalents are comprised of short-term, highly-liquid investments with maturities of 90 days or less at the date of purchase. At September 30, 2021 and December 31, 2020, the Company's cash equivalents consisted of money market funds.

Restricted Cash

Restricted cash consists of a deposit securing a collateral letter of credit issued in connection with the Company's facility operating lease.

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the condensed balance sheets that sum to the amounts shown in the condensed statements of cash flows (in thousands):

	September 30, 2021	December 31, 2020
Cash and cash equivalents	\$ 300,660	\$ 386,569
Restricted cash	350	350
Total cash and cash equivalents and restricted cash	<u>\$ 301,010</u>	<u>\$ 386,919</u>

Investments

The Company invests excess cash in investment grade intermediate-term fixed income securities. These investments are included in long-term investments on the condensed balance sheets, classified as available-for-sale, and reported at fair value with unrealized gains and losses included in accumulated other comprehensive loss. Realized gains and losses on the sale of these securities are recognized in net loss.

The Company periodically evaluates whether declines in fair values of its investments below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the investment until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any investment before recovery of its amortized cost basis. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly available information that may affect the value of the investments, duration and severity of the decline in value, and the Company's strategy and intentions for holding the investment.

Concentrations of Credit Risk

The Company is subject to credit risk from holding its cash and cash equivalents at a limited number of commercial banks. The Company limits its exposure to credit losses by investing in money market funds through a U.S. bank with high credit ratings and U.S. Treasury securities. Cash may consist of deposits held with banks that may at times exceed federally insured limits, however, exposure to credit risk in the event of default by the financial institution is limited to the extent of amounts recorded on the balance sheets. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Leases

Leases consist of the Company's operating leases. In accordance with ASC 842, Leases, the Company determines if an arrangement is a lease at inception and evaluates each lease agreement to determine whether the lease is an operating or finance lease. For leases where the Company is the lessee, right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. Operating lease ROU assets also include any prepaid lease payments, lease incentives received, and costs which will be incurred in exiting a lease.

The Company's leases include options to extend or terminate the leases. Periods covered by an option to extend a lease are included in the lease term when it is reasonably certain that the Company will exercise that option. Periods covered by an option to terminate a lease are included in the lease term when it is reasonably certain that the Company will not exercise that option.

Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company does not have material short-term lease costs. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. For real estate leases, the Company does not separate lease and non-lease components. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Research and Development Expenses

All research and development costs are expensed in the period incurred. Research and development expenses consist primarily of direct and indirect costs incurred in connection with the development of the Company's ImmunoTAC technology platform, discovery efforts, and preclinical study and clinical trial activities related to the Company's program pipeline, including the Company's lead product candidate, SBT6050, and other pipeline programs, including SBT6290 and SBT8230. Direct costs include expenses incurred under agreements with contract research organizations ("CROs") and other vendors that conduct the Company's preclinical and clinical activities, expenses associated with manufacturing the Company's product candidates including under agreements with contract development and manufacturing organizations ("CDMOs") and other vendors, and consulting fees. Indirect costs include personnel-related expenses, consisting of employee salaries, bonuses, benefits, and stock-based compensation expense and recruiting costs for personnel engaged in research and development activities, facility and equipment related expenses, consisting of indirect and allocated expenses for rent, depreciation, and equipment maintenance, and other unallocated research and development expenses incurred in connection with the Company's research and development programs, including laboratory materials and supplies and license fees. Research and development expenses are charged to operating expenses as incurred when these expenditures relate to the Company's research and development efforts and have no alternative future uses.

The Company is obligated to make upfront payments upon execution of certain research and development agreements. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are capitalized until such goods are delivered or the related services are performed, or such time when the Company does not expect the goods to be delivered or services to be performed. The Company estimates the period over which such services will be performed and the level of effort to be expended in each period. If actual timing of performance or the level of effort varies from the estimate, the Company will adjust the amounts recorded accordingly. Since inception, the Company has not experienced any material differences between accrued or prepaid costs and actual costs.

Stock-Based Compensation

The cost of employee services received in exchange for an award of an equity instrument is measured at the grant date based on the award's estimated fair value using the Black-Scholes option pricing model. The estimated fair value of the awards is recognized into expense on a straight-line basis over the requisite service period. Stock-based compensation expense for an award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized, and any previously recognized compensation expense is reversed. Management evaluates when the achievement of a performance condition is probable based on the expected satisfaction of the performance condition at each reporting date. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur. The option plan permits, but does not require, the inclusion of early exercise provisions in individual awards. Proceeds from early option exercises are recorded as a liability until the underlying restricted shares vest. While the restricted shares have voting rights, they are not considered outstanding for accounting purposes.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company presents one continuous Statement of Operations and Comprehensive Loss. The Company's comprehensive loss includes unrealized gains and losses on investments.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since the effect of potentially dilutive securities is anti-dilutive given the net loss of the Company. For purposes of this calculation, redeemable convertible preferred stock, stock options, employee stock purchase rights, and unvested common stock subject to repurchase are considered to be common stock equivalents but are not included in the calculations of diluted net loss per share for the periods presented as their effect would be antidilutive.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 ("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. The Company has elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (1) no longer an emerging growth company or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The objective of the standard is to provide information about expected credit losses on financial instruments at each reporting date and to change how other-than temporary impairments on investment securities are recorded. The guidance is effective for the Company beginning on January 1, 2023, with early adoption permitted. The Company is currently evaluating the impact the standard may have on its financial statements and related disclosures.

3. Fair Value Measurements

The Company follows authoritative accounting guidance, which among other things, defines fair value, establishes a consistent framework for measuring fair value, and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as the exchange price that would be received to sell an asset or paid to transfer a liability (at exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The three levels of inputs that may be used to measure fair value include:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities in active markets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity.

The following table identifies the Company's assets and liabilities that were measured at fair value on a recurring basis (in thousands):

	Level	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Fair Value
September 30, 2021					
Money market funds	1	\$ 300,660	\$ —	\$ —	\$ 300,660
Long-term investments - U.S. Treasury securities	1	39,971	—	34	39,937
Total		340,631	—	34	340,597
December 31, 2020					
Money market funds	1	\$ 386,369	\$ —	\$ —	\$ 386,369

There were no transfers between the Level 1 and Level 2 categories or into or out of the Level 3 category during the periods presented.

The Company's long-term investments portfolio contains investments in U.S. Treasury securities that have an effective maturity date that is more than one year, but less than two years, from the respective balance sheet date. The Company evaluated its investments for other-than-temporary impairment and considers the decline in market value for the securities to be primarily attributable to current economic and market conditions. For the investments, it is not more-likely-than-not that the Company will be required to sell the investments, and the Company does not intend to do so prior to the recovery of the amortized cost basis.

4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Research and development expenses	\$ 8,638	\$ 2,063
Employee compensation and benefits	3,279	2,634
Professional services and other	620	581
Total accrued expenses	\$ 12,537	\$ 5,278

5. Leases

The Company leases office and laboratory space in Seattle, Washington. The components of lease expense and related cash flows were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Lease expense				
Operating lease expense	\$ 402	\$ 347	\$ 1,096	\$ 1,041
Variable lease expense	121	119	333	299
Total lease expense	523	466	1,429	1,340
Operating cash outflows from operating leases	\$ 499	\$ 396	\$ 1,333	\$ 1,183

On July 1, 2021, the Company entered into a sublease agreement for additional office space in Seattle, Washington. The commencement date of the sublease was August 1, 2021. The contractual term of the sublease is two years with an option to extend for one additional year and an option to terminate after one year subject to a termination fee. The annual minimum rent payable by the Company under the sublease is \$0.3 million annually. The ROU asset obtained in exchange for the new operating lease liability is \$0.6 million.

Other information related to the Company's operating leases as of September 30, 2021 was as follows:

Weighted-average remaining lease term (in years)	4.7
Weighted-average discount rate	7.5%

During the three months ended September 30, 2021, there was a change in the expected lease term of the Company's Seattle, Washington headquarters, whereby the Company became reasonably certain that it will not exercise its option to terminate the lease. As a result, the ROU asset and lease liability were remeasured using the present value of the remaining lease payments. The re-measurement resulted in an addition to the ROU asset and lease liability of \$3.1 million. The change in the expected lease term has no effect on the classification of the lease.

Future minimum commitments due under the operating lease agreements as of September 30, 2021 are as follows (in thousands):

Years Ending December 31,	Amount
2021 (remaining 3 months)	\$ 268
2022	1,615
2023	1,513
2024	1,348
2025	1,389
Thereafter	1,186
Total undiscounted lease payments	7,319
Present value adjustment	(1,149)
Total present value of lease payments	\$ 6,170

6. Term Loan Payable

In November 2016, the Company entered into a loan and security agreement with Silicon Valley Bank ("SVB") and borrowed \$3.5 million as a term loan. The outstanding principal amount of the term loan accrued interest at an annual rate of 1.75% per annum. At closing, the Company incurred de minimis debt issuance costs and owed a final payment fee of \$0.3 million, both of which are amortized to interest expense over the remaining term of the debt under the effective interest method. The effective interest rate of the Company's term loan was 5.14%.

The term loan's original maturity date was November 1, 2020. However, in April 2020, the Company amended the loan and security agreement to defer principal payments for six months and extend the maturity date to May 1, 2021. There were no costs or additional warrant issuances in connection with this amendment. The Company accounted for the amendment as a debt modification and amortized the remaining debt discount over the remaining term.

On May 1, 2021, the Company made its final scheduled payment to SVB under the loan and security agreement including the final payment fee.

7. Stockholders' Equity (Deficit)

Redeemable Convertible Preferred Stock

Prior to its conversion to common stock in December 2020, the Company's redeemable convertible preferred stock was classified as mezzanine equity on the Company's balance sheets as the shares are contingently redeemable upon a deemed liquidation such as a change in control and in that event, there is no guarantee that all stockholders would be entitled to receive the same form of consideration. No accretion to redemption value was recorded during the nine months ended September 30, 2020 as a deemed liquidation event was not considered probable.

In March 2020, the Company issued 14,701,054 shares of its Series B redeemable convertible preferred stock, including 4,673,388 shares issued upon conversion of then outstanding convertible notes and accrued interest, and 10,027,666 shares issued for cash at a purchase price of \$2.16 per share, resulting in gross proceeds of \$21.5 million. The Series B purchase agreement provided that the Company would issue, and the Series B holders would purchase, an additional 21,732,862 shares of the Company's Series B redeemable convertible preferred stock across two tranches for aggregate proceeds of \$46.9 million in the event that certain agreed upon milestones were achieved or the preferred majority approved their closing. The Series B tranches did not meet the definition of freestanding instruments or the definition of derivatives, therefore, they were not accounted for separately or bifurcated.

On July 1, 2020, the Company issued 10,669,834 shares of its Series B redeemable convertible preferred stock for cash at a purchase price of \$2.16 per share, resulting in gross proceeds of \$23.0 million. Proceeds received in advance of the July 1, 2020 issuance of Series B redeemable convertible preferred stock totaled \$12.0 million. Given the noncancelable nature of the Series B issuance on July 1, 2020 and in light of the call exercise notice mailed by the Company 20 days prior, the proceeds received in June 2020 were recorded as mezzanine equity at June 30, 2020 despite the related shares not becoming legally issued and outstanding until July 1, 2020.

In September 2020, the Company issued 11,063,028 additional shares of its Series B redeemable convertible preferred stock for cash at a purchase price of \$2.16 per share, resulting in gross proceeds of \$23.9 million, and 24,926,685 shares of its Series C redeemable convertible preferred stock for cash at a purchase price of \$3.41 per share, resulting in gross proceeds of \$84.9 million. The Series C purchase agreement did not contain any embedded features that meet the definition of freestanding instruments or the definition of derivatives, therefore, they were not accounted for separately or bifurcated.

Common Stock

The Company has reserved shares of common stock for the following potential future issuances:

	September 30, 2021	December 31, 2020
Shares underlying outstanding equity awards	6,451,285	6,316,569
Shares available for future equity award grants	2,877,457	1,506,806
Shares underlying early exercised equity awards	30,615	100,263
Shares underlying ESPP withholdings	22,668	4,393
Total	<u>9,382,025</u>	<u>7,928,031</u>

8. Stock-Based Compensation

Stock-based compensation expense recognized for all equity awards has been reported in the statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development expense	\$ 2,144	\$ 87	\$ 6,147	191
General and administrative expense	2,875	104	7,887	175
Total stock-based compensation expense	<u>\$ 5,019</u>	<u>\$ 191</u>	<u>\$ 14,034</u>	<u>\$ 366</u>

As of September 30, 2021, the total unrecognized stock-based compensation expense was \$56.7 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.66 years.

Stock Option Awards

As of September 30, 2021, the Company's equity incentive plans authorized a total of 9,564,798 shares, of which 2,877,457 shares are available for future grant, and 6,451,285 shares are outstanding. Not included in the outstanding option balance are 30,615 shares pursuant to stock options that were early exercised and subject to repurchase under the Company's 2016 Equity Incentive Plan that remain unvested as of September 30, 2021.

A summary of the Company's stock option activity for the nine months ended September 30, 2021 is as follows (in thousands, except share and per share data and years):

	Stock Options Outstanding			
	Shares Subject to Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance at December 31, 2020	6,316,569	\$ 10.93	9.5	\$ 223,647
Granted	436,773	36.64		
Exercised	(234,710)	2.65		1,721
Cancelled	(67,347)	19.61		
Balance at September 30, 2021	6,451,285	12.88	8.83	21,707
Vested at September 30, 2021	1,549,117	8.83	8.48	7,670

The total fair value of shares vested during the nine months ended September 30, 2021 and 2020 was \$11.7 million and \$0.2 million, respectively. The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the Company's common stock for all options that were in-the-money at September 30, 2021. The weighted-average grant date fair value per share of option grants for the nine months ended September 30, 2021 and 2020 was \$24.92 and \$1.47, respectively.

The grant date fair value of stock options was estimated using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Nine Months Ended September 30,	
	2021	2020
Expected term (in years)	5.9	6.0
Expected volatility	80 %	80 %
Risk-free interest rate	0.94 %	0.51 %
Expected dividend yield	—	—

The fair value of stock options was determined using the Black-Scholes option-pricing model and the assumptions below. Each of these inputs is subjective and generally requires significant judgement.

Fair Value of Common Stock. The grant date fair market value of the shares of common stock underlying stock options is determined by the Company's board of directors. Following the closing of the Company's IPO, the fair market value of the Company's common stock is based on its closing price as reported on the date of grant on the primary stock exchange on which the Company's common stock is traded. Prior to the Company's IPO, because there was no public market for the Company's common stock, the board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair market value, which included contemporaneous valuations performed by an independent third-party, the Company's results of operations and financial position, including its levels of available capital resources, its stage of development and material risks related to the Company's business, progress of the Company's research and development activities, the Company's business conditions and projections, the lack of marketability of the Company's common stock and preferred stock as a private company, the prices at which the Company sold shares of its redeemable convertible preferred stock to outside investors in arms-length transactions, the rights, preferences and privileges of the Company's redeemable convertible preferred stock relative to those of its common stock, the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry, the likelihood of achieving a liquidity event for the Company's securityholders, such as an IPO or a sale of the company, given prevailing market conditions, the hiring of key personnel and the experience of management, trends and developments in the Company's industry and external market conditions affecting the life sciences and biotechnology industry sectors.

Expected Term. The expected term represents the period that the options granted are expected to be outstanding. The expected term of stock options issued is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term) as the Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected term.

Expected Volatility. Given the Company's limited historical stock price volatility data, the Company derived the expected volatility from the average historical volatilities over a period approximately equal to the expected term of comparable publicly traded companies within its peer group that were deemed to be representative of future stock price trends as the Company has limited trading history for its common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-free Interest Rate. The risk-free interest rate is based on the U.S. Treasury rate, with maturities similar to the expected term of the stock options.

Expected Dividend Yield. The Company has never paid dividends on its common stock and does not anticipate paying any dividends in the foreseeable future. Therefore, the Company uses an expected dividend yield of zero.

9. Licensing Agreement

Cell Line License Agreement with WuXi Biologics (Hong Kong) Limited

In October 2019, the Company entered into a cell line license agreement with WuXi Biologics (Hong Kong) Limited ("WuXi Bio"). Under the license agreement, WuXi Bio granted the Company a non-exclusive, worldwide, sublicensable, under certain of WuXi Bio's intellectual property rights, know-how and biological materials ("WuXi Bio Licensed Technology"), to make, use, sell, offer for sale and import a product developed through the use of the WuXi Bio Licensed Technology ("WuXi Bio Licensed Product"). The WuXi Bio Licensed Technology is currently used to manufacture a component of the Company's lead product, SBT6050. The Company has paid an aggregate of \$150,000 in license fees that were recorded in research and development expense when incurred.

