Table of Contents

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

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)**	**81-1489190** **(I.R.S. Employer Identification No.)**
500 Fairview Ave N, Suite 600 **Seattle, Washington** **(Address of principal executive offices)**	**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 Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The registrant's common stock was not publicly traded as of the last business day of the registrant's most recently completed second fiscal quarter.

The number of shares of Registrant's Common Stock outstanding as of March 26, 2021 was 34,903,497.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2021 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2020, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

PART I

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, many of which are beyond our control. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements as a result of various factors, including those set forth below under the caption “Risk Factors.”

Forward-looking statements include, but are not limited to, statements regarding:

- 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 CROs, 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 JOBS Act;
- 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 on the intellectual property rights of others; and
- the impact of the COVID-19 pandemic on our business and operations.

In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions described in the sections of this Annual Report on Form 10-K titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report. We discuss many of the risks associated with the forward-looking statements in this Annual Report on Form 10-K in greater detail under the heading “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. You should be aware that the occurrence of any of the events discussed under the caption “Risk Factors” and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this Annual Report on Form 10-K. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Except as required by law, we assume no obligation to update our forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for our product candidates, including data regarding the estimated size of markets for oncology therapeutics and the incidence of certain medical conditions, statements that certain drugs, classes of drugs, or dosages are widely prescribed in the United States or other markets, statements regarding the perceptions and preferences of patients and physicians regarding certain therapies and other prescription, prescriber and patient data, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

You should read the following together with the more detailed information regarding our company, our common stock and our financial statements and notes to those statements appearing elsewhere in this report or incorporated by reference. The Securities and Exchange Commission, or SEC, allows us to “incorporate by reference” information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this report.

Risk Factors Summary

Below is a summary of the material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading “Risk Factors” under Part I, Item 1A of this Annual Report and should be carefully considered, together with other information in this Annual Report before making investment decisions regarding our common stock.

- 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.
- 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, undesirable side effects or other unexpected properties of our product candidates may be identified 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 FDA to obtain approval of a companion diagnostic test 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, 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 manufacturing 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.
- The COVID-19 pandemic could continue to adversely impact our business, including our ongoing and planned clinical trials, supply chain and business development activities.
- 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.

Item 1. Business.

As used in this Annual Report on Form 10-K, unless the context indicates or otherwise requires, “Silverback,” “our company,” “we,” “us,” and “our” refer to Silverback Therapeutics, Inc., a Delaware corporation.

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 immuno-oncology agents that direct a myeloid cell activator to the tumor microenvironment (TME) 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 tumors such as certain breast, gastric and non-small cell lung cancers. SBT6050 is currently 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 this trial, we have observed changes in pharmacodynamic markers in the first dose cohort, and we anticipate providing an update on interim data from the Phase 1 single

agent dose-escalation cohorts in the second half of 2021. SBT6290 is our second product candidate, expanding 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 anticipate submitting an investigational new drug application (IND) for SBT6290 in the fourth quarter of 2021. Our third TLR8 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 (cHBV). 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

Our ImmunoTAC platform is the result of a focused effort to discover ways to systemically deliver disease-modifying small molecules in a directed fashion to sites of disease. Many potentially promising systemic therapies fail to maximize their therapeutic potential due to toxicities in healthy tissues. Our approach is designed to increase the therapeutic window and avert unacceptable toxicities by directly targeting specific disease sites where our therapeutics are locally active.

As shown in the figure below, our ImmunoTAC platform is comprised of three components:

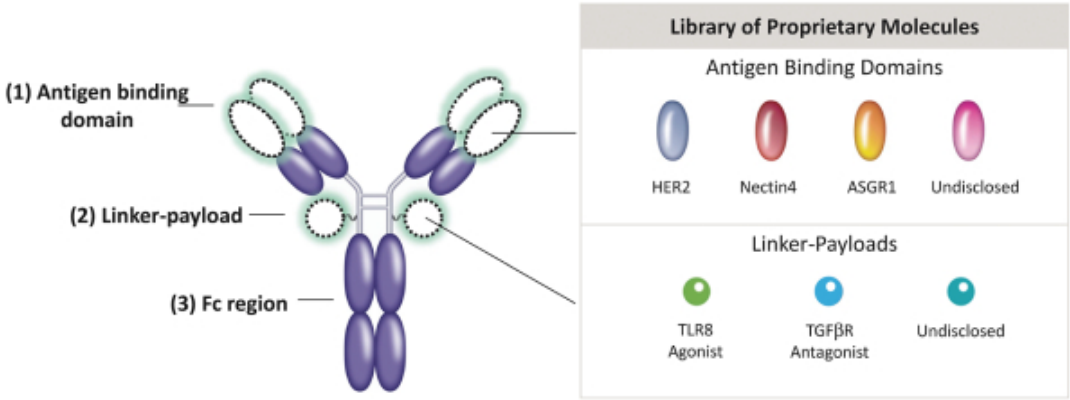
(1) **Antigen binding domain**—which is responsible for localizing the therapeutic activity of the payload to the site of the disease;

(2) **Linker-payload**—a disease-modifying small molecule optimized for potency when conjugated to a monoclonal antibody via its linker; and

(3) **Fc region**—tuned for requisite effector function.

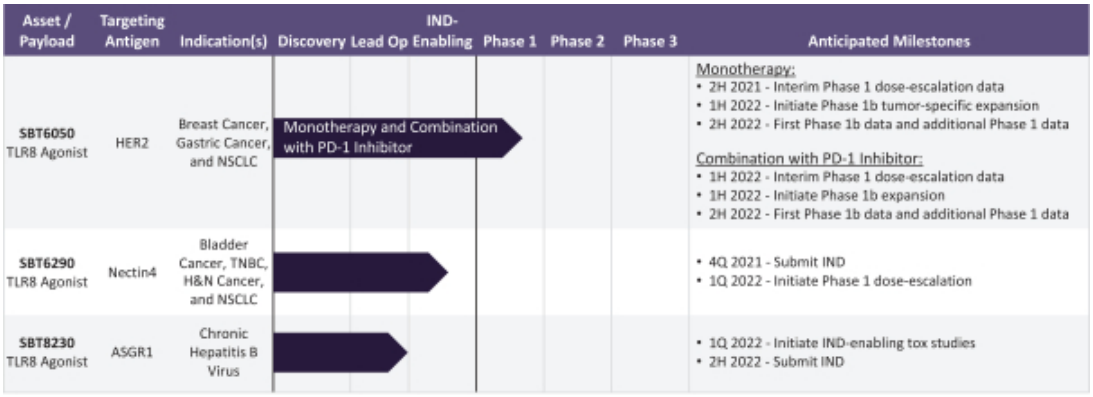
We have built a library of proprietary small molecule linker-payloads and antigen binding domains that allows us to mix and match these components to strategically pair and create new therapeutic agents.

Our ImmunoTAC Platform Strategically Pairs Antigen Binding Domains with Linker-Payloads to Modulate Pathways Underlying Difficult-to-Treat Diseases



Our Development Pipeline

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



SBT6050

Our lead product candidate, SBT6050, is comprised of a TLR8 agonist linker-payload conjugated to a HER2-directed monoclonal antibody and is designed to activate myeloid cells in tumors expressing moderate to high levels of HER2. TLR8 is expressed in myeloid cell types prevalent in human tumors and TLR8 agonism can activate a broad spectrum of anti-tumor immune mechanisms. Therefore, we believe that TLR8 is the optimal target for activating human myeloid cell types in the TME.

Myeloid cells are a class of innate immune cells that develop from common monocyte-dendritic cell progenitor cells and are comprised of both immunosuppressive and pro-inflammatory subpopulations. Tumors are permeated with myeloid cells, which can comprise between 5% and 10% of the tumor. Activation of myeloid cells, either by reprogramming immunosuppressive myeloid cells towards a more pro-inflammatory phenotype or stimulating other myeloid cells that have been silenced (e.g., dendritic cells), results in direct tumor killing and recruitment of immune cells. Further, activated myeloid cells can prime and amplify T cell and natural killer (NK) cell responses, bridging the innate and adaptive immunity to elicit broad, durable anti-tumor responses.