In the event the Company manufactures its commercial supplies of a product produced by the Licensed Cell Line using a manufacturer other than WuXi Bio or its affiliates, the Company will become obligated to pay WuXi Bio aggregate milestone payments, upon achievement of certain sales milestones, of up to \$10.8 million.

The Company has the right to terminate the license by giving at least six months prior written notice to WuXi Bio and paying all amounts due to them through the termination date. In the event the Company fails to pay all amounts due to WuXi Bio under the license agreement, and fails to pay the amounts within 30 days after receiving written notice of such failure, WuXi Bio may terminate the license with 45 days written notice to the Company. In the event either party commits a material breach under the license and fails to cure the breach within 30 days after receiving written notice from the other party of such breach, either party may terminate the license immediately upon written notice to the other party.

10. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount.

Indemnifications

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless, and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions or related to any indemnification agreements. The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

COVID-19

The global COVID-19 pandemic continues to rapidly evolve, and management continue to monitor the situation closely. The extent of the impact of COVID-19 on the Company's business, operations and clinical development and manufacturing timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on the Company's clinical trial enrollment, trial sites, CROs, third-party manufacturers, supply chains necessary for research and development and manufacturing, and other third parties with whom the Company does business, as well as its impact on regulatory authorities and the Company's key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, management is conducting business as usual, with necessary or advisable modifications to employee travel and some of the Company's non-lab based employees working remotely. Management will continue to actively monitor the rapidly evolving situation related to COVID-19 and may take further actions that alter Company operations, including those that may be required by federal, state or local authorities, or that management determines are in the best interests of the Company's employees and other third parties with whom the Company does business. At this point, the extent to which the COVID-19 pandemic may affect the Company's business, operations and clinical development timelines and plans, including the resulting impact on Company expenditures and capital needs, remains uncertain and is subject to change.

11. Employee Benefit Plans

The Company maintains a retirement plan, which is qualified under section 401(k) of the Internal Revenue Code of 1986, as amended, for the Company's U.S. employees. The plan allows eligible employees to defer, at the employee's discretion, pretax compensation up to the IRS annual limits. The Company does not match contributions made by employees.

12. Net Loss Per Share Attributable to Common Stockholders

The following outstanding shares of potentially dilutive securities were excluded from the computation of the diluted net loss per share attributable to common stockholders for the periods presented because their effect would have been anti-dilutive:

	As of September 30,	
	2021	2020
Redeemable convertible preferred stock	—	20,758,098
Common stock options	6,451,285	2,468,163
Unvested common stock	30,615	124,233
Common stock warrants	—	9,154
ESPP withholdings	22,668	—
Total potentially dilutive shares	6,504,568	23,359,648

13. Subsequent Events

On November 5, 2021, a securities class action complaint was filed against the Company and certain of the Company's officers and directors in the U.S. District for the Western District of Washington, captioned *Dresner v. Silverback Therapeutics, Inc., et al.*, Case No. 2:21-cv-01499. The complaint alleges that between December 3, 2020 and September 10, 2021, the Company and certain of the Company's officers and directors violated (1) Sections 11 and 15 of the Securities Act; and (2) Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder, by making allegedly false and misleading statements in various SEC filings and press releases regarding the clinical and commercial prospects of the Company's lead product candidate, SBT6050. The complaint seeks unspecified damages and interest, as well as attorneys' fees and other costs. The Company and the other defendants have not yet filed a response to the complaint, and do not anticipate doing so until after the court's appointment of lead plaintiff and counsel, as well as the filing of an amended complaint.

The Company cannot predict the outcome of this suit, and failure by the Company to obtain a favorable resolution could have a material adverse effect on its business, results of operations and financial condition. The Company's chances of success on the merits are still uncertain and any possible loss or range of loss cannot be reasonably estimated and as such the Company has not recorded a liability as of September 30, 2021.

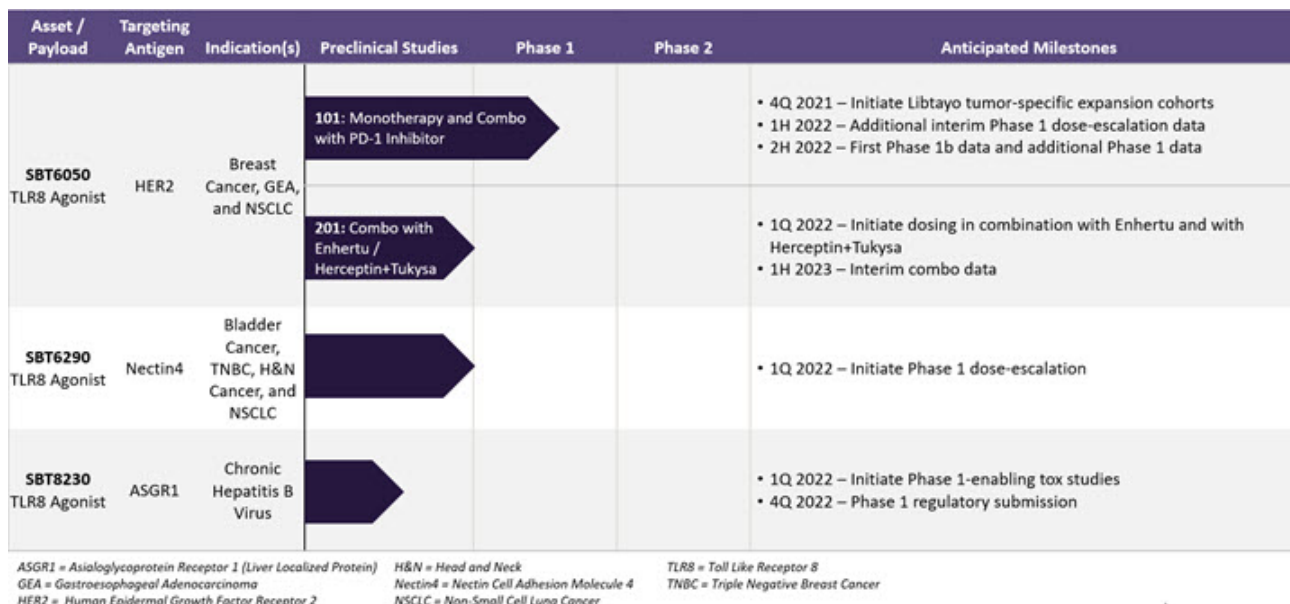
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis together with our unaudited financial statements and related notes thereto included in “Item 1. Financial Statements (Unaudited)” of this Quarterly Report on Form 10-Q and the audited financial statements and related notes thereto as of and for the year ended December 31, 2020 included in the Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC), on March 29, 2021. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the “Risk Factors” section of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the “Risk Factors” section of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company with one product candidate in a Phase 1/1b clinical trial, and we are focused on leveraging our proprietary ImmunoTAC technology platform to develop systemically delivered, tissue targeted therapeutics for the treatment of cancer, chronic viral infections, and other serious diseases. Our platform enables us to strategically pair proprietary linker-payloads that modulate key disease-modifying pathways with monoclonal antibodies directed to specific disease sites. Initially, we are applying our platform to create a new class of targeted immunology agents that direct a myeloid cell activator to the tumor microenvironment in solid tumors to promote cancer cell killing. Our lead product candidate, SBT6050, is comprised of a TLR8 agonist linker-payload conjugated to a HER2-directed monoclonal antibody that targets HER2-expressing solid tumors, such as certain breast, gastric and non-small cell lung cancers. SBT6050 is currently being evaluated in a Phase 1/1b clinical trial as a monotherapy and in combination with pembrolizumab, in patients with advanced or metastatic HER2-expressing solid tumors. In September 2021, we presented interim clinical results from our ongoing Phase 1/1b study of SBT6050 with a data cut-off date of August 1, 2021. The interim update included data we believe are consistent with proof-of-mechanism through SBT6050’s ability to activate myeloid, T and NK cells, as well as evidence of SBT6050 payload localization in the tumor microenvironment, observed adverse events consistent with on-mechanism immune activation, and early signals of anti-tumor activity. Since the September 2021 update, we have selected a dose of 0.3 mg/kg for dose expansion in combination with Libtayo in gastroesophageal and non-small cell lung cancer which we anticipate will initiate in the fourth quarter of 2021. We also anticipate initiating a Phase 1/2 study in the first quarter of 2022, in which SBT6050 is combined with trastuzumab deruxtecan (T-DXd) or trastuzumab and tucatinib with or without capecitabine in patients with HER2-expressing or HER2-amplified breast, gastroesophageal, and non-small cell lung cancers. SBT6290, our second product candidate, expands on the potential of a TLR8 agonist as a payload. SBT6290 is a TLR8 linker-payload conjugated to a monoclonal antibody that targets Nectin4, which is expressed in certain bladder, triple negative breast, head and neck, and non-small cell lung cancers. We submitted an investigational new drug application for SBT6290 in the fourth quarter of 2021, and we anticipate beginning clinical development in the first quarter of 2022. Our third program, SBT8230, is comprised of a TLR8 linker-payload conjugated to an ASGR1 monoclonal antibody that is under development for the treatment of chronic hepatitis B virus infection. We will be presenting a preclinical update on this program at the American Association for the Study of Liver Diseases (AASLD) meeting in the fourth quarter of 2021. We are also developing agents that localize therapies to modulate important pathways in additional oncology and fibrosis indications using TLR8 and other linker-payloads.

Our ImmunoTAC platform drives our development pipeline of tissue targeted therapeutic candidates as summarized in the chart below:



We have incurred significant operating losses since our inception. As of September 30, 2021, we had an accumulated deficit of \$162.8 million. Our net losses were \$22.7 million and \$8.1 million for the three months ended September 30, 2021 and 2020, respectively. Our net losses were \$66.0 million and \$19.9 million for the nine months ended September 30, 2021 and 2020, respectively. Our losses have resulted primarily from costs incurred in connection with raising capital, research and development activities and general and administrative expenses. We do not have any products approved for sale and have not generated any revenue from product sales or otherwise.

We expect our expenses will increase substantially and that we will continue to incur significant losses for the foreseeable future as we continue our development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products, seek to expand our product pipeline, invest in our organization and technology platform, as well as incur expenses associated with operating as a public company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on a variety of factors including the timing and scope of our preclinical studies and clinical trials. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses or other similar arrangements.

In December 2020, we completed our initial public offering in which we sold 13,225,000 shares of our common stock at \$21.00 per share and received net proceeds, after underwriting discounts and offering costs, of \$255.3 million. Further, in March, July, and September 2020, we raised net proceeds of \$153.3 million from the sale of our redeemable convertible preferred stock.

Clinical Update on SBT6050 in Combination with Anti-PD-1 Therapy

We have selected 0.3 mg/kg as the SBT6050 dose for evaluation in combination with anti-PD-1 therapy in expansion cohorts. We are prioritizing our combination with Libtayo in non-small cell lung and gastroesophageal cancers and plan to initiate these expansion cohorts in the fourth quarter of 2021. As reported in the September 2021 interim update, at the 0.15 mg/kg and 0.3 mg/kg SBT6050 dose levels in combination with pembrolizumab, we observed induction of pharmacodynamic biomarkers indicative of myeloid, T, and NK cell activation, early signs of anti-tumor activity, and no dose limiting toxicities (DLTs).

At SBT6050 dose levels above 0.3 mg/kg in combination with pembrolizumab, DLTs were observed. Two patients dosed at 0.6 mg/kg each experienced a DLT, including hypotension and cytokine release syndrome (CRS). These adverse events resolved with supportive care and both patients continued treatment at a reduced dose. Two patients were subsequently enrolled at a dose level of 0.45 mg/kg plus pembrolizumab. The first patient tolerated the first dose well and remained on study. The second patient, a 75-year-old with metastatic gastric cancer and underlying conditions including diabetes, hyperlipidemia and anemia, experienced serious adverse events (SAEs) of CRS, hypoxia, and hypotension following the first dose. The patient received supportive care that included tocilizumab and vasopressors; however, the patient developed decreased cardiac function due to demand-related ischemia. The patient made the decision not to further escalate supportive care and subsequently passed away. The investigator reported that the cause of death was attributed to Grade 5 hypotension considered related to SBT6050. Patients currently enrolled in the pembrolizumab dose-escalation arm were dose-reduced to 0.3 mg/kg, as applicable.

Components of Our Results of Operations

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Our research and development expenses consist primarily of direct and indirect costs incurred in connection with the development of our ImmunoTAC technology platform, product candidates, discovery efforts and preclinical studies and clinical trial activities related to our program pipeline, including our lead product candidate, SBT6050.

Our direct costs include:

- expenses incurred under agreements with CROs and other vendors that conduct our preclinical and clinical activities;
- expenses associated with manufacturing our product candidates including under agreements with CDMOs and other vendors; and
- consulting fees.

Our indirect costs include:

- personnel-related expenses, consisting of employee salaries, bonuses, benefits, and stock-based compensation expense and recruiting costs for personnel engaged in research and development activities;
- facility and equipment related expenses, consisting of indirect and allocated expenses for rent, depreciation, and equipment maintenance; and
- other unallocated research and development expenses incurred in connection with our research and development programs, including laboratory materials and supplies and license fees.

We expense research and development costs as incurred. Non-refundable advance payments for goods and services that will be used over time for research and development are capitalized and recognized as goods are delivered or as the related services are performed. In-licensing fees and other costs to acquire technologies used in research and development that have not yet received regulatory approval and that are not expected to have an alternative future use are expensed when incurred. We track direct costs by stage of program, clinical or preclinical. However, we do not track indirect costs on a program specific or stage of program basis because these costs are deployed across multiple programs and, as such, are not separately classified.

We expect that our research and development expenses will substantially increase for the foreseeable future as we continue the clinical development of SBT6050 and discovery and development of our other development candidates and discovery programs and development, particularly as our product candidates move into later stages of development which increases costs considerably. We cannot reasonably determine the timing of initiation, the duration or the completion costs of future clinical trials and preclinical studies of IND and development candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which development candidates and discovery programs to pursue and how much funding to direct to each product candidate or program on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses, including employee salaries, bonuses, benefits, and stock-based compensation, and recruiting costs for personnel in executive, finance, and other administrative functions. Other significant general and administrative expenses include legal fees relating to intellectual property and corporate matters, professional fees for accounting, tax and consulting services, insurance costs, travel expenses, and facility related expenses.

We expect that our general and administrative expenses will substantially increase for the foreseeable future as we continue to increase our general and administrative headcount to support our continued research and development activities and, if any product candidates receive marketing approval, commercialization activities, as well as to support our operations generally. We also expect to incur increased expenses associated with operating as a public company, including costs related to accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Interest Income (Expense), Net

Interest income (expense), net includes interest earned on our cash and cash equivalents carried at fair value, and interest expense on our borrowings.

Results of Operations

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

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Dollar Change	% Change
	2021	2020		
	(in thousands)			
Operating expenses:				
Research and development	\$ 15,641	\$ 6,200	\$ 9,441	152%
General and administrative	7,040	1,912	5,128	268
Total operating expenses	22,681	8,112	14,569	180
Loss from operations	(22,681)	(8,112)	(14,569)	180
Interest income (expense), net	26	(4)	30	*
Net loss	<u>\$ (22,655)</u>	<u>\$ (8,116)</u>	<u>\$ (14,539)</u>	<u>179%</u>

* Not meaningful

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Dollar Change	% Change
	2021	2020		
	(in thousands)			
Direct costs:				
SBT6050	\$ 4,741	\$ 827	\$ 3,914	473%
Preclinical programs	3,505	2,243	1,262	56
Total direct costs	8,246	3,070	5,176	169
Indirect costs:				
Personnel-related expenses, including stock-based compensation	5,921	2,096	3,825	182
Facility and equipment related expenses	714	612	102	17
Other unallocated research and development expenses	760	422	338	80
Total research and development expenses	<u>\$ 15,641</u>	<u>\$ 6,200</u>	<u>\$ 9,441</u>	<u>152%</u>

Research and development expenses were \$15.6 million and \$6.2 million for the three months ended September 30, 2021 and 2020, respectively. The increase of \$9.4 million was due primarily to an increase in direct costs related to the development of SBT6050 of \$3.9 million. The increase was also due to an increase in preclinical programs of \$1.3 million as we continued to advance certain pipeline programs, including SBT6290 and SBT8230, through preclinical development. The increase was also due to increases in personnel-related expenses of \$3.8 million, and facility and equipment related and other unallocated research and development expenses of \$0.4 million.