SBT6050 utilizes HER2 to localize and facilitate the delivery of the TLR8 agonist conjugate into myeloid cells in the TME. Therefore, unlike HER2 targeted therapies that have been approved by the U.S. Food and Drug Administration (FDA) such as Herceptin (trastuzumab), SBT6050 does not require HER2 to be an oncogenic driver to elicit anti-tumor activity. Furthermore, SBT6050 recognizes the HER2 sub-domain II, the pertuzumab epitope, and does not cross-block trastuzumab, allowing for potential combinations with trastuzumab-based agents, which are standard of care therapies in some HER2-expressing cancers.

We are currently evaluating the safety and tolerability of SBT6050 in a Phase 1 dose-escalation trial in patients with advanced or metastatic HER2-expressing solid tumors. Changes in pharmacodynamic markers have been observed in the first dose-escalation cohort of this trial. We anticipate providing an update on interim data from the Phase 1 single agent dose-escalation cohorts in the second half of 2021.

SBT6290

SBT6290 is our second product candidate, expanding on the potential of a TLR8 agonist as a payload. The same TLR8 linker-payload used in SBT6050 is conjugated to a monoclonal antibody that targets Nectin4. Nectin4 is expressed in subsets of solid tumors including bladder, triple negative breast, head and neck, and non-small cell lung cancers, and has been clinically validated through the approval of the antibody-drug conjugate enfortumab vedotin (Padcev). We anticipate submitting the IND for SBT6290 in the fourth quarter of 2021.

SBT8230

SBT8230, an ASGR1-TLR8 ImmunoTAC therapeutic, is our third TLR8 program. SBT8230 is engineered to potently activate human myeloid cells in the liver for the treatment of cHBV. Selgantolimod (GS-9688), an existing untargeted, orally administered TLR8 agonist being developed by Gilead Sciences, generated anti-viral immune responses in a cHBV animal model. The clinical development of this untargeted TLR8 agonist has shown promise, but we believe that toxicity prevented the use of a sufficient dose to elicit optimal clinical activity. We believe liver- localized TLR8 agonism could better realize the potential for effective therapy and potentially lead to functional cures, which is defined as sustained loss of hepatitis B surface antigen (HBsAg) in the blood, in patients suffering from cHBV. We selected a development candidate for this program in the fourth quarter of 2020, and we anticipate initiating IND-enabling tox studies in the first quarter of 2022 and submitting the IND in the second half of 2022.

Additional Immuno-Oncology Programs

In addition to SBT6050 and SBT6290, we are evaluating other solid tumor targets to leverage the TLR8 linker-payload paired with additional tumor directed antibodies. These targets are differentially expressed on tumors compared to normal tissue.

ASGR1-TGFß Receptor Antagonist—Fibrosis Program

TGFß signaling is a key mediator of fibrosis across multiple organ systems, including the liver. In the liver, TGFß drives fibrosis initiation and progression through multiple mechanisms, including hepatocyte apoptosis, hepatic stellate cell transdifferentiation to myofibroblasts, and pro-fibrotic macrophage activation. Our ASGR1-TGFßR1 antagonist conjugate pairs the ASGR1 antibody used in SBT8230 with a proprietary TGFßR1 antagonist to achieve liver-localized inhibition of TGFß signaling to treat fibrosis. Our tissue-directed approach has been designed to prevent toxicities associated with untargeted systemically distributed TGFßR1 antagonist agents. Our ASGR1-TGFßR1 antagonist conjugates are currently in preclinical testing and have demonstrated potent inhibition of TGFß signaling *in vitro*. We are currently evaluating conjugates *in vivo* in mouse disease models.