General and Administrative Expenses

General and administrative expenses were \$7.0 million and \$1.9 million for the three months ended September 30, 2021 and 2020, respectively. The increase of \$5.1 million was due primarily to an increase of \$3.8 million in personnel-related expenses due to increased headcount during the period, including new executives, as well as increases in salaries, bonuses, stock-based compensation, and recruiting expenses. To a lesser extent, the increase in general and administrative expenses was due to an increase of \$1.3 million in other various general and administrative expenses as we now operate as a public company.

Interest Income (Expense), Net

Interest income (expense), net was \$26,000 and \$(4,000) for the three months ended September 30, 2021 and 2020, respectively. The change of \$30,000 was primarily due to a decrease in principal on our notes payable and an increase in our cash balance. Also contributing to the change was the investment in higher interest-bearing assets during the period.

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

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020:

	<u>Nine Months Ended September 30,</u>		<u>Dollar</u>	<u>%</u>
	<u>2021</u>	<u>2020</u>		
	<u>(in thousands)</u>			
Operating expenses:				
Research and development	\$ 45,630	\$ 15,740	\$ 29,890	190 %
General and administrative	20,447	4,077	16,370	402
Total operating expenses	66,077	19,817	46,260	233
Loss from operations	(66,077)	(19,817)	(46,260)	233
Interest income (expense), net	59	(45)	104	*
Net loss	<u>\$ (66,018)</u>	<u>\$ (19,862)</u>	<u>\$ (46,156)</u>	<u>232 %</u>

* *Not meaningful*

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		Dollar Change	% Change
	2021	2020		
(in thousands)				
Direct costs:				
SBT6050	\$ 11,141	\$ 2,914	\$ 8,227	282 %
Preclinical programs	13,328	3,925	9,403	240
Total direct costs	24,469	6,839	17,630	258
Indirect costs:				
Personnel-related expenses, including stock-based compensation	16,383	5,907	10,476	177
Facility and equipment related expenses	2,341	1,754	587	33
Other unallocated research and development expenses	2,437	1,240	1,197	97
Total research and development expenses	\$ 45,630	\$ 15,740	\$ 29,890	190 %

Research and development expenses were \$45.6 million and \$15.7 million for the nine months ended September 30, 2021 and 2020, respectively. The increase of \$29.9 million was due primarily to an increase in preclinical programs of \$9.4 million as we continued to advance certain pipeline programs, including SBT6290 and SBT8230, through preclinical development. The increase was also due to an increase of \$8.2 million in direct costs related to the development of SBT6050. The increase was also due to increases in personnel-related expenses of \$10.5 million, and facility and equipment related expenses and other unallocated research and development expenses of \$1.8 million.

General and Administrative Expenses

General and administrative expenses were \$20.4 million and \$4.1 million for the nine months ended September 30, 2021 and 2020, respectively. The increase of \$16.4 million was due primarily to an increase of \$11.3 million in personnel-related expenses due to increased headcount during the period, including new executives, as well as increases in salaries, bonuses, stock-based compensation, and recruiting expenses. To a lesser extent, the increase in general and administrative expenses was due to an increase in insurance expense of \$2.1 million, legal fees of \$1.3 million, professional fees of \$1.1 million, and \$0.6 million in other various general and administrative expenses as we now operate as a public company.

Interest Income (Expense), Net

Interest income (expense), net was \$59,000 and \$(45,000) for the nine months ended September 30, 2021 and 2020, respectively. The change of \$104,000 was primarily due to a decrease in principal on our notes payable and an increase in our cash balance. Also contributing to the change was the investment in higher interest-bearing assets during the period.

Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. Since our inception, we have funded our operations almost exclusively with proceeds from the sale and issuance of shares of our redeemable convertible preferred stock and common stock, and debt financings. We will need to raise substantial additional capital in the future.

As of September 30, 2021, we had \$340.9 million in cash, cash equivalents, restricted cash, and investments. The following table sets forth a summary of the net cash flow activity for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (45,455)	\$ (20,100)
Investing activities	(40,793)	(670)
Financing activities	339	153,111
Net increase (decrease) in cash, cash equivalents, and restricted cash	\$ (85,909)	\$ 132,341

Operating Activities

During the nine months ended September 30, 2021, net cash used in operating activities was \$45.5 million. This consisted primarily of a net loss of \$66.0 million, partially offset by non-cash charges of \$15.5 million and a decrease in our operating assets and liabilities of \$5.0 million. The non-cash charges primarily consisted of stock-based compensation expense of \$14.0 million, non-cash lease expense of \$0.9 million, and depreciation expense of \$0.6 million. The decrease in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses of \$6.4 million. The decrease was partially offset by a decrease in lease liability of \$0.8 million and an increase in prepaid expenses and other assets of \$0.6 million.

During the nine months ended September 30, 2020, net cash used in operating activities was \$20.1 million. This consisted primarily of a net loss of \$19.9 million and an increase in our operating assets and liabilities of \$1.9 million, partially offset by non-cash charges of \$1.6 million. The non-cash charges primarily consisted of non-cash lease expense of \$0.8 million, depreciation expense of \$0.4 million, and stock-based compensation expense of \$0.4 million. The increase in our operating assets and liabilities was primarily due to a decrease in accounts payable and accrued expenses of \$0.9 million after adjusting for non-cash items, a decrease in our lease liability of \$0.7 million, and an increase in prepaid expenses and other assets of \$0.3 million.

Investing Activities

During the nine months ended September 30, 2021, cash used in investing activities was \$40.8 million. This consisted of purchases of investments of \$40.0 million and purchases of property and equipment of \$0.8 million.

During the nine months ended September 30, 2020, cash used in investing activities was less than \$0.7 million due to purchases of property and equipment.

Financing Activities

During the nine months ended September 30, 2021, cash provided by financing activities was \$0.3 million. This was primarily driven by proceeds from the exercise of common stock options and the employee stock purchase program of \$1.2 million, which was partially offset by \$0.8 million of principal payments on the term loan payable.

During the nine months ended September 30, 2020, cash provided by financing activities was \$153.1 million. This consisted primarily of net proceeds received from the issuance of shares of our redeemable convertible preferred stock of \$153.4 million and proceeds from the exercise of common stock options of \$0.2 million, which were partially offset by principal payments on the term loan payable of \$0.5 million.

Future Funding Requirements

We believe that our cash, cash equivalents, restricted cash, and investments of \$340.9 million at September 30, 2021 will be sufficient to fund our operating expenses and capital expenditure requirements into 2024. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future capital requirements will depend on many factors, including:

- the initiation, trial design, progress, timing, costs and results of drug the discovery, preclinical studies and clinical trials of our product candidates, and in particular the clinical trials for SBT6050;
- the number and characteristics of product candidates that we pursue;
- the length of our clinical trials;
- the outcome, timing and costs of seeking FDA, European Medicines Agency (EMA) and any other regulatory approvals;
- the costs of manufacturing our product candidates, in particular for clinical trials in preparation for marketing approval and in preparation for commercialization;
- the costs of any third-party products used in our combination clinical trials that are not covered by such third-party or other sources;
- the costs associated with hiring additional personnel and consultants as our preclinical, manufacturing and clinical activities increase;
- the receipt of marketing approval and revenue received from any commercial sales of any of our product candidates, if approved;
- the cost of commercialization activities for any of our product candidates, if approved, including marketing, sales and distribution costs;
- the emergence of competing therapies and other adverse market developments;

- the ability to establish and maintain strategic collaboration, licensing or other arrangements and the financial terms of such agreements;
- the extent to which we in-license or acquire other products and technologies;
- the amount and timing of any payments we may be required to make pursuant to our current or future license agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- our need and ability to retain key management and hire scientific, technical, business, and medical personnel;
- our implementation of additional internal systems and infrastructure, including operational, financial and management information systems;
- or costs associated with expanding our facilities or building out our laboratory space;
- the effects of the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide from the COVID-19 pandemic; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses or other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise funds through strategic collaborations or other similar arrangements with third parties, we may have to relinquish valuable rights to our platform technology, future revenue streams, research programs or product candidates or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic or otherwise. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses and cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Contractual Obligations and Commitments

During the nine months ended September 30, 2021, there have been no material changes outside the ordinary course of business to our contractual obligations from those disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K filed with the SEC on March 29, 2021.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

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

During the nine months ended September 30, 2021, there were no material changes to our critical accounting policies. Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” in our Annual Report on Form 10-K filed with the SEC on March 29, 2021 and Note 2 to our unaudited condensed financial statements appearing in Part I, Item 1 of this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- Research and Development Costs;
- Stock-based Compensation;
- Income Taxes.

Recent Accounting Pronouncements

See Note 2 to our unaudited condensed financial statements appearing in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Emerging Growth Company Status

We are an emerging growth company, as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to

Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved.

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 certain new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that 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 the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have at least \$1.07 billion in annual revenue; (ii) the date upon which we are deemed to be a “large accelerated filer,” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the Exchange Act); (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt securities during the prior three-year period; and (iv) December 31, 2025.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable to a “smaller reporting company” as defined under Item 10(f)(1) of Regulation S-K of the Securities Act of 1933, as amended (the Securities Act).

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. 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 officer, 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 September 30, 2021, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2021 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

On November 5, 2021, a securities class action complaint was filed against us and certain of our officers and directors in the U.S. District for the Western District of Washington, captioned *Dresner v. Silverback Therapeutics, Inc., et al.*, Case No. 2:21-cv-01499. The complaint alleges that between December 3, 2020 and September 10, 2021, we and certain of our officers and directors violated (1) Sections 11 and 15 of the Securities Act; and (2) Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder, by making allegedly false and misleading statements in various SEC filings and press releases regarding the clinical and commercial prospects of our lead product candidate, SBT6050. The complaint seeks unspecified damages and interest, as well as attorneys' fees and other costs. The Company and the other defendants have not yet filed a response to the complaint, and do not anticipate doing so until after the court's appointment of lead plaintiff and counsel, as well as the filing of an amended complaint.

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Quarterly Report on Form 10-Q and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition. The risk factors set forth below that are marked with an asterisk () did not appear as separate risk factors in, or contain changes to the similarly titled risk factor included in Item 1A. of our Annual Report on Form 10-K, filed with the SEC on March 29, 2021.*

Risks Related to Our Business and Industry

We have a limited operating history, have incurred net losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, may not be able to sustain it.*

We are an early-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing and optimizing our technology platform, identifying potential product candidates, undertaking research and preclinical studies and a clinical trial for our lead program, engaging in manufacturing for our development programs, establishing and enhancing our intellectual property portfolio, and providing general and administrative support for these operations. We have one product candidate in early clinical development and all of our other product candidates are in preclinical development, and none have been approved for commercial sale. We have never generated any revenue from product sales and have incurred net losses each year since we commenced operations. For the nine months ended September 30, 2021 and 2020, our net losses were \$66.0 million and \$19.9 million, respectively. We expect that it will be several years, if ever, before we have a product candidate ready for regulatory approval and commercialization. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future as we advance our product candidates through clinical development. Our prior losses, combined with expected future losses, had and will continue to have an adverse effect on our stockholders' deficit and working capital.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenue that is significant or large enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown challenges. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

As a public company listed on the Nasdaq Global Market, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and the Nasdaq Global Market have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Recent legislation permits smaller “emerging growth companies” to implement many of these requirements over a longer period and up to five years from the pricing of our initial public offering. We intend to continue to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costlier. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we are required to incur substantial costs to maintain our current levels of such coverage.

If we are unable to raise additional capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.*

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially during the next few years. The development of biopharmaceutical product candidates is capital intensive. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory, quality and manufacturing capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. Furthermore, following the completion of our initial public offering in December 2020, we have incurred and expect to continue to incur additional costs associated with operating as a public company.

As of September 30, 2021, we had \$340.9 million in cash, cash equivalents, restricted cash, and investments. Based upon our current operating plan, we estimate that our existing cash, cash equivalents, restricted cash, and investments will be sufficient to fund our operating expenses and capital expenditure requirements into 2024. However, we believe that our existing cash, cash equivalents, restricted cash, and investments will not be sufficient to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the initiation, trial design, progress, timing, costs and results of drug discovery, preclinical studies and clinical trials of our product candidates, and in particular the clinical trials for SBT6050;
- the number and characteristics of product candidates that we pursue;
- the length of our clinical trials, including, among other things, as a result of delays in enrollment, difficulties enrolling sufficient subjects or delays or difficulties in clinical trial site initiations;
- the outcome, timing, and costs of seeking FDA, EMA and any other regulatory approvals;
- the costs of manufacturing our product candidates, in particular for clinical trials in preparation for marketing approval and in preparation for commercialization;
- the costs of any third-party products used in our combination clinical trials that are not covered by such third-party or other sources;
- the costs associated with hiring additional personnel and consultants as our preclinical, manufacturing and clinical activities increase;
- the receipt of marketing approval and revenue received from any commercial sales of any of our product candidates, if approved;

- the cost of commercialization activities for any of our product candidates, if approved, including marketing, sales and distribution costs;
- the emergence of competing therapies and other adverse market developments;
- the ability to establish and maintain strategic collaboration, licensing or other arrangements and the financial terms of such agreements;
- the extent to which we in-license or acquire other products and technologies;
- the amount and timing of any payments we may be required to make pursuant to our current or future license agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- our need and ability to retain key management and hire scientific, technical, business, and medical personnel;
- our implementation of additional internal systems and infrastructure, including operational, financial and management information systems;
- or costs associated with expanding our facilities or building out our laboratory space;
- the effects of the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide from the COVID-19 pandemic; and
- the costs of operating as a public company.

Because we do not expect to generate revenue from product sales for many years, if at all, we will need to obtain substantial additional funding in connection with our continuing operations and expected increases in expenses. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses or other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. The impact of the COVID-19 pandemic on capital markets may affect the availability, amount and type of financing available to us in the future. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potential collaborations, licenses, or other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants further limiting or restricting our ability to take specific actions, such as further limitations on our ability to incur additional debt, make capital expenditures or declare dividends.

If we raise funds through collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

The COVID-19 pandemic could continue to adversely impact our business, including our ongoing and planned clinical trials, supply chain, and business development activities. *

In December 2019, COVID-19, a novel strain of coronavirus, was first reported in Wuhan, China and has since become a global pandemic. The President of the United States declared the COVID-19 pandemic a national emergency and many states and municipalities in the United States have announced aggressive actions to reduce the spread of the disease, including limiting non-essential gatherings of people, ceasing all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing “shelter-in-place” orders which direct individuals to shelter at their places of residence (subject to limited exceptions). For example, on March 23, 2020, the Office of the Governor issued Proclamation 20-25, ordering all individuals in the State of Washington to stay at their place of residence except as needed to maintain continuity of operations of the federal critical infrastructure sectors. As a result of the Washington state order, almost all of our non-lab based employees are currently telecommuting, which has impacted certain of our operations and may continue to do so over the long term. We may experience further limitations on employee resources in the future, including because of sickness of employees or their families. The effects of government actions and our own policies and those of third parties to reduce the spread of COVID-19 may negatively impact productivity and slow down or delay our ongoing and future clinical trials, preclinical studies and research and development activities, and may cause disruptions to our supply chain and impair our ability to execute our business development strategy. In the event that government authorities were to enhance current restrictions, our employees who currently are not telecommuting may no longer be able to access our facilities, and our operations may be further limited or curtailed.

As COVID-19 continues to spread, we may experience ongoing disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- interruption or delays in our operations, which may impact our ability to conduct and produce preclinical results required for submission of an IND;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; and
- refusal of the FDA to accept data from clinical trials in affected geographies.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

Our clinical trials have been, and may in the future be, affected by the COVID-19 pandemic. For example, some of our clinical trial sites have slowed down or stopped further enrollment of new patients in clinical trials, and otherwise curtailed certain operations. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be adversely impacted. Our ongoing or planned clinical trials may also be impacted by interruptions or delays in the operations of the FDA and comparable foreign regulatory agencies. We and our CROs have also made certain adjustments to the operation of our trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA, and may need to make further adjustments in the future. Many of these adjustments are new and untested, may not be effective, and may have unforeseen effects on the enrollment, progress and completion of these trials and the findings from these trials. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials.

In addition, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our product candidates. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to the COVID-19 pandemic, our ability to continue meeting clinical supply demand for our product candidates or otherwise advancing development of our product candidates may become impaired.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

COVID-19 and actions taken to reduce its spread continue to rapidly evolve. The extent to which COVID-19 may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section, such as those relating to the timing and results of our clinical trials and our financing needs.

Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates

We are early in our development efforts and we have only one product candidate in clinical development. We have a limited history of conducting clinical trials to test our product candidates in humans.

We are early in our development efforts and most of our operations to date have been limited to developing our platform technologies and conducting drug discovery and preclinical studies. Our lead product candidate, SBT6050, entered Phase 1/1b clinical trial in July 2020, which was the first time one of our product candidates had been tested in humans. As a result, we have limited infrastructure, experience conducting clinical trials as a company and regulatory interactions, and cannot be certain that our current or planned clinical trials will be completed on time, if at all, that our planned development programs would be acceptable to the FDA or other comparable foreign regulatory authorities, or that, if approval is obtained, such product candidates can be successfully commercialized.

Because of the early stage of development of our products candidates, our ability to eventually generate significant revenues from product sales will depend on a number of factors, including:

- successful completion of additional preclinical studies;
- submission of our INDs or other regulatory applications to allow for initiation of our planned clinical trials or future clinical trials and authorizations from regulators to initiate clinical studies;
- successful enrollment in, and completion of, clinical trials and achieving positive results from the trials;
- demonstrating a risk-benefit profile acceptable to regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing manufacturing capabilities or arrangements with third-party manufacturers for clinical supply and, if and when approved, for commercial supply;

- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in combination with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- developing and implementing marketing and reimbursement strategies;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- the ability to obtain clearance or approval of companion diagnostic tests, on a timely basis, or at all; and
- maintaining a continued acceptable safety profile of any product following approval, if any.

If we do not achieve one or more of these requirements in a timely manner, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

Preclinical and clinical development is a lengthy, expensive, and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance into clinical trials, including SBT6050, may not achieve favorable results in later clinical trials, if any, or receive marketing approval. *

The research and development of drugs and biological products is extremely risky. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, can take many years to complete and its outcome is uncertain. We may face unforeseen challenges in our product candidate development strategy, and we can provide no assurances that we will ultimately be successful in our current and future clinical trials or that our product candidates will be able to receive regulatory approval. The results of preclinical studies and early clinical trials of our product candidates and other products, even those with the same or similar mechanisms of action, may not be predictive of the results of later-stage clinical trials. For example, it is not uncommon for product candidates to exhibit unforeseen safety or efficacy issues when tested in humans despite promising results in preclinical animal models. In particular, while we have conducted preclinical studies of SBT6050, we do not know how SBT6050 will perform in the ongoing Phase 1/1b clinical trial or in future clinical trials, whether any initial tumor responses that may be observed will be durable or whether adverse events will arise over time. Future results of preclinical and clinical testing of our product candidates are also less certain due to the novel and relatively untested nature of our approach to TLR8 and related platform technologies. In general, clinical trial failure may result from a multitude of factors including flaws in study design, dose selection, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Prior to obtaining approval to commercialize any product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidate is safe and effective for its intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe that the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program, requiring their alteration.

If the results of our clinical trials are inconclusive or if there are safety concerns or other adverse events associated with our product candidates, we may:

- incur unplanned costs;
- be delayed in or prevented from continuing clinical development and obtaining marketing approval for our product candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings including boxed warnings;

- be subject to changes or limitations in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a modified Risk Evaluation and Mitigation Strategy (REMS);
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Treatment of cancer patients with our oncology product candidates may be used in combination with other cancer drugs, such as other immunology agents, monoclonal antibodies or other protein-based drugs or small molecule anti-cancer agents such as targeted agents or chemotherapy, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. Additionally, our product candidates could potentially cause adverse events. For example, we have observed SAEs in our Phase 1/1b clinical trial of SBT6050, including but not limited to hypotension, cytokine release syndrome (CRS), and a patient death in our combination trial with pembrolizumab. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. As described above, any of these events could prevent us from obtaining regulatory approval or achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products. Because all of our product candidates are derived from our platform technologies, a clinical failure of one of our product candidates may also increase the actual or perceived likelihood that our other product candidates will experience similar failures.

Of the large number of products in development, only a small percentage successfully complete the FDA or comparable foreign regulatory authorities' approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical testing and receive approval of a biologics license application (BLA) or foreign marketing application for our product candidates, the FDA or the comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authorities also may approve a product candidate for a more limited indication or patient population than we originally request, and the FDA or comparable foreign regulatory authorities may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects.

In addition, the FDA or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.*

We have concentrated our research and development efforts on product candidates using our platform technologies, and our future success depends on the successful development of this approach. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates based on our platform technologies in clinical trials or in obtaining marketing approval thereafter, and use of our platform technologies may not ever result in marketable products. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or establishing our own commercial manufacturing capabilities, which may prevent us from completing our clinical trials or commercializing any products on a timely or profitable basis, if at all.

Our product candidates are targeted to treat tumors that express specific antigens at certain levels, such as those that express moderate to high levels of HER2 or Nectin4. This requires diagnostic assays that may be subject to scrutiny by regulatory authorities. Commercial tests are available for HER2, but not currently for Nectin4. We may not be successful in developing diagnostic assays or securing the assays for use. If we are successful in securing a diagnostic assay for a specific antigen, it may be difficult to enroll patients with tumors that have the required level of antigen expression.

In addition, the clinical trial requirements of the FDA, EMA and other regulatory agencies, such as in Australia and South Korea, and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. 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 pharmaceutical or other product candidates.

The immuno-oncology industry is also rapidly developing, and our competitors may introduce new technologies improving the immune response to cancer that render our technologies obsolete or less attractive. New technology could emerge at any point in the development cycle of our product candidates.

The TLR field is also rapidly evolving and as competitors use or develop alternative TLR technologies, any failures of such technologies could adversely impact our programs. For example, companies are developing other TLR8, TLR7, TLR7/8 and TLR9 agonists, some of which are conjugated to monoclonal antibodies. Regardless of our belief that our approach to activating the innate immune system has advantages, issues encountered with other TLR programs will create a negative perception of or increase scrutiny for our technologies and product candidates.

We depend on enrollment of patients in our clinical trials for our product candidates. If we experience delays or difficulties enrolling in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. These trials and other trials we conduct may be subject to delays as a result of patient enrollment taking longer than anticipated, patient withdrawal or adverse events. For example, we have an ongoing Phase 1/1b clinical trial for our lead product candidate, SBT6050, which could generate adverse events that may cause us to delay the trial or halt further development. As has been described with other immune agonists administered in the presence of anti-drug antibodies (ADAs) in preclinical species, anaphylaxis upon repeat intravenous dosing with SBT6050 was observed in animal models. While our product candidate in humans is administered by the subcutaneous route of administration, if similar adverse events were to manifest, that could adversely impact our enrollment.

Our clinical trials will likely compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Patient enrollment depends on many factors, including the size and nature of the patient population, the severity of the disease under investigation, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the ability to obtain and maintain patient consents, the ability to recruit clinical trial investigators with the appropriate competencies and experience, the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some 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.

Serious adverse events of our product candidates have been observed in our clinical trials, and other serious adverse events, undesirable side effects, or unexpected properties may be observed during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.*

To date, we have only tested SBT6050 in a limited number of patients with cancer and these clinical trial participants have only been observed for a limited period of time after dosing. As we continue developing our product candidates and initiate clinical trials of our additional product candidates, SAEs, undesirable side effects, relapse of disease, or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or in which efficacy is more pronounced or durable. For example, we have observed SAEs in our Phase 1/1b clinical trial of SBT6050, including but not limited to hypotension, CRS, and a patient death in our combination trial with pembrolizumab. Should we observe additional SAEs in our clinical trials or identify other undesirable side effects or other unexpected findings, depending on their severity, our trials could be delayed or even stopped and our development programs may be halted entirely.

Our TLR8 agonist containing product candidates, including SBT6050, activate dendritic cells among other innate immune cells. As a result, significant ADA generation could neutralize the effects of SBT6050 by reducing exposure. The development of ADAs could also trigger hypersensitivity reactions that manifest as SAEs. For example, as has been described with other immune agonists administered in the presence of ADAs in preclinical species, anaphylaxis upon repeat intravenous dosing with SBT6050 was observed. As a result, we have modified our dosing to subcutaneous; however, if patients experience adverse events, including anaphylaxis, our trials could be delayed or stopped and our development programs may be halted entirely if this is observed during clinical development. Even if ADAs are not detected in the early clinical trials, they may be detected after product launch and may significantly reduce the commercial potential or even result in the product being pulled from the market.

Even if our product candidates initially show promise in early clinical trials, the side effects of biological products are frequently only detectable after they are tested in larger, longer, and more extensive clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development or after approval and are determined to be attributed to our product candidate, we may be required to develop a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Product-related side effects could also result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or ADAs caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

- we may be required to change the way a product is administered or conduct additional clinical trials;
- the product may become less competitive, and our reputation may suffer;
- we may decide to remove the product from the marketplace; and
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties.

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

From time to time, we may publicly disclose preliminary, interim, or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as patient enrollment and treatment continues and more patient data become available. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects. We may also announce topline data following the completion of a preclinical study or clinical trial, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available.

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

We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities. *

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. Clinical trials are expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. For example, we cannot begin our planned Phase 1 clinical trials for SBT6290, our Nectin4-targeted product candidate until we complete certain preclinical development and submit and receive authorization to proceed under INDs. We also dosed the first patient in a Phase 1/1b clinical trial for SBT6050 in July 2020 and cannot predict how our technology may work in solid tumor indications until we have completed dose-escalation and dose expansion. For example, we have observed SAEs in our Phase 1/1b clinical trial of SBT6050, including but not limited to hypotension, CRS, and a patient death in our combination trial with pembrolizumab. Finally, the COVID-19 pandemic has impacted clinical trials broadly, including our own with some sites pausing or slowing enrollment.

A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory authorities on trial design or implementation of any future potential collaborators', clinical trials;
- delays in reaching agreement or failing to agree on acceptable terms with prospective CROs and clinical trial sites;
- delays in opening sites, including delays in obtaining required approvals from institutional review boards (IRBs) and recruiting suitable patients to participate in our clinical trials;
- delays in enrollment due to travel or quarantine policies, or other factors, related to COVID-19, other pandemics or other events outside our control;

- failure by our CROs, other third parties or us to adhere to the trial protocol or applicable regulatory requirements, including the FDA's good clinical practices (GCPs) or applicable regulatory requirements in other countries;
- regulatory authorities may find deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we or any of our potential future collaborators contract for clinical and commercial supplies;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the treatment sites, including due to a facility manufacturing any of our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practices (cGMP) regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- imposition of a clinical hold by IRBs or regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates, after an inspection of our clinical trial operations or trial sites, or for other reasons;
- suspensions or terminations by us, the IRBs of the institutions at which such trials are being conducted, by the Safety Review Committee or Data Safety Monitoring Board, for such trial or by regulatory authorities due to a number of factors, including those described above;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of SAEs associated with the product candidate that are viewed to outweigh its potential benefits or the discovery of other safety issues;
- lack of adequate funding; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

For instance, the ongoing COVID-19 pandemic and the measures taken by the governmental authorities could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research and clinical trials, delay, limit or prevent our employees and CROs from continuing research and development activities, impede the ability of patients to enroll or continue in clinical trials, or impede testing, monitoring, data collection and analysis or other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations.

Our drug product is shipped from overseas and the ongoing COVID-19 pandemic and measures taken by the governmental authorities could disrupt the timing and therefore our clinical trials may not proceed or may be delayed, interrupted, or stopped as a result.

Any inability to timely and successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to achieve regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable drugs to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or other SAEs associated with our product candidates, we may:

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;

- be sued; or
- experience damage to our reputation.

Our development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all. Any delay in, or termination of, our clinical trials will delay the submission of a BLA to the FDA or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates, if approved, and generate product revenue. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims for differentiation or the effectiveness or safety of our product candidate. The FDA has substantial discretion in the review and approval process and may disagree that our data support the claims we propose.

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

Further, we, the FDA or an institutional review board may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current GCP, regulations, that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our INDs or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenues from our product candidates may be delayed or eliminated entirely.

We may seek Breakthrough Therapy designation or Fast Track designation by the FDA for one or more of our product candidates, but we may not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek Breakthrough Therapy or Fast Track designation for some of our product candidates. If a product candidate is intended for the treatment of a serious or life-threatening condition and clinical or preclinical data demonstrate the potential to address unmet medical needs for this condition, the product candidate may be eligible for Fast Track Designation. The benefits of fast track designation include more frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval, more frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers, eligibility for Accelerated Approval and Priority Review, if relevant criteria are met, and rolling review, which means that a drug company can submit completed sections of its BLA for review by FDA, rather than waiting until every section of the BLA is completed before the entire application can be reviewed. BLA review usually does not begin until the entire application has been submitted to the FDA.

A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biologics designated as breakthrough therapies by the FDA may be eligible for all features of Fast Track designation, intensive guidance on an efficient drug development program, beginning as early as Phase 1, and organizational commitment involving senior managers at FDA.

The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible, we cannot assure you that the FDA would decide to grant it. Even if we have obtained Fast Track Designation and/or Breakthrough Therapy Designation for one or more of our product candidates, we may not experience a faster development process, review or approval compared to non-expedited FDA review procedures. In addition, the FDA may withdraw Fast Track Designation or Breakthrough Therapy Designation if it believes that the designation is no longer supported. These designations do not guarantee qualification for the FDA's priority review procedures or a faster review or approval process.

If we are required by the FDA to obtain approval of a companion diagnostic in connection with approval of any of our product candidates, and we do not obtain or face delays in obtaining FDA approval of a diagnostic device or test, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

If safe and effective use of any of our product candidates depends on an *in vitro* diagnostic that is not otherwise commercially available, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves our product candidates, if at all. Commercially available diagnostics are available for HER2, but not currently available for Nectin4. As an existing companion diagnostic does not currently exist for Nectin4, unless one is developed and approved, we may need to develop and obtain approval for a companion diagnostic for the SBT6290 program. The process of obtaining or creating such diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable regulatory authorities. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect. If the FDA or a comparable regulatory authority requires approval of a companion diagnostic for any of our product candidates, whether before or after it obtains marketing approval, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for such product candidate. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of such product candidate.

We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidate, if approved, on a timely or profitable basis, if at all.

Even if we obtain regulatory approval for our product candidates, they will remain subject to ongoing regulatory oversight. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Even if we obtain regulatory approval for any of our product candidates, they will be subject to extensive and ongoing regulatory requirements for manufacturing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling and record-keeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP regulations, as well as GCPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the 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. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Such regulatory requirements may differ from country to country depending on where we have received regulatory approval.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our 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. Moreover, if there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include:

- issuing warning or untitled letters;
- mandating modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labeling or marketing of such products;
- seeking an injunction or imposing civil or criminal penalties or monetary fines;
- suspension or imposition of restrictions on operations, including product manufacturing;
- seizure or detention of products, refusal to permit the import or export of products or request that we initiate a product recall;
- suspension, modification or withdrawal of our marketing authorizations;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to applications submitted by us;
- refusal to permit the import or export of products; or
- requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization.

Moreover, the FDA and other regulatory authorities strictly regulate the promotional claims that may be made about biologic products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Companies may only share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and harm our business, financial condition, results of operations and prospects.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could harm our business, financial condition, results of operations and prospects.

The market opportunities for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA customarily approves new therapies only for a second line or later lines of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapies, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect to initially seek approval of our product candidates in most instances at least as a second line therapy. Subsequently, depending on the nature of the clinical data and experience with any approved products or product candidates, if any, we may pursue approval as an earlier line therapy and potentially as a first line therapy. But there is no guarantee that our product candidates, even if approved as a second or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have HER2 expression, are based on our assumptions and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved for a second or third line of therapy, the number of patients who may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020 the FDA resumed certain on-site inspections of domestic manufacturing facilities on a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our discovery and development on select product candidates and indications. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued using our platform technologies. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications 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 products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may also 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.

We may not be successful in our efforts to identify or discover additional product candidates in the future.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the properties that we desire; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable additional candidates for preclinical and clinical development, our opportunities to successfully develop and commercialize therapeutic products will be limited.