Our Strategy

Our goal is to transform the treatment of cancer and other serious diseases with unmet need using our ImmunoTAC platform to deliver a new class of systemically delivered, tissue-directed, and locally active therapies. The key elements of our business strategy are to:

- ***Advance SBT6050 through clinical development in late-stage disease that may allow us to seek expedited approval using regulatory pathways available from the FDA such as Accelerated Approval, Breakthrough Therapy, Priority Review or Fast Track designation.*** In early clinical trials, we will be examining the anti-tumor activity of SBT6050 in patients that have failed all available therapies associated with clinical benefit, in addition to measuring biomarkers of immune cell activation. This approach may allow us to seek expedited approval

from the FDA based on surrogate endpoints (through the Accelerated Approval path) and expedited FDA review through programs such as Breakthrough Therapy, Priority Review, or Fast Track designation. We are evaluating activity broadly across HER2-expressing cancer types, including cancers where no HER2-directed therapies are currently approved, and have identified several tumor types and lines of therapy that potentially present opportunities for utilizing one or more of these accelerated approval pathways.

- ***Advance SBT6050 subsequently into earlier lines of therapy to maximize patient benefit and commercial success, if approved.*** Our long-term clinical development goal is to position SBT6050 in early-line standard of care regimens in key indications to potentially provide benefit to patients. We seek to accomplish this by evaluating combination therapy approaches with therapeutics approved as standard of care. We believe SBT6050 has the potential to be an ideal combination therapy in early line settings.
- ***Maximize the therapeutic potential of TLR8 in oncology and other serious diseases*.** We are adapting learnings from our SBT6050 program to expand the TLR8 agonist franchise by conjugating this payload to antibodies that target different tumor antigens that are prevalent in other cancer types. Additionally, the ability to drive myeloid cell activation in the liver presents an opportunity to treat cHBV infections, which is our most advanced initiative outside of immuno-oncology.
- ***Leverage our ImmunoTAC platform for promising new antibody-linker-payload combinations*.** We are strategically pairing our disease-modulating payloads with tissue targeted antibodies, such as our ASGR1-TGFßR1 antagonist conjugate, to create new therapeutic agents with the goal of providing benefits to patients who suffer from cancer and other serious diseases. We plan to continue to leverage our ImmunoTAC platform, discovery of targeted binding proteins (including antibodies), and efficient therapeutic discovery infrastructure to discover and develop novel small molecule therapeutics and ImmunoTAC conjugates.
- ***Evaluate opportunities to accelerate development timelines and/or enhance the commercial potential of our programs in partnership with third parties***. We plan to selectively explore potential strategic partnerships on a program-by-program basis with biopharmaceutical partners whose research, development, commercial, and/or geographic capabilities complement our own. We believe strategic partnerships can help mitigate clinical and commercial risk, accelerate timelines, and/or maximize global commercial potential.

Our Team

We have assembled an accomplished management team with a proven track record of therapeutic development expertise and of generating meaningful shareholder value. The members of our team have deep experience in discovering, developing, and commercializing therapeutics with a particular focus on cancer, having worked at companies such as Synthorx (acquired by Sanofi), Juno Therapeutics (acquired by Celgene), Cascadian Therapeutics (acquired by Seagen (formerly Seattle Genetics)), Acerta Pharma (acquired by AstraZeneca), Ignyta (acquired by Roche), Roche/Genentech, Seagen (formerly Seattle Genetics), SUGEN (acquired by Pharmacia), and Trubion Pharmaceuticals (acquired by Emergent Biosolutions).

Lead Product Candidate SBT6050: TLR8 Agonist Conjugated to a HER2 Antibody

SBT6050 is our lead product candidate, engineered using our ImmunoTAC platform. SBT6050 is comprised of a TLR8 agonist conjugated to a HER2-directed monoclonal antibody and is designed for subcutaneous delivery with tumor-localized activation of myeloid cells.

Background and Our Approach in Addressing Limitations with Current Immuno-oncology Therapies

Checkpoint inhibitors (CPIs) such as a programmed death receptor-1 (PD-1) and CTLA-4 blockers have emerged as important foundational immuno-oncology therapies because of their ability to generate durable responses in some patients, in previously intractable cancers and to improve the overall survival. Despite the significant benefit for patients with durable responses to CPIs, most patients unfortunately do not respond or have limited benefit. One of the important reasons why patients do not respond to CPIs is the absence of a sufficient number of T cells within the tumor. To achieve an anti-tumor response with a CPI, a baseline level of T cells must already be present in the tumor. Scientists and clinicians have termed tumors that lack the requisite T cell levels as “immune cell deserts” or “cold tumors,” but more accurately these are “T cell deserts.”