Risks Related to Manufacturing, Commercialization and Reliance on Third Parties

We rely on third parties to conduct, supervise, and monitor our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. *

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are and expect to remain dependent on third parties to conduct our preclinical studies, including GLP toxicology studies and ongoing Phase 1/1b clinical trial and any future clinical trials of our product candidates. Specifically, CROs that manage preclinical studies, GLP toxicology studies and our clinical studies as well as clinical investigators, and consultants play a significant role in the conduct of our preclinical studies and clinical trials and the subsequent collection and analysis of data. The timing of the initiation and completion of these studies and trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal requirements, and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GLP and GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GLP and GCP requirements through periodic inspections of preclinical study sites, trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GLP or GCP requirements, the data generated in our preclinical studies and clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical or clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. These risks are heightened as a result of the efforts of government agencies and the CROs themselves to limit the spread of COVID-19, including quarantines and shelter-in-place orders, which have also adversely impacted the supply chain for many research and clinical supplies. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or any comparable foreign regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

We contract with third parties for the manufacture and supply of certain of our product candidates for use in preclinical testing and clinical trials, which supply may become limited or interrupted or may not be of satisfactory quality and quantity.

We do not have any manufacturing facilities. We produce in our laboratory relatively small quantities of product for evaluation in our research programs. We rely on third parties for the manufacture of a portion of our product candidates for preclinical testing and all of our product candidates for clinical testing and we will continue to rely on such third parties for commercial manufacture if any of our product candidates are approved. We currently have limited manufacturing arrangements and expect that each of our product candidates, including SBT6050, will only be covered by single source suppliers for the foreseeable future. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Furthermore, all entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's Good Laboratory Practice regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Comparable foreign regulatory authorities may require compliance with similar requirements. The facilities and quality systems of our third-party contract manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing activities of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations.

In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, including due to the impact of the COVID-19 pandemic, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. 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 transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to or voluntarily 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 that the product produced is equivalent to that produced in a prior facility. The delays associated with the verification of a new manufacturer and equivalent product could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our or a third-party's failure to execute on our manufacturing requirements, do so on commercially reasonable terms and timelines and comply with cGMP requirements could adversely affect our business in a number of ways, including:

- inability to meet our product specifications and quality requirements consistently;
- an inability to initiate or continue clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates, if at all;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates.

Manufacturing antibody drug conjugate products is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing antibody drug conjugate products is complex and require the use of innovative technologies to handle living cells. Manufacturing these products requires facilities specifically designed for and validated for this purpose and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at manufacturing facilities, 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. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

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 good manufacturing practices, lot consistency, significant lead times and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that we or our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial 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, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Due to the early nature of our product candidates, the drug product may not be stable over time causing changes to be made to the manufacturing or storage process which may result in delays or stopping the development of the product candidate.

Changes in methods of product candidate manufacturing may result in additional costs or delays.

As product candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize yield, manufacturing batch size, change drug product dosage form, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

Any approved products may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and physicians may continue to rely on these treatments. Most of our product candidates target mechanisms for which there are limited or no currently approved products, which may result in slower adoption by physicians, patients and payors. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support; and
- the prevalence and severity of any side effects.

We may not be able to successfully commercialize our product candidates, if approved, due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates profitably.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process, with uncertain results, that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may not be available, or may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, there is no uniform policy among third-party payors for coverage and reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement are critical to a new product's acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, the Centers for Medicare and Medicaid Services (CMS) revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System, which may result in reduced Medicare payments.

We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Additionally, we or our collaborators may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we may seek for our product candidates. While we have not yet developed any companion diagnostic tests for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates.

Outside of the United States, many countries require approval of the sale price of a product before it can be marketed, and the pricing review period only begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate 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 revenue, if any, 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 such product candidates obtain marketing approval.

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the Affordable Care Act) signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA) which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action, court decisions or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If any approved products are subject to biosimilar competition sooner than we expect, we will face significant pricing pressure and our commercial opportunity will be limited.

If the market opportunities for any of our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

We are focused initially on the development of treatments for cancer. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

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

Because we rely on third parties to research and develop and to manufacture our product candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business. In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint research and development programs may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets through breach of our agreements with third parties, independent development, or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize future products on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product portfolios; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenue to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market any future products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

Risks Related to Our In-Licenses and Other Strategic Agreements

We may not realize the benefits of any acquisitions, in-license, or strategic alliances that we enter into.

We have entered into in-license agreements with multiple licensors and in the future may seek and form strategic alliances, create joint ventures or collaborations, or enter into acquisitions or additional licensing arrangements with third parties that we believe will complement or augment our existing technologies and product candidates.

These transactions can 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. As a result, if we enter into acquisition or in-license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, or if there are materially adverse impacts on our or the counterparty's operations resulting from COVID-19, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

We may wish to form collaborations in the future with respect to our product candidates, but may not be able to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may, in the future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of those product candidates, including in territories outside the United States or for certain indications. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third-party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third-party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, product candidates and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators.

Collaborations are complex and time-consuming to negotiate and document. 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 collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Our product candidates may also require specific components to work effectively and efficiently, and rights to those components may be held by others. We may be unable to in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Risks Related to Our Business Operations

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, 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, misconduct, 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. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause 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 comply with these laws or regulations. If any such actions are instituted against us those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our product candidates harms patients or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims. *

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;

- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claims, or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with cancer and other diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. For example, we have observed SAEs in our Phase 1/1b clinical trial of SBT6050, including but not limited to hypotension, CRS, and a patient death in our combination trial with pembrolizumab. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

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

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

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

We expect to expand our development, regulatory and operational capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.*

As of September 30, 2021, we had 83 employees which represents an increase of 27 employees since January 1, 2021. As we advance our research and development programs, we may be required to further increase the number of our employees and the scope of our operations, particularly in the areas of clinical development, quality, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage any future growth, we must:

- identify, recruit integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates, both as a monotherapy and in combination with other therapeutics; and
- improve our operational, financial and management controls, reporting systems and procedures.

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

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

We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us.*

The development and commercialization of new products is highly competitive. We largely compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, if ever, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. Moreover, with the proliferation of new drugs and therapies into oncology, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical.

Other products in a similar class as some of our product candidates have already been approved and other products in the same class are further along in development. As more product candidates within a particular class of biopharmaceutical products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for product candidates in those class will likely need to show a risk benefit profile that is competitive with or more favorable than those products and product candidates in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those products or product candidates, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenue and financial condition would be materially and adversely affected.

Specifically, there are many companies pursuing a variety of approaches to TLR-directed therapies, including Ambrx, AproS Therapeutics, Ascendis, BioNTech, Bolt Biotherapeutics, Bristol Myers Squibb, Checkmate Pharmaceuticals, CureVac, Exicure, Galaderma, Gilead, Idera, Mologen, Nektar, Novartis, Primmune Therapeutics, Roche, Seven&Eight Biopharmaceuticals, Shanghai De Novo, Sumitomo Dainippon, Tallac Therapeutics, TriSalus, and UroGen. Other companies using antibody-drug conjugates to target innate immune receptors include Actym Therapeutics, Mersana, and Takeda Pharmaceuticals. Immunotherapy and validated pathway approaches are further being pursued by many smaller biotechnology companies as well as larger pharmaceutical companies. We also face competition from validated pathway therapy treatments offered by companies such as AstraZeneca, Byondis, Daiichi Sankyo, Klus Pharma, MacroGenics, Pieris, Puma, RemeGen, Seagen, Spectrum Pharmaceuticals, and Zymeworks. We also face competition from companies that continue to invest in innovation in the antibody-drug conjugate field, including but not limited to AbbVie, ADC Therapeutics, Astellas, BioAtla, Bicycle Therapeutics, Celldex, CytomX, Eli Lilly and Company, GlaxoSmithKline, Genmab, ImmunoGen, Millennium Pharmaceuticals, MorphoSys AG, Novartis, Pfizer, Sanofi, Seagen, and Sutro Biopharma.

Many of our competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, preclinical testing, clinical trials, manufacturing and marketing than we do. Future collaborations and mergers and acquisitions may result in further resource concentration among a smaller number of competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors will also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety, and convenience. If we are not successful in developing, commercializing and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be materially harmed.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused U.S. federal net operating loss carryforwards (NOLs) for taxable years beginning before January 1, 2018, may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under legislation informally titled the Tax Cuts and Jobs Act (the Tax Act) enacted in 2017, as modified by legislation enacted on March 27, 2020, entitled the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), U.S. federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such U.S. federal NOLs in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or to the CARES Act.

As of December 31, 2020, we had \$89.7 million of U.S. federal NOLs. If not used, \$18.2 million of the U.S. federal NOLs will begin to expire in 2036 and \$71.5 million can be carried forward indefinitely under current law. As of December 31, 2020, we also had aggregate U.S. federal research and development (R&D) credits of approximately \$1.5 million. Our NOL carryforwards and R&D credits are subject to review and possible adjustment by the U.S. and state tax authorities.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards, R&D credits and certain other tax attributes to offset its post-change income or taxes may be limited. This could limit the amount of NOLs, R&D credit carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U.S. tax rules in respect of the utilization of NOLs, R&D credits and other applicable tax attributes carried forward may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors, and customers are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, transparency laws, privacy laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.*

Although we do not currently have any products on the market, our operations may be, directly or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws, the Physician Payments Sunshine Act, and the Health Insurance Portability and Accountability Act (HIPAA), and their implementing regulations. Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers and other parties through which we may market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims, including the False Claims Act, which can be enforced through whistleblower actions, and Civil Monetary Penalties Laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them, and their covered subcontractors, that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of such individually identifiable health information;
- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will 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 of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may charge for such product candidates. *

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

In March 2010, the Affordable Care Act was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless Congress takes additional action.

Recently, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration’s proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 2022. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration’s Most Favored Nation (MFN) executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the MFN model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the MFN interim final rule. In July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process.

Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control costs of pharmaceutical and biological products. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

We expect that the healthcare reform measures that have been adopted, and 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 and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We, and the third parties with whom we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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 hazardous materials, this insurance may not provide adequate coverage against potential liabilities. 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, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, or collectively, Trade Laws, prohibit, among other things, companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and our collaborators and third-party providers may be subject to federal, state and foreign data privacy and security laws and regulations. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

In many jurisdictions, enforcement actions and consequences for noncompliance are rising. In the United States, these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no customer information is compromised, we may incur significant fines or experience a significant increase in costs. Many state legislatures have adopted legislation that regulates how businesses operate online, including measures relating to privacy, data security and data breaches. Laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly. States are also constantly amending existing laws, requiring attention to frequently changing regulatory requirements. Furthermore, California recently enacted the California Consumer Privacy Act (the CCPA) which became effective on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. At this time, we do not collect personal information relating to residents of California but should we begin to do so, the CCPA will impose new and burdensome privacy compliance obligations on our business and will raise new risks for potential fines and class actions.

Foreign data protection laws, including the EU General Data Protection Regulation (the GDPR), may also apply to health-related and other personal information obtained outside of the United States. The GDPR, which came into effect on May 25, 2018, imposes strict requirements for processing the personal data of individuals within the European Economic Area (EEA) and the United Kingdom, including clinical trial data, as well as potential fines for noncompliant companies of up to the greater of €20 million or 4% of annual global revenue. The GDPR imposes strict requirements for the collection, use and disclosure of personal data, including stringent requirements relating to obtaining consent, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches and taking certain measures when engaging third-party processors. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. At this time, we do not believe we are subject to the GDPR, but should this change, the GDPR will increase our responsibility and potential liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and third-party providers to comply with U.S. and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose such information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to maintain effective disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are subject to requirements of the Sarbanes-Oxley Act, the rules and regulations of the Nasdaq Global Market, the rules and regulations of the Securities and Exchange Commission. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time-consuming and costly and place significant strain on our personnel, systems and resources. Company responsibilities required by the Sarbanes-Oxley Act include, among other things, that we maintain corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. We are also continuing to improve our internal control over financial reporting. In order to develop, maintain, and improve the effectiveness of our internal controls and procedures, and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs and significant management oversight.

Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our results of operations or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain, or any disruptions or difficulties in implementing or using, such a system could adversely affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business, results of operations, and financial condition and could cause a decline in the trading price of our common stock.

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Accounting Pronouncements."

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

New income, sales, use, or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified, or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market.

Our success depends in large part on our ability to obtain and maintain patent protection for our platform technologies, product candidates and their uses, as well as our ability to operate without infringing the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued or that issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner, including delays as a result of the COVID-19 pandemic impacting our or our licensors' operations. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications directed to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review (PGR) proceedings, oppositions, derivations, reexaminations, or *inter partes* review (IPR) proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, 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. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know-how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially-viable terms, then we may not be able to launch our product. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition and results of operations.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. We have pending U.S. and foreign patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or

- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the “prior art,” information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

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

Patent protection is available on a national or regional level. Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. As such, our intellectual property rights outside the United States may not extend to all other possible countries outside the United States and we may not be able to prevent third parties from practicing our inventions in countries outside the United States where we do not have patent protection, or from selling in and importing products into other jurisdictions made using our inventions in such countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products or technology and may export otherwise infringing products or technology to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Further, the legal systems of certain countries particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any such lawsuits that we initiate and the damages and other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. We currently have and may in the future enter into more contract research and manufacturing relationships with organizations that operate in certain countries that are at heightened risk of theft of technology, data and intellectual property, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties at nominal or no consideration. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third-party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

Should any of these or similar events occur, they could significantly harm our business, results of operations and prospects.

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

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

We are currently party to an in-license agreement under which we were granted rights to manufacture certain components of our product candidates. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these technologies or both, which would adversely affect our business and prospects.

We rely, in part, on license and other strategic agreements, which subject us to various obligations, including payment obligations for achievement of certain milestones on product sales. For example, with respect to SBT6050, we have licensed a cell line to manufacture these products under an agreement with WuXi Biologics. If we fail to comply with the obligations under our license agreements, including as a result of COVID-19 impacting our operations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If our license agreements are terminated, we may experience significant delays, difficulties, and costs in developing new cell lines and identifying an alternative source to manufacture components of our candidate products covered by our agreements and those being tested or approved in combination with such products. Such an occurrence could materially adversely affect the value of the product candidates being developed under any such agreement.

In addition, the agreements under which we license intellectual property or technology to or 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.

We control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. 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 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;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the creation or use of intellectual property by us alone or with our licensors and partners;
- the scope and duration of our payment obligations; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described herein. If we or our licensor fail to adequately protect this intellectual property, our ability to develop, manufacture, or commercialize products could suffer.

In addition, while we cannot currently determine 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.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant research programs or product candidates and our business, financial condition, results of operations and prospects could suffer.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We currently own intellectual property directed to our product candidates and other proprietary technologies. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

Moreover, some of our owned and in-licensed patents or patent applications or future patents are or may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. 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. 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.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates. We cannot be certain that our product candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights. For example, we have identified certain third-party patents that may be asserted against us with respect to our lead product SBT6050. These patents may expire prior to commercial launch of SBT6050, if approved. We believe that the relevant claims of these third-party patents are likely invalid or unenforceable, and we may choose to challenge those patents, though the outcome of any challenge that we may initiate in the future is uncertain. We may also decide in the future to seek a license to those third-party patents, but we might not be able to do so on reasonable terms. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing candidate product or product. Alternatively, we may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing candidate product or product. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our investigational products or force us to cease some of our business operations, which could materially harm our business.

We may not be aware of patents that have already been issued and that a third-party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidate. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. 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 litigation. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

We may choose to challenge the enforceability or validity of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies.

If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing, or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, and could divert the time and attention of our technical personnel and management, cause development delays, and/or require us to develop non-infringing technology, which may not be possible on a cost-effective basis, any of which could materially harm our business. In the event of a successful claim of infringement against us, we may have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone 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 is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271I(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 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 shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third-party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, 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. For example, in the 2013 case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, 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, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse, including due to the effect of the COVID-19 pandemic on us or our patent maintenance vendors, can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

We may rely on trade secret and proprietary know-how, which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our product candidate, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with whom we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. 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 inside and outside the United States are less willing or unwilling to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, 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 or other third-party, our competitive position would be harmed.

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

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

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

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

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

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. 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 product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, the term of a patent can be increased by patent term adjustment, which is based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The term of a United States patent may also be shortened if the patent is terminally disclaimed over an earlier-filed patent. A patent term extension (PTE) based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the PTE does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous PTEs in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain PTE or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

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 current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive 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. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to the Securities Markets and Ownership of Our Common Stock

An active trading market for our common stock may not continue to be developed or be sustained, which may make it difficult for you to sell your shares.

Prior to our initial public offering in December 2020, there had been no public market for our common stock. The trading market for our common stock on The Nasdaq Global Market has been limited and an active trading market for our shares may not be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell your shares at a price that is attractive to you, or at all.