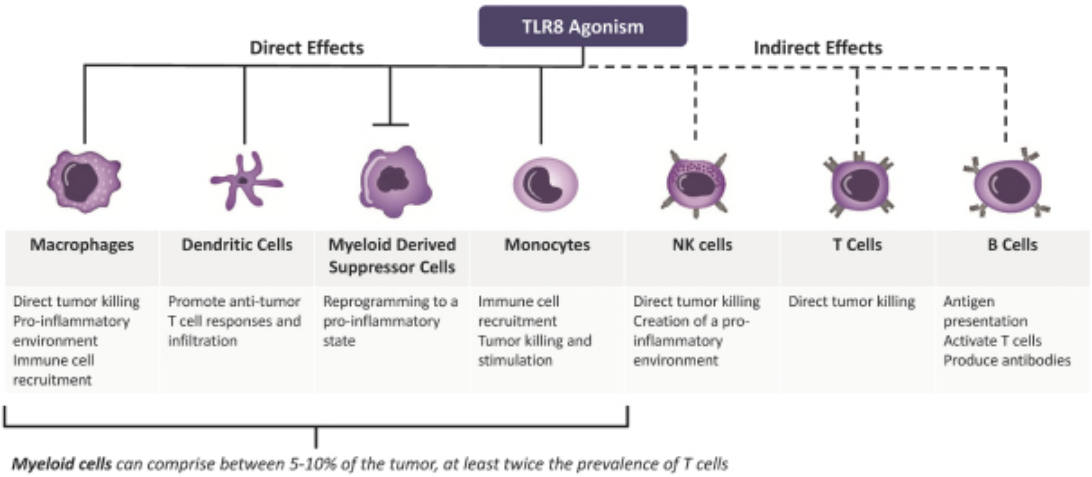
Solid tumors, including those resistant to T cell targeted immunotherapy, such as PD-1 and CTLA-4 blockers, are permeated with myeloid cells, which can comprise between 5% and 10% of the tumor—at least twice the number of T cells in the TME. Myeloid cells are a class of innate immune cells comprised of both immunosuppressive and pro-inflammatory subpopulations. Activation of myeloid cells, either by reprogramming immunosuppressive myeloid cells towards a more pro-inflammatory phenotype or stimulating other myeloid cells that have been silenced (e.g., dendritic cells), results in direct tumor killing and recruitment of immune cells. Further, activated myeloid cells can prime and amplify T cell and NK cell responses, bridging the innate and adaptive immunity to elicit broad, durable anti-tumor responses. Successful activation of myeloid cells can lead to anti-tumor immunity, even in tumors that are refractory to immune checkpoint blockade, which we believe may bring substantial benefit to a larger fraction of patients.

We designed SBT6050 to potently activate the myeloid cell compartment in the TME. We performed a thorough assessment of innate immune receptors with the goal of identifying a payload target that was well expressed in human myeloid cells. We believe TLR8 is unique in its breadth of expression across human myeloid cell subpopulations and its restricted expression to the myeloid cell lineage. In consideration of internally generated data and emerging external research on human myeloid cell biology, we selected TLR8 as the best payload target for activation of myeloid cells resulting in direct tumor killing and recruitment and activation of additional immune cells, such as T cells and NK cells, to further effect the anti-tumor response.

Activating the Myeloid Cell Compartment Through TLR8 Agonism

Myeloid cells develop from common monocyte-dendritic cell progenitor cells and are critical mediators of innate immune responses. These cells are plastic in nature and their function and phenotype are heavily influenced by environmental cues. In the TME and tumor draining lymph nodes, macrophages, conventional dendritic cells, myeloid derived suppressor cells, and monocytes are highly prevalent, but also skewed towards inactive or immunosuppressive states. We believe TLR8 is the optimal target for activating these myeloid cell types due to its restricted expression and function within these cells. As shown in the figure below, TLR8 activation of human myeloid cells elicits an anti-tumor response through a multi-pronged mechanism of action, including direct tumor cell killing, recruitment of immune cells, and the secondary activation of NK cells, T cells and B cells, thus driving both an innate and adaptive immune response against the tumor.