*The price of our common stock could be subject to volatility related or unrelated to our operations.**

Our stock price may be volatile. The stock market in general and the market for biotechnology and pharmaceutical companies, in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your shares at a price that is attractive to you, or at all. The market price for our common stock may be influenced by numerous factors, many of which are beyond our control, including:

- results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- adverse results or delays in clinical trials;
- failure to commercialize our product candidates;
- unanticipated serious safety concerns related to immuno-oncology or related to the use of our product candidates;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to future product candidates or clinical development programs;
- our failure to achieve product development goals in the timeframe we announce;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock;
- the expiration of market standoff or contractual lock-up agreements;
- the size of our market float;
- political uncertainty and/or instability in the United States;
- the ongoing and future impact of the COVID-19 pandemic and actions taken to slow its spread; and
- any other events or factors discussed in this report.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many immune-oncology companies. Stock prices of many immune-oncology companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. The trading prices for common stock of other biopharmaceutical companies have also been highly volatile as a result of the COVID-19 pandemic. In the past, stockholders have filed securities class action lawsuits following periods of market volatility. For example, following a decline in our stock price, a federal securities class action complaint was filed against us and certain of our officers and directors in the U.S. District for the Western District of Washington, captioned *Dresner v. Silverback Therapeutics, Inc., et al.*, Case No. 2:21-cv-01499, which alleges violations of (i) Sections 11 and 15 of the Securities Act; and (ii) Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder. Even if we are successful in defending against this action or any similar claims that may be brought in the future, such litigation could subject us to substantial costs, divert resources and the attention of management from our business, and adversely affect our business.

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.

Certain of our executive officers, directors and large stockholders own a significant percentage of our outstanding capital stock. As a result of their share ownership, these stockholders will have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

If there are substantial sales of shares of our common stock, the price of our common stock could decline.*

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. As of September 30, 2021, we had 35,067,751 outstanding shares of our common stock.

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

As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. *

Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. 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. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2020 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares of our common stock reserved for issuance under our 2020 Plan will automatically increase on January 1 of each calendar year through January 1, 2030, in an amount equal to the lesser of (i) 5.0% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of each automatic increase; or (ii) a lesser number of shares determined by our board of directors prior to the applicable January 1st. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

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

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

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

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

We are and in the future could be subject to securities class action litigation. *

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. For example, following a decline in our stock price, a federal securities class action complaint was filed against us and certain of our officers and directors in the U.S. District for the Western District of Washington, captioned *Dresner v. Silverback Therapeutics, Inc., et al.*, Case No. 2:21-cv-01499, which alleges violations of (i) Sections 11 and 15 of the Securities Act; and (ii) Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder. Even if we are successful in defending against this action or any similar claims that may be brought in the future, such litigation could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

We are an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;

- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

In addition, as an “emerging growth company” the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies, unless we later irrevocably elect not to avail ourselves of this exemption. We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have at least \$1.07 billion in annual revenue; (ii) the date upon which we are deemed to be a “large accelerated filer,” as defined in Rule 12b-2 under the Exchange Act; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt securities during the prior three-year period; and (iv) December 31, 2025.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66-2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders’ meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer’s own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

Our amended and restated certificate of incorporation designates the state courts the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, and the federal district courts of the United States of America to be the exclusive forums for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against our company and our directors, officers and employees.

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom shall will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees, governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction.

In addition, our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, unless we consent in writing to the selection of an alternative forum.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

General Risk Factors

Our internal information technology systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business, or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to 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 also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party contractors who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to data leakage. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our product candidates could be delayed.

We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our headquarters and main research facility are located in Seattle, Washington, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

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

Use of Proceeds

On December 3, 2020, we commenced our initial public offering pursuant to a registration statement on Form S-1 (File No. 333-250009) that was declared effective by the SEC on December 3, 2020, for 11,500,000 shares of our common stock for sale to the public at a price of \$21.00 per share. In addition, in December 2020, the underwriters exercised their over-allotment option to purchase 1,725,000 additional shares of our common stock in the initial public offering at the public offering price of \$21.00 per share, such that the aggregate offering price of our initial public offering was \$277.7 million. The net offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, were \$255.3 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates. The underwriters for our initial public offering were Goldman Sachs & Co. LLC, SVB Leerink LLC, Stifel, Nicolaus & Company, Incorporated, and H.C. Wainwright & Co., LLC.

Upon receipt, the net proceeds from our initial public offering (IPO) were held in cash and cash equivalents, primarily in treasury money market accounts. Through September 30, 2021, we have used approximately \$30.0 million of the net proceeds from our IPO. There has been no material change in the use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on December 4, 2020.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K, filed with the SEC on December 8, 2020).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K, filed with the SEC on December 8, 2020).
4.1	Reference is made to Exhibit 3.1 and 3.2 .
4.2	Form of Common Stock Certificate of the registrant (incorporated by reference to Exhibit 4.1 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 30, 2020).
4.3	Amended and Restated Investors' Rights Agreement, by and between the registrant and certain of its stockholders, dated September 22, 2020 (incorporated by reference to Exhibit 4.2 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
4.4	Warrant to purchase stock issued to Silicon Valley Bank, dated November 21, 2016 (incorporated by reference to Exhibit 4.3 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
4.5	Warrant to purchase stock issued to Silicon Valley Bank, dated December 22, 2017 (incorporated by reference to Exhibit 4.4 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.1 Y	Sublease, by and between the registrant and Delta Dental, dated July 1, 2021.
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Principal Executive and Financial Officers Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted in Inline XBRL and included in Exhibit 101)

~~Y~~ Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.

The information in Exhibit 32.1 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Quarterly Report on Form 10-Q), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

SIGNATURES

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

SILVERBACK THERAPEUTICS, INC.

Date: November 10, 2021

By: /s/ Laura Shawver

Laura Shawver

Chief Executive Officer and Director (*Principal Executive Officer*)

Date: November 10, 2021

By: /s/ Jonathan Piazza

Jonathan Piazza

Chief Financial Officer (*Principal Financial Officer*)



Jones Lang LaSalle
601 Union St. Ste 2800
Seattle, WA 98101
Phone: 206-607-1700
Fax: 206-607-1701

© Commercial Brokers
Association ALL RIGHTS RESERVED
Form: SUB_LS
Sublease Agreement
Rev. 9/2020
Page 1 of 20



SUBLEASE AGREEMENT

THIS SUBLEASE AGREEMENT ("Sublease") is entered and effective this 1st day of July, 2021, by DELTA DENTAL OF WASHINGTON, a(n) Washington nonprofit corporation, ("Tenant"), and SILVERBACK THERAPEUTICS, INC., a(n) Delaware corporation ("Subtenant"). Tenant entered into that certain lease agreement dated October 16th, 2016 ("Master Lease") with T-C/SK 400 FAIRVIEW OWNER LLC, a(n) Delaware limited liability company as ("Landlord"), for the leased premises legally described in the attached Exhibit 1 (the "Master Premises"). The Master Premises is located in that certain building commonly known as 400 Fairview (the "Building"), and situated on real property legally described in the Master Lease (the "Property"). A copy of the Master Lease, including all amendments and addenda thereto, is attached as Exhibit 2.

Tenant and Subtenant agree as follows:

1. SUBLEASE SUMMARY.

- a. **Subleased Premises.** Tenant leases to Subtenant and Subtenant leases from Tenant that portion of the Master Premises (the "Subleased Premises") consisting of an agreed area of 9,188 rentable square feet on the 6th floor(s) of the Master Premises, as outlined on the floor plan attached as Exhibit 3 (except that Tenant shall not have access to the stairwell depicted thereon) and commonly known as 400 Fairview Avenue North, Seattle, WA 98109 (Suite 600).
 - b. **Sublease Commencement Date.** The term of this Sublease shall commence upon the later of (i) receipt of Landlord's written consent to this Sublease in a form acceptable to Subtenant, (ii) possession of the Subleased Premises is delivered to Subtenant and (iii) Tenant's Work (cap of the stairwell) is completed (the "Sublease Commencement Date"), but this date may not occur prior to July 1, 2021 unless Subtenant agrees.
 - c. **Sublease Termination Date.** The term of this Sublease shall terminate at midnight on the last day of the 24th full month following the Sublease Commencement Date, or one (1) day prior to the termination date of the Master Lease, whichever is earlier, unless sooner terminated in accordance with the terms of this Sublease (the "Sublease Termination Date"). So long as Subtenant is not in default (beyond applicable notice and cure periods) of its obligations under this Sublease, Subtenant shall have the right to terminate this sublease any time following the twelfth (12th) month of the sublease term by providing at least 90 days prior written notice. Subtenant shall pay a termination fee equal to one month of rent due at the time of written notice to Tenant. So long as Subtenant is not in default (beyond applicable notice and cure periods) of its obligations under this Sublease, Subtenant shall have the option to extend the Sublease term for a period of twelve-months (the "Extended Sublease Term"). Subtenant shall provide three-months' written notice of its exercise of this option to extend prior to the Sublease Termination Date unless sooner terminated pursuant to the provisions of the Sublease Agreement. The monthly base rent for the Extended Sublease Term shall be \$30,054.42.
 - d. **Base Rent.** Subtenant shall pay to Tenant monthly base rent (check one): \$28,329.67 for the first twelve months, then \$29,179.56 thereafter, or according to the Rent Rider attached hereto ("Base Rent). Rent shall be payable at Tenant's address shown in Section 1(h) below, or such other place designated in writing by Tenant. Provided Subtenant shall faithfully perform all of the terms and conditions of the Sublease, Subtenant shall not be required to pay any Rent for the first full calendar month of the Term of this Sublease. For the avoidance of doubt, the parties to this Sublease intend that this Base Rent payment is the only payment owing by Subtenant to Sublandlord for use of the Subleased Premises, and Subtenant shall not be responsible for paying any portion of the Operating Costs, utility costs or other costs owing under the Master Lease. Sublandlord at its sole cost shall timely pay Landlord for all Operating Costs, utility charges and other charges and fees owing under the Master Lease throughout the Term of this Sublease.
 - e. **Prepaid Rent.** Upon execution of this Sublease, Subtenant shall deliver to Tenant the sum of \$28,329.67, as prepaid rent to be applied to Rent due for month 2 of the Sublease.
-



Jones Lang LaSalle
601 Union St. Ste 2800
Seattle, WA 98101
Phone: 206-607-1700
Fax: 206-607-1701

© Commercial Brokers
Association ALL RIGHTS RESERVED
Form: SUB_LS
Sublease Agreement
Rev. 9/2020
Page 2 of 20



- f. **Security Deposit.** Upon execution of this Sublease, Subtenant shall deliver to Tenant the sum of \$29,179.56 (equal to last month's rent) to be held as a security deposit pursuant to Section 5 below. The security deposit shall be in the form of (check one): cash, check or wire transfer, letter of credit, or according to the Letter of Credit Rider (CBA Form LCR) attached hereto.
- g. **Permitted Use.** The Subleased Premises shall be used only for office and administrative use, subject to the Master Lease, applicable zoning, and other laws, and for no other purpose without the prior written consent of Tenant (the "Permitted Use").
- h. **Notice and Payment Addresses:**

Tenant: DELTA DENTAL OF WASHINGTON
400 Fairview Avenue N, Suite 800
Seattle, WA 98109

Attn: Ryan Bartlett
Email: rbartlett@deltadentalwa.com

Subtenant: SILVERBACK THERAPEUTICS, INC

Email:

- i. **Subtenant's Sublease Share.** Subtenant's Sublease Share of any operating costs, common area charges, additional rent, or other amounts payable by Tenant under the Master Lease is 0% of such amounts, based upon the ratio of the rentable area of the Subleased Premises to the rentable area of the Master Premises.

2. PREMISES

- a. **Lease of Premises.** Tenant leases to Subtenant, and Subtenant leases from Tenant the Subleased Premises upon the terms specified in this Sublease. In addition to use of the Subleased Premises, Subtenant shall have the same rights of ingress and egress to the Subleased Premises, and any common areas and the benefit of any appurtenant easements and rights of way, all on such conditions and at such times as permitted by Landlord and granted under the Master Lease.
-



- b. **Acceptance of Premises.** Except as specified elsewhere in this Sublease, Tenant makes no representations or warranties to Subtenant regarding the Subleased Premises, including the structural condition of the Subleased Premises or the condition of all mechanical, electrical, and other systems on the Subleased Premises. Except for any subtenant improvements to be completed by Tenant as described in the Work Letter attached as Exhibit 4 ("Tenant's Work"), Subtenant shall accept the Subleased Premises and its appurtenances in their respective AS-IS, WHERE-IS condition, and shall further be responsible for performing any work necessary to bring the Subleased Premises into a condition satisfactory to Subtenant. By signing this Sublease, Subtenant acknowledges that it has had adequate opportunity to investigate the Subleased Premises, acknowledges responsibility for making any corrections, alterations and repairs to the Subleased Premises (other than Tenant's Work), and acknowledges that the time needed to complete any such items shall not delay the Sublease Commencement Date. However, Sublandlord shall at its cost deliver the Subleased Premises to Subtenant (i) broom clean; and (ii) with the Tenant's Work (cap of the stairwell) substantially completed. Sublandlord further agrees to work in good faith with Subtenant and Landlord to facilitate Subtenant's use of existing cabling infrastructure within the Subleased Premises (while ensuring that Sublandlord's data and network security and performance is not compromised). To Sublandlord's knowledge, all lighting, electrical outlets, and any other electrical/mechanical systems are in a fully functional condition consistent with a class A building in Seattle. Notwithstanding anything to the contrary in this Sublease, Subtenant shall have no obligation to correct any defects in the Subleased Premises (including, without limitation, any condition that is a default under the Master Lease) existing as of the Commencement Date of this Sublease, and Sublandlord shall be responsible at its cost for correcting any such defects or defaults to the extent such obligations are Sublandlord's obligation to maintain pursuant to the Master Lease.
- c. **Subtenant Improvements.** The Work Letter attached as Exhibit 4 sets forth all of Tenant's Work, if any, and all improvements to be completed by Subtenant ("Subtenant's Work"), if any, that will be performed on the Subleased Premises. Responsibility for design, payment and performance of all such work shall be as set forth in the Work Letter.
3. **TERM.** The term of this Sublease shall commence on the Commencement Date and shall end on the Termination Date (the "Term").
- a. **Early Possession.** Subtenant acknowledges that Tenant may need to obtain Landlord's consent to this Sublease prior to Subtenant occupying the Subleased Premises, and that Subtenant shall not occupy the Subleased Premises without the prior written consent of Tenant. In the event Tenant gives Subtenant access to the Subleased Premises preceding the Sublease Commencement Date for the purpose of installing Subtenant's furniture, telecommunications, fixtures, telephone systems and computer cabling and the performance of Subtenant's Work, if any, such access shall be fully coordinated with Tenant in advance and Subtenant shall not interfere with Tenant's Work. In no event shall Subtenant have access to any portion of the Master Premises except for the Subleased Premises. All of the terms and conditions of this Sublease, including Subtenant's insurance and indemnification obligations, shall apply during such time, except for payment of Base Rent. If Subtenant occupies the Subleased Premises before the Sublease Commencement Date specified in Section 1, then such date of occupancy shall not advance the Sublease Commencement Date or Sublease Termination Date set forth above. Subtenant shall have fifteen (15) days early access to the Premises for FF&E at no additional cost.
-



- b. **Delayed Possession.** Tenant shall act diligently to make the Subleased Premises available to Subtenant, provided, however, that neither Tenant nor any agent or employee of Tenant shall be liable for any damage or loss due to Tenant's inability or failure to deliver possession of the Premises to Subtenant as provided in this Sublease. If possession is delayed, the Sublease Commencement Date set forth in Section 1 shall also be delayed, but the Sublease Termination Date shall not be extended by such delay. If the Sublease Commencement Date does not occur within ___ days ((60) days if not filled in) after the mutual execution and delivery of this Sublease : Subtenant may elect to cancel this Sublease by giving written notice to Tenant no later than ((10) days if not filled in) after such time period ends, or then all Base Rent and Additional Rent (as defined below) shall be abated for each one (1) day after the Sublease Commencement Date during which possession of the Subleased Premises has not been delivered to Subtenant. If Subtenant gives notice of cancellation, as Subtenant's sole and exclusive remedy, this Sublease shall be cancelled, all prepaid rent and security deposits shall be refunded to Subtenant, and neither Tenant nor Subtenant shall have any further obligations to the other.

Notwithstanding anything in this Section 3 to the contrary, to the extent that any portions of the Tenant's Work or the Subtenant's Work have not been completed in time for the Subtenant to occupy or take possession of the Subleased Premises on the Sublease Commencement Date due to the failure of Subtenant to fulfill any of its obligations under this Sublease ("Subtenant Delays"), the Sublease shall nevertheless commence on the Sublease Commencement Date, including without limitation, Subtenant's obligation to pay Base Rent and Additional Rent, as set forth in Section 1, or upon the date that the Sublease Commencement Date would have occurred but for the Subtenant Delays.

4. RENT

- a. **Payment of Rent.** Subtenant shall pay Tenant without notice, demand, deduction or offset, in lawful money of the United States, the monthly Base Rent stated in Section 1 in advance on or before the first day of each month during the Sublease Term beginning on (check one): the Sublease Commencement Date, or ___ (if no date specified, then on the Sublease Commencement Date), and any other additional payments due to Tenant ("Additional Rent", and together with Base Rent, the "Rent") when required under this Sublease. Payments for any partial month during the Term shall be prorated. All payments due to Tenant under this Sublease, including late fees and interest, shall also constitute Additional Rent, and upon Subtenant's failure to pay any such costs, charges or expenses, Tenant shall have the same rights and remedies as otherwise provided in this Sublease for the failure of Subtenant to pay Rent.
- b. **Late Charges; Default Interest.** If any sums payable by Subtenant to Tenant under this Sublease are not received within five (5) days of their due date, Subtenant shall pay Tenant an amount equal to the sum which would be payable by Tenant to the Landlord for or 5% of the delinquent amount for the cost of collecting and handling such late payment in addition to the amount due and as Additional Rent, whichever is greater. All delinquent sums not paid by Subtenant within five (5) business days of the due date shall, at Tenant's option, bear interest at the rate the Tenant would pay the Landlord under the Master Lease for an equivalent default or the highest rate of interest allowable by law, whichever is less. Interest on all delinquent amounts shall be calculated from the original due date to the date of payment.
- c. **Less Than Full Payment.** Tenant's acceptance of less than the full amount of any payment due from Subtenant shall not be deemed an accord and satisfaction or compromise of such payment unless Tenant specifically consents in writing to payment of such lesser sum as an accord and satisfaction or compromise of the amount which Tenant claims. Any portion that remains to be paid by Tenant shall be subject to the late charges and default interest provisions of this Section.
-

5. **SECURITY DEPOSIT.** Upon execution of this Sublease, Subtenant shall deliver to Tenant the security deposit specified in Section 1 above. Tenant's obligations with respect to the security deposit are those of a debtor and not of a trustee, and Tenant may commingle the security deposit with its other funds. If Subtenant defaults in the performance of any covenant or condition of this Sublease, Tenant shall have the right, but not the obligation, to use or retain all or any portion of the security deposit for the payment of: (i) Base Rent, Additional Rent, or any other sum as to which Subtenant is in default; or (ii) the amount Tenant spends or may become obligated to spend, or to compensate Tenant for any losses incurred by reason of Subtenant's default. Subtenant acknowledges, however, that the security deposit shall not be considered as a measure of Subtenant's damages in case of default by Subtenant, and any payment to Tenant from the security deposit shall not be construed as a payment of liquidated damages for Subtenant's default. If at any time during the Term of the Sublease the security deposit delivered by Subtenant becomes insufficient to cover the amounts required under this Section 5, whether or not due to Tenant's application of all or a portion of the security deposit contemplated by this Section, Subtenant shall, within five (5) days after written demand therefore by Tenant, deposit with Tenant an amount sufficient to replenish the security deposit to the amount required in Section 1 above. If Subtenant is not in default of any covenant or condition of this Sublease at the end of the Term, Tenant shall return any unused portion of the security deposit without interest within 30 days after the surrender of the Subleased Premises by Subtenant in the condition required by Section 9 of this Sublease.
6. **MASTER LEASE.** Tenant represents to Subtenant that as of the effective date of this Sublease: (a) Tenant has delivered to Subtenant a complete copy of the Master Lease (which may contain redacted business terms), which represents all agreements between Landlord and Tenant relating to the leasing, use, and occupancy of the Subleased Premises, and (b) Tenant has not received notice from Landlord of a breach under the Master Lease that is uncured as of the date of mutual execution and delivery of this Sublease. Tenant shall not agree to an amendment to the Master Lease which would have an adverse effect on Subtenant's occupancy of the Subleased Premises or its intended use of the Subleased Premises, without obtaining Subtenant's prior written consent, which consent shall not be unreasonably withheld, conditioned, or delayed. Subtenant represents that it has read and is familiar with the terms of the Master Lease.

This Sublease is subject to and subordinate to the Master Lease. If the Master Lease terminates, this Sublease shall automatically terminate. Tenant and Subtenant shall not, by their omission or act, do or permit anything to be done which would cause a default under the Master Lease. If the Master Lease terminates or is forfeited as a result of a default or breach by Tenant or Subtenant under this Sublease and/or the Master Lease, then the defaulting party shall be liable to the non-defaulting party for the actual damage suffered as a result of such termination or forfeiture provided that in no event shall one party be liable to the other for consequential damages. Tenant shall exercise diligent, commercially reasonable efforts to cause Landlord to perform its obligations under the Master Lease for the benefit of the Subtenant, provided that in no event shall the foregoing requirements require Tenant to file a lawsuit.



Except as set forth below and except as may be inconsistent with the terms contained in this Sublease, all the terms, covenants and conditions contained in the Master Lease are incorporated into and made a part of this Sublease by this reference with the following modified definitions : (i) all references in the Master Lease to "Landlord" shall be deemed to mean Tenant, (ii) all references in the Master Lease to "Tenant" shall be deemed to mean Subtenant, (iii) all references in the Master Lease to "Lease" shall mean this Sublease, (iv) all references in the Master Lease to "Premises" shall mean Subleased Premises, (v) all references in the Master Lease to "Commencement Date" shall mean Sublease Commencement Date, and (vi) all references in the Master Lease to "Term" shall mean "Sublease Term". Tenant and Subtenant agree that as between Tenant and Subtenant the following terms of the Master Lease shall not be incorporated into this Sublease: the entire Lease Summary; Sections 1.1, 1.3, 1.5, 1.6, 2, 3, 4, 7, 8.1.9, 8.6, 10, 11, 15, 16, 18, and 20, 22.14, 22.17, 22.18, Exhibits A, C, D, E, G, and H. Notwithstanding the foregoing incorporation of the terms and conditions of the Master Lease, Tenant shall not be responsible for the performance of any obligations to be performed by Landlord under the Master Lease, and Subtenant agrees to look solely to Landlord for the performance of such obligations. Tenant shall not be liable to Subtenant for any failure by Landlord to perform its obligations under the Master Lease, nor shall such failure by Landlord excuse performance by Subtenant of its obligations hereunder. The parties acknowledge that Subtenant has no "Guarantor" as defined in the Master Lease, and no performance of obligations by or notice to any guarantor shall be required under the terms of this Sublease.

7. **CONSENT OF LANDLORD.** Notwithstanding anything to the contrary in this Sublease, whenever the consent of Landlord is required under the Master Lease, Subtenant shall obtain the consent of both Tenant and Landlord, but in all instances Subtenant shall first request and obtain the consent of Tenant before requesting the consent of Landlord. This Sublease shall not become effective until Landlord has provided its written consent to this Sublease. If Landlord does not consent to this Sublease within sixty (60) days of the parties' execution of this Sublease, then this Sublease shall be deemed void and the parties shall have no further rights or obligations hereunder.
 8. **ALTERATIONS.** Subtenant may make alterations, additions or improvements to the Subleased Premises (the "Alterations"), only with the prior written consent of Tenant which shall not be unreasonably withheld, conditioned or delayed, and, to the extent required by the Master Lease, Landlord. The term "Alterations" shall not include: (i) any of Subtenant's Work approved by Tenant pursuant to Exhibit 4, and (ii) the installation of shelves, movable partitions, or Subtenant's equipment and trade fixtures, which may be installed and removed without damaging existing improvements or the structural integrity of the Subleased Premises, Master Premises, Building, or Property, and Tenant's consent shall not be required for Subtenant's installation of those items except to the extent Tenant must obtain the consent of Landlord under the Master Lease for such installations. Subtenant shall perform all work within the Subleased Premises at Subtenant's expense in compliance with all applicable laws and shall complete all Alterations in accordance with plans and specifications approved by Tenant, using contractors approved by Tenant, and in a manner so as to not unreasonably interfere with other tenants. Subtenant shall pay when due, all claims for labor or materials furnished to or for Subtenant at or for use in the Subleased Premises, which claims are or may be secured by any mechanics' or materialmen's liens against the Subleased Premises or Property or any interest therein. Except as otherwise provided in the Work Letter attached as Exhibit 4 with respect to Subtenant's Work, Subtenant shall remove all Alterations at the end of the Sublease term unless Tenant conditioned its consent upon Subtenant leaving a specified Alteration at the Subleased Premises, in which case Subtenant shall not remove such Alteration and it shall become Tenant's property. Subtenant shall immediately repair any damage to the Subleased Premises or adjacent portions of the Master Premises, Building and Property caused by installation and/or removal of improvements performed as part of Subtenant's Work and/or Alterations. Notwithstanding anything to the contrary, Subtenant shall have no obligation to remove or restore any alterations or improvements present upon the Subleased Premises as of the Commencement Date of this Sublease. Subtenant shall remove any cabling that was installed in the Subleased Premises by Subtenant only upon request by Tenant.
-



- 9. REPAIRS AND MAINTENANCE; SURRENDER.** Subtenant shall, at its sole cost and expense, maintain the Subleased Premises in good condition and promptly make all repairs and replacements, whether structural or non-structural, necessary to keep the Subleased Premises safe and in good condition, including all utilities and other systems serving the Subleased Premises. Subtenant shall not damage any demising wall or disturb the structural integrity of the Subleased Premises and shall promptly repair any damage or injury done to any such demising walls or structural elements caused by Subtenant or its employees, officers, agents, servants, contractors, customers, clients, visitors, guests, or other licensees or invitees. If Subtenant fails to maintain or repair the Subleased Premises, Tenant may enter the Subleased Premises and perform such repair or maintenance on behalf of Subtenant. In such case, Subtenant shall be obligated to pay to Tenant immediately upon receipt of demand for payment, as Additional Rent, all costs incurred by Tenant in performing such repair or maintenance on behalf of Subtenant. Subtenant shall be obligated to repair or maintain only those portions of the Subleased Premises as required of Tenant under the Master Lease. Tenant shall not be required to perform any maintenance, repairs, or improvements that are the obligation of Landlord under the Master Lease (provided that Tenant shall exercise diligent, commercially reasonable efforts to cause Landlord to perform its obligations under the Master Lease for the benefit of the Subtenant) or to make any changes to the Subleased Premises because of the enactment of any law, ordinance, regulation, order or code during the Term. Notwithstanding anything in this Section to the contrary, Subtenant shall not be responsible for any repairs to the Subleased Premises made necessary by the acts of Tenant, Landlord, or their respective employees, officers, agents, servants, contractors, customers, clients, visitors, guests, or other licensees or invitees.

Upon expiration or earlier termination of the Term, Subtenant shall promptly and peacefully surrender the Subleased Premises to Tenant, together with all keys, in as good condition as when received by Subtenant or as thereafter improved (but subject to any obligations to remove any Subtenant's Work and Alterations and/or to restore the same as provided elsewhere in this Sublease), reasonable wear and tear and insured casualty excepted.

- 10. ACCESS AND RIGHT OF ENTRY.** After reasonable written notice from Tenant (except in cases of emergency, where no notice is required) and subject to any and all rights of Landlord to enter the Premises under the Master Lease, Subtenant shall permit Tenant and/or Landlord and their respective agents, employees and contractors to enter the Subleased Premises at reasonable times to make repairs, alterations, improvements or inspections. **This Section shall not impose any repair or other obligation upon Tenant or Landlord not expressly stated** elsewhere in this Sublease. After reasonable notice to Subtenant, each of Tenant and Landlord, as the case may be, shall have the right to enter the Subleased Premises for the purpose of (a) showing the Subleased Premises to prospective purchasers or lenders at any time, and to prospective tenants within 180 days prior to the expiration or sooner termination of the Term; and (b) posting "for lease" signs within 180 days prior to the expiration or sooner termination of the Term.
- 11. DESTRUCTON OR CONDEMNATION.**
-



- a. **Damage and Repair.** If either Landlord or Tenant terminates the Master Lease as a result of condemnation of or casualty to the Subleased Premises, Master Premises, or Building or Property in accordance with the Master Lease, this Sublease shall terminate on the same date and in accordance therewith. If the Sublease is not terminated pursuant to the prior sentence and the Subleased Premises or the portion of the Building or Property reasonably necessary for Subtenant's occupancy are damaged, destroyed or rendered untenable, by fire or other casualty, Tenant may, at its option: (a) terminate this Sublease, or (b) restore (or cause Subtenant to restore) the Subleased Premises and the portion of the Building and Property reasonably necessary for Subtenant's occupancy to the same or substantially similar condition that existed before the casualty event. Provided, however, if such casualty event occurs during the last six (6) months of the Term, then either Subtenant or Tenant may elect to terminate this Sublease. If, within 60 days after Tenant's receipt of written notice from Subtenant that Subtenant deems the Subleased Premises or the portion of the Property reasonably necessary for Subtenant's occupancy untenable, Tenant fails to notify Subtenant of its election to restore those areas, or if Tenant is unable to restore those areas which Tenant is expressly required hereunder to restore within six (6) months of the date of the casualty event, then Subtenant may elect to terminate this Sublease by written notice given to Tenant at any time prior to the date on which Tenant substantially completes restoration of those areas which it is required hereunder to restore.

If Tenant restores the Subleased Premises or the Property as provided under this Section, Tenant shall proceed with reasonable diligence to complete the work, and Base Rent shall be abated in the same proportion as the untenable portion of the Subleased Premises bears to the whole Subleased Premises, provided that there shall be a Base Rent abatement only if the damage or destruction of the Subleased Premises or the Property did not result from, or was not contributed to directly or indirectly by, the act, fault or neglect of Subtenant or Subtenant's employees, officers, agents, servants, contractors, customers, clients, visitors, guests, or other licensees or invitees. No damages, compensation or claim shall be payable by Tenant for Subtenant's inconvenience, loss of business or annoyance directly, incidentally or consequentially arising from any repair or restoration of any portion of the Subleased Premises, Master Premises, Building, or Property. Tenant shall have no obligation to carry insurance of any kind for the protection of Subtenant or any Alterations or improvements paid for or installed by or on behalf of Subtenant; any Tenant's Work or Subtenant's Work identified in Exhibit 4 (regardless of who may have completed them); Subtenant's furniture; or on any fixtures, equipment, improvements or appurtenances of Subtenant under this Sublease; and Tenant shall not be obligated to repair any damage thereto or replace the same unless the damage is caused by Tenant's gross negligence or willful misconduct.

- b. **Condemnation.** If either Landlord or Tenant terminates the Master Lease based on any provision in the Master Lease relating to eminent domain or conveyance under threat of condemnation, this Sublease shall terminate on the same date and in accordance therewith. If the Sublease is not terminated pursuant to the prior sentence and the Subleased Premises, the portion of the Building or Property reasonably necessary for Subtenant's occupancy, or 50% or more of the total rentable area of the Property are made untenable by eminent domain, or conveyed under a threat of condemnation, this Sublease shall terminate at the option of each of Tenant and Subtenant as of the earlier of the date title vests in the condemning authority or the condemning authority first has possession of the portion of the Property taken by the condemning authority. All Rent and other payments required under this Sublease shall be paid to that date.



Jones Lang LaSalle
601 Union St. Ste 2800
Seattle, WA 98101
Phone: 206-607-1700
Fax: 206-607-1701

© Commercial Brokers
Association ALL RIGHTS RESERVED
Form: SUB_LS
Sublease Agreement
Rev. 9/2020
Page 9 of 20



If the condemning authority takes a portion of the Subleased Premises or the portion of the Property necessary for Subtenant's occupancy that does not render them untenable, then this Sublease shall continue in full force and effect and the Base Rent shall be equitably reduced based on the proportion by which the floor area of the Subleased Premises is reduced. The reduction in Base Rent shall be effective on the earlier of the date the condemning authority first has possession of such portion or title vests in the condemning authority. The Subleased Premises or the portion of the property reasonably necessary for Subtenant's occupancy shall not be deemed untenable if 25% or less of each of those areas is condemned. As between Tenant and Subtenant, Tenant shall be entitled to the entire award from the condemning authority attributable to the value of the Master Premises, Subleased Premises, or the Property or Building, and Subtenant shall make no claim for the value of its subleasehold estate or the Subtenant's Work or any Alterations. Subtenant shall be permitted to make a separate claim against the condemning authority for moving expenses or damages resulting from interruption in its business if this Sublease is terminated under this Section, provided that in no event shall Subtenant's claim reduce Landlord's or Tenant's awards.