TLR8 is Highly Expressed in Human Myeloid Cell Types That Drive Anti-Tumor Responses When Activated

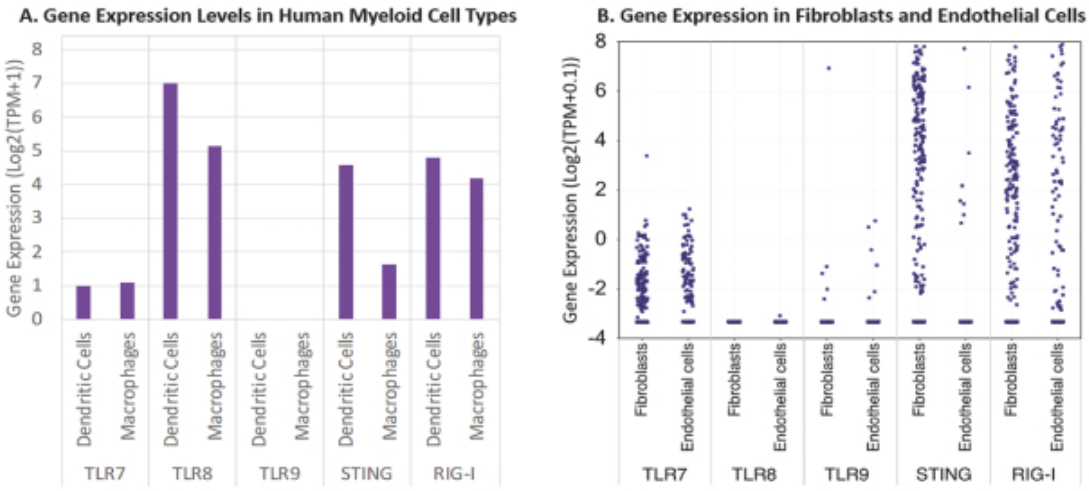


As a result of the broad immune activation triggered by a TLR8 agonist, systemically administered but untargeted TLR8 small molecule therapeutic candidates from other companies have resulted in an adverse event profile that we believe has limited achieving a dose level sufficient to produce the desired therapeutic benefit. An exemplary TLR8 small molecule agonist is motolimod, originally developed by Array Biopharma and licensed to VentiRx. Motolimod was the first TLR8 specific, but untargeted, agonist tested in the clinic for the treatment of solid tumors. Early trials of subcutaneously administered motolimod yielded adverse events we believe to be consistent with broad myeloid cell activation in the periphery, including injection site reactions and symptoms associated with systemic cytokine release, which limited dose-escalation. As a result, we believe that sufficient drug exposure in the TME was not reached to elicit meaningful anti-tumor activity. Similarly, Gilead Sciences is developing an orally administered untargeted TLR8 agonist for the treatment of cHBV. This therapeutic has resulted in adverse events consistent with myeloid cell activation in the gastrointestinal tract, including diarrhea and nausea. We believe these two cases support our hypothesis that tissue directed, localized activation is critical to maximizing the therapeutic potential of a TLR8 agonist.

TLR8 was selected as a target for an agonist after bioinformatic and functional assessments of several innate immune receptor targets. Important criteria of these targets we considered during our payload selection was intracellular localization and robust expression in myeloid cell compartments, with limited expression in non-immune FcR positive cells. Our selection of TLR8 as the optimal target to activate myeloid cells without activating other cell types outside of the hematopoietic lineage was supported by both external research results and internal data.

As shown in figure A below, unlike other intracellular innate immune receptors, TLR8 is highly expressed in human myeloid cell types, including conventional dendritic cells and macrophages. Conversely, as shown in figure B below, TLR8 is not expressed in fibroblasts and endothelial cells and we believe this restricted expression will reduce the risk of toxicities due to on-target, off-cell activation.

TLR8's Expression is Restricted to Human Myeloid Cells



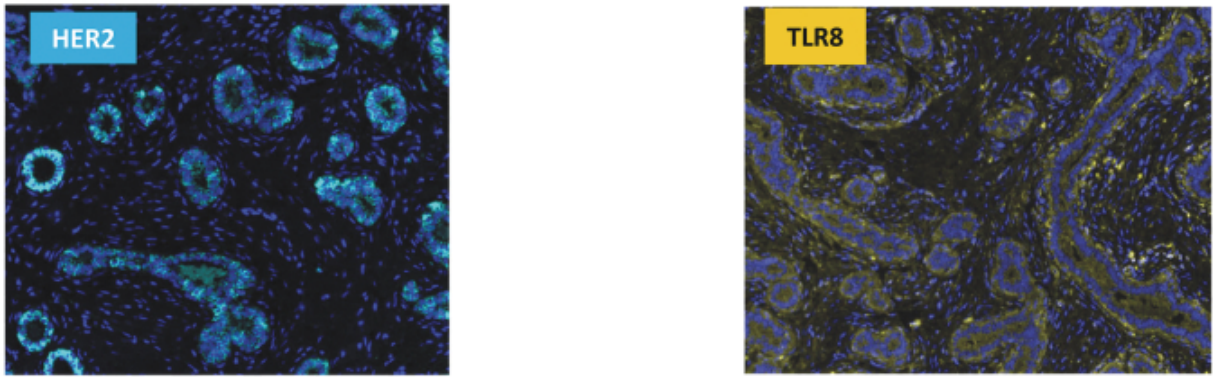
A) Unlike other intracellular innate immune receptors, TLR8 is highly expressed in human myeloid cell types, including conventional dendritic cells and macrophages
B) TLR8 is not expressed in fibroblasts and endothelial cells and we believe this restricted expression will reduce the risk of toxicities due to on-target, off-cell activation

Following the identification of TLR8 as the optimal receptor to activate myeloid cells in the TME, we designed and created a library of TLR8 agonists. Our proprietary TLR8 agonists were evaluated in the format of HER2 antibody conjugates for their ability to activate myeloid cells *ex vivo*. Within this library, we identified a HER2 antibody-TLR8 conjugate that activated myeloid cells in moderate and high HER2 settings as is found in HER2-expressing tumors.

Tissue Directed and Localized Activation Through HER2 Expression

Many solid tumors, including those expressing HER2, are refractory to immunotherapy due to minimal T cell infiltrates. As shown in the figures below, HER2-expressing tumors (stained in blue, left panel) frequently contain abundant populations of tumor-associated myeloid cells which express TLR8 (stained in yellow, right panel).

HER2-Expressing Tumors and TLR8-Expressing Myeloid Cells are Adjacent in the Human TME



HER2 is an optimal marker to direct therapies like TLR8 agonist conjugates due to its differential expression between tumors and healthy tissue. Furthermore, HER2 expression is prevalent in meaningfully large patient sub-populations in a wide variety of tumor types including breast (estimated 83,000), gastric (estimated 6,400), non-small cell lung (estimated 31,500), colorectal (estimated 9,000), bladder (estimated 7,500), uterine (estimated 11,000), pancreatic (estimated 4,000), head and neck (estimated 2,000), ovarian (estimated 1,100), esophageal (estimated 2,500), and biliary (estimated 3,000) cancers, providing the potential to address a large HER2-expressing tumor agnostic market estimated to be more than 160,000 newly-diagnosed patients annually in the United States based in part on estimated prevalence rates. The 2020 American Cancer Society annual report on cancer statistics was used to determine the estimated incidence for each cancer type. HER2 overexpression and amplification prevalence rates documented in the literature were applied to the incidence rate for each cancer type to approximate the HER2-overexpressing sub-populations in each cancer type; 30.0%, 16.4%, and 23.2% HER2 overexpression rates were used for breast cancer, gastric cancer, and non-small cell lung cancer (NSCLC), respectively.