- 12. INSURANCE.** Subtenant shall procure and maintain, at its sole cost and expense, such insurance as is required to be carried by Tenant under the Master Lease, and shall comply with all requirements with respect to the insurance of Tenant under the Master Lease, including, without limitation, obtaining additional insured endorsement(s) naming Tenant and Landlord as additional insureds, in the manner required therein, and property insurance as is required to be carried by Tenant under the Master Lease to the extent property insurance pertains to the Subleased Premises. If the Master Lease requires Tenant to insure leasehold improvements or Alterations, then Tenant shall insure the leasehold improvements which are located in the Subleased Premises, as well as the Tenant's Work, and Subtenant shall insure any Alterations in the Subleased Premises performed by or on behalf of Subtenant. Subtenant shall furnish to Tenant certificates of Subtenant's insurance policies and copies of any endorsements required hereunder not later than 10 days prior to Subtenant's taking possession of the Subleased Premises. Tenant shall carry insurance as required by the Master Lease and shall not be obligated to carry property or liability insurance to the extent such insurance is an obligation of Landlord under the Master Lease.

Tenant and Subtenant hereby release each other and their respective employees, officers, agents, servants, contractors, customers, clients, visitors, guests, or other licensees or invitees, from responsibility for and waive their respective claims for recovery of any loss or damage arising from any cause covered by insurance required to be carried by each of them. Each party shall provide notice to the insurance carrier or carriers of this mutual waiver of subrogation, and shall cause its respective insurance carriers to waive all rights of subrogation against the other. This waiver shall not apply to the extent of the deductible amounts to any such policies or to the extent of liability exceeding the limits of such policies. Tenant agrees to use reasonable efforts to obtain from Landlord for the benefit of Subtenant the same waiver of claims for any loss or damage arising from any cause covered by insurance required to be carried by Landlord under the Master Lease and, if and to the extent of such waiver received from Landlord, Subtenant agrees to grant the same waiver to Landlord.

In no event shall Sublandlord be liable to Subtenant for business losses or consequential damages. In no event shall Subtenant be liable to Sublandlord for business losses or consequential damages.



- 13. ASSIGNMENT AND SUBLETTING.** Subtenant shall not assign, sublet, mortgage, encumber or otherwise transfer any interest in this Sublease or any part of the Subleased Premises (collectively referred to as a "Transfer"), without first obtaining the written consent of Tenant, which shall not be unreasonably withheld, conditioned or delayed. Tenant may condition its consent on (a) obtaining any required consent from Landlord; (b) Subtenant satisfying any conditions to the Transfer imposed by Landlord and/or required to be satisfied by Tenant under the Master Lease; and (c) such other reasonable conditions that Tenant may impose. No Transfer shall relieve Subtenant of any liability under this Sublease notwithstanding Tenant's consent to such Transfer. Consent to any Transfer shall not operate as a waiver of the necessity for Tenant's consent to any subsequent Transfer. In connection with each request for consent to a Transfer, Subtenant shall pay the reasonable cost of processing same, including attorneys' fees and any cost charged by Landlord for granting its consent under the Master Lease, upon demand of Tenant.

Any transfer of this Sublease by merger, consolidation, redemption or liquidation of Subtenant, or any change in the ownership of, or power to vote, which singularly or collectively represents a majority of the beneficial interest in Subtenant, shall constitute a Transfer.

As a condition to the Landlord's and Tenant's approval, if given, any potential assignee or sublessee otherwise approved shall assume all obligations of Subtenant under this Sublease and shall be jointly and severally liable with Subtenant and any guarantor for the payment of Rent and other charges due hereunder and performance of all obligations of Subtenant under this Sublease. In connection with any Transfer, Subtenant shall provide Landlord and Tenant with copies of all assignments, subleases and assumption agreements and related documents.

- 14. MORTGAGE SUBORDINATION AND ATTORNMENT.** This Sublease shall automatically be subordinate to any mortgage or deed of trust created by Landlord to the extent the Master Lease is subordinate to the same mortgage or deed of trust, and Subtenant shall attorn upon the same terms and conditions as the Tenant in the Master Lease, provided Subtenant shall enjoy the terms and conditions relating to such subordination and attornment to the same extent as Tenant under the terms of the Master Lease.
- 15. HOLDOVER.** If Subtenant shall, without the written consent of Tenant, remain in possession of the Subleased Premises and shall fail to return the Subleased Premises to Tenant after the expiration or termination of the Sublease, the tenancy shall be a holdover tenancy at sufferance, which may be terminated in accordance with Washington law; provided that, upon expiration of the Master Lease, such holdover tenancy by Subtenant shall automatically be deemed a tenancy at sufferance, terminable immediately.

Unless Tenant agrees in writing to a different rental rate Subtenant agrees to pay to Tenant 150% of the rate of Base Rent last payable under this Sublease, during any holdover tenancy, in addition to all Additional Rent and other sums due under this Sublease. All other terms of the Sublease shall remain in effect. Nothing herein shall be deemed Tenant's consent to holdover by Subtenant, or be deemed to permit Subtenant to remain in possession of the Subleased Premises on and after expiration of the Master Lease.

- 16. NOTICES.** All notices under this Sublease shall be in writing and effective (i) when delivered in person or via overnight courier to the other party, or (ii) three (3) days after being sent by registered or certified mail to the other party at the addresses set forth in Section 1. The addresses for notices and payment of Rent set forth in Section 1 may be modified by either party only by written notice delivered in conformance with this Section.
- 17. ESTOPPEL CERTIFICATES.** Upon the written request of Tenant, Subtenant shall execute and deliver to Tenant and/or Landlord or their designee a written estoppel certificate on the same terms and conditions as required of Tenant under the Master Lease.
- 18. GENERAL.**
- a. **Heirs and Assigns.** This Sublease shall apply to and be binding upon Tenant and Subtenant and their respective heirs, executors, administrators, successors and assigns.
-



- b. **Brokers' Fees.** Subtenant represents and warrants to Tenant that except for Subtenant's Broker, if any, described and disclosed in Section 20 of this Sublease, it has not engaged any firm, finder or other person who would be entitled to any commission or fees for the negotiation, execution or delivery of this Sublease and shall indemnify and hold harmless Tenant against any loss, cost, liability or expense incurred by Tenant as a result of any claim asserted by any such firm, finder or other person on the basis of any arrangements or agreements made or alleged to have been made by or on behalf of Subtenant. Tenant represents and warrants to Subtenant that except for Tenant's Broker, if any, described and disclosed in Section 20, it has not engaged any firm, finder or other person who would be entitled to any commission or fees for the negotiation, execution or delivery of this Sublease and shall indemnify and hold harmless Subtenant against any loss, cost, liability or expense incurred by Subtenant as a result of any claim asserted by any such firm, finder or other person on the basis of any arrangements or agreements made or alleged to have been made by or on behalf of Tenant.
- c. **Entire Agreement.** This Sublease, which incorporates portions of the Master Lease, contains all of the covenants and agreements between Tenant and Subtenant relating to the Subleased Premises. No prior or contemporaneous agreements or understandings pertaining to the Sublease shall be valid or of any force or effect and the covenants and agreements of this Sublease shall not be altered, modified, or amended to except in writing signed by Tenant and Subtenant.
- d. **Severability.** Any provision of this Sublease which shall prove to be invalid, void or illegal shall in no way affect, impair or invalidate any other provision of this Sublease.
- e. **Governing Law.** This Sublease shall be governed by and construed in accordance with the laws of the State of Washington.
- f. **Memorandum of Sublease.** Neither this Sublease nor any memorandum or "short form" thereof shall be recorded without Tenant's prior consent.
- g. **Submission of Sublease Form Not an Offer.** One party's submission of this Sublease to the other for review shall not constitute an offer to sublease the Subleased Premises. This Sublease shall not become effective and binding upon Tenant and Subtenant until it has been fully executed by both Tenant and Subtenant, and consented to by Landlord (if required by the Master Lease).
- h. **Authority of Parties.** Each party to this Sublease represents and warrants to the other that the person executing this Sublease on behalf of such party has the authority to enter into this Sublease on behalf of this Sublease, that the execution and delivery of this Sublease has been duly authorized, and that upon such execution and delivery this Sublease shall be binding upon and enforceable against such party upon execution and delivery.

19. EXHIBITS AND RIDERS. The following exhibits and riders are made a part of this Sublease:

- Exhibit 1: Legal Description of the Master Premises or Property
- Exhibit 2: Master Lease
- Exhibit 3: Outline of Subleased Premises
- Exhibit 4: Work Letter
- Other: Parking Rider, FF&E

20. AGENCY DISCLOSURE. At the signing of this Sublease, Tenant is represented by Adam Chapman of Jones Lang LaSalle Brokerage, Inc. (insert name of Broker and Firm as licensed) (the "Tenant's Broker"); and Subtenant is represented Hans Kemp and Austin Arper Flinn Ferguson (insert name of Broker and Firm as licensed) (the "Subtenant's Broker").



Jones Lang LaSalle
 601 Union St. Ste 2800
 Seattle, WA 98101
 Phone: 206-607-1700
 Fax: 206-607-1701

© Commercial Brokers
 Association ALL RIGHTS RESERVED
 Form: SUB_LS
 Sublease Agreement
 Rev. 9/2020
 Page 12 of 20



This Agency Disclosure creates an agency relationship between Subtenant, Subtenant's Broker (if any such person is disclosed), and any managing brokers who supervise Subtenant's Broker's performance (collectively the "Supervising Brokers"). In addition, this Agency Disclosure creates an agency relationship between Tenant, Tenant's Broker (if any such person is disclosed), and any managing brokers who supervise Tenant's Broker's performance (also collectively the "Supervising Brokers"). If Tenant's Broker and Subtenant's Broker are different real estate licensees affiliated with the same Firm, then both Tenant and Subtenant confirm their consent to that Firm and both Tenant's and Subtenant's Supervising Brokers acting as dual agents. If Tenant's Broker and Subtenant's Broker are the same real estate licensee who represents both parties, then both Subtenant and Tenant acknowledge that the Broker, his or her Supervising Brokers, and his or her Firm are acting as dual agents and hereby consent to such dual agency. If Tenant's Broker, Subtenant's Broker, their Supervising Brokers, or their Firm are dual agents, Subtenant and Tenant consent to Tenant's Broker, Subtenant's Broker, and their Firm being compensated based on a percentage of the rent or as otherwise disclosed on an attached addendum. Neither Tenant's Broker, Subtenant's Broker nor either of their Firms are receiving compensation from more than one party to this transaction unless otherwise disclosed on an attached addendum, in which case Subtenant and Tenant consent to such compensation. Subtenant and Tenant confirm receipt of the pamphlet entitled "The Law of Real Estate Agency."

21. COMMISSION AGREEMENT. If Tenant has not entered into a listing agreement (or other compensation agreement with Tenant's Firm), Tenant agrees to pay a commission to Tenant's Firm (as identified in the Agency Disclosure Section above) as follows:

- \$1.25 per RSF per year to Subtenant's Broker & \$0.75 per RSF per year to Tenant's Broker
- _____% of the gross rent payable pursuant to this Sublease
- \$ _____per rentable square foot of the Subleased Premises
- Other

Tenant's Broker shall shall not (shall not if not filled in) be entitled to a commission upon the extension by Subtenant of the Term pursuant to any right reserved to Subtenant under the Sublease calculated as provided above or as follows _ (if no box is checked, as provided above). Tenant's Broker shall shall not (shall not if not filled in) be entitled to a commission upon any expansion of the Subleased Premises pursuant to any right reserved to Subtenant under the Sublease, calculated as provided above or as follows _____ (if no box is checked, as provided above).

With respect to any commission earned upon execution of this Sublease or pursuant to any expansion of the Subleased Premises, Tenant shall pay upon EXECUTION OF THE SUBLEASE. With respect to any commission earned upon extension of the Term of this Sublease, Tenant shall pay one-half upon execution of any amendment/addenda to the Sublease extending the Term. Tenant's Broker shall pay to Subtenant's Broker (as identified in the Agency Disclosure section above), the amount stated in a separate agreement between them or, if there is no agreement, \$ _____ or _____% (complete only one) of any commission paid to Tenant's Broker, within five (5) days after receipt by Tenant's Broker.

If any other lease or sale is entered into between Tenant and Subtenant pursuant to a right reserved to Subtenant under the Sublease, Tenant shall shall not (shall not if not filled in) pay an additional commission according to any commission agreement or, in the absence of one, according to Tenant's Broker's commission schedule in effect as of the execution of this Sublease. Tenant's successor shall be obligated to pay any unpaid commissions upon any transfer of this Sublease and any such transfer shall not release the transferor from liability to pay such commissions.

Notwithstanding anything to the contrary herein, Tenant represents and warrants that it has not used any broker in connection with this Sublease except for Tenant's Broker and Subtenant represents and warrants that it has not used any broker in connection with this Sublease except for Subtenant's Broker.



Jones Lang LaSalle
 601 Union St. Ste 2800
 Seattle, WA 98101
 Phone: 206-607-1700
 Fax: 206-607-1701

© Commercial Brokers
 Association ALL RIGHTS RESERVED
 Form: SUB_LS
 Sublease Agreement
 Rev. 9/2020
 Page 13 of 20



22. BROKER PROVISIONS. TENANT'S BROKER AND SUBTENANT'S BROKER HAVE MADE NO REPRESENTATIONS OR WARRANTIES CONCERNING THE SUBLEASED PREMISES; THE MEANING OF THE TERMS AND CONDITIONS OF THIS SUBLEASE; LANDLORD'S, TENANT'S OR SUBTENANT'S FINANCIAL STANDING; ZONING; COMPLIANCE OF THE SUBLEASED PREMISES WITH APPLICABLE LAWS; SERVICE OR CAPACITY OF UTILITIES; OPERATING COSTS; OR HAZARDOUS MATERIALS. LANDLORD, TENANT AND SUBTENANT ARE EACH ADVISED TO SEEK INDEPENDENT LEGAL ADVICE ON THESE AND OTHER MATTERS ARISING UNDER THIS SUBLEASE.

DELTA DENTAL OF WASHINGTON,
 a Washington nonprofit corporation

SILVERBACK THERAPEUTICS, INC.,
 a Delaware corporation

TENANT

SUBTENANT

TENANT

SUBTENANT

/s/ Brad A. Berg

/s/ Laura K. Mawry

By:

By:

Chief Operating Officer

Chief Exec Officer

Its:

Its:

SUBLEASE AGREEMENT

STATE OF WASHINGTON
 COUNTY OF King

This record was acknowledged before me on June 24 21, by Brad A. Berg as
COO & CFO of Delta Dental of Washington

/s/ Julie Stewart

My commission expires: 3-04-2024

STATE OF WASHINGTON
 COUNTY OF KING

This record was acknowledged before me on July 1st 20 21, by LAURA SHAWVER as
CEO of SILVERBACK THERAPEUTICS

/s/ Veronique Moleris

My commission expires: 4/26/25

SUBLEASE AGREEMENT

EXHIBIT 1

**[Legal Description of Master Premises or Property]
 [Omitted]**



Jones Lang LaSalle
601 Union St. Ste 2800
Seattle, WA 98101
Phone: 206-607-1700
Fax: 206-607-1701

© Commercial Brokers
Association ALL RIGHTS RESERVED
Form: SUB_LS
SubleaseAgreement
Rev. 9/2020
Page 14 of 20



**SUBLEASE AGREEMENT
EXHIBIT 2
[Master Lease]
[Omitted]**

**SUBLEASE AGREEMENT
EXHIBIT 3
[Outline of the Subleased Premises]
[Omitted]**

**SUBLEASE AGREEMENT
EXHIBIT 4
[Work Letter]
[Omitted]**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Laura Shawver, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 of Silverback Therapeutics, Inc.;
2. To 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. To my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2021

By:

/s/ Laura Shawver, Ph.D.

Laura Shawver, Ph.D.

Chief Executive Officer

(Principal Executive Officer)

**CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jonathan Piazza, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 of Silverback Therapeutics, Inc.;
2. To 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. To my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2021

By:

/s/ Jonathan Piazza

Jonathan Piazza
Chief Financial Officer
(Principal Financial Officer)