As shown in the figure below, the SBT6050 potential mechanism of action is outlined sequentially as follows:

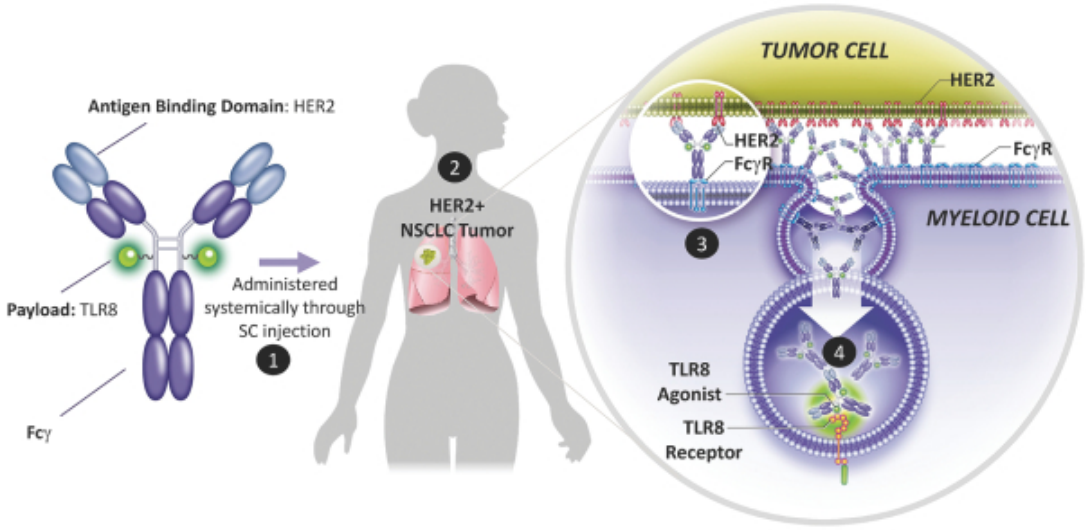
(1) SBT6050 is administered systemically through subcutaneous injection. Systemic dosing is essential to access myeloid cells in both primary lesions and metastatic lesions, and in secondary lymphoid organs, to result in productive and durable anti-tumor responses.

(2) SBT6050 is directed to tumors expressing HER2 and the TME, which is permeated with myeloid cells that express Fcg receptors on their cell surface, and TLR8 within endosomes.

(3) Upon co-engagement of the HER2 protein on the tumor and Fcg receptors on the myeloid cell, SBT6050 is designed to be internalized by the myeloid cell into the endo-lysosomal compartment once there is a sufficient increase in avidity, which is provided by HER2 binding on the tumor cell.

(4) SBT6050's TLR8 linker-payload engages TLR8 present in the endosomes of myeloid cells, which in turn drives activation.

Potential Mechanism of Action: SBT6050 is Designed to Localize TLR8 Activation of Myeloid Cells in Tumors via a HER2-Directed Antibody



Preclinical Development of SBT6050

Our preclinical studies have shown the potential for SBT6050 to activate innate and adaptive anti-tumor responses in the TME and demonstrate anti-tumor activity as a single agent and in combination with standard of care agents such as anti-PD-1 and trastuzumab-based therapies in HER2-expressing solid tumors. Highlights of our preclinical work using SBT6050 *in vitro* and SBT6050-S (our mouse surrogate) *in vivo* via subcutaneous delivery demonstrated:

- Potent activation of multiple anti-tumor immune mechanisms induced in the presence of HER2-expressing tumor cells.
- Equipotent immune cell activation in settings of moderate and high HER2 expression.
- Curative activity as a single agent in a xenograft model lacking T cells and B cells, and deficient in NK cells, highlighting the potential of myeloid cell activation alone to mediate robust tumor cell killing.
- Potent single agent activity in tumor models with low tumor infiltrating lymphocytes, highlighting the potential for clinical activity in tumors displaying immune evasive characteristics.
- Anti-tumor responses upon tumor re-challenge without additional dosing, highlighting the potential for durable effects through the activation and expansion of tumor antigen-specific T memory cells.
- Enhanced anti-tumor activity when used in combination with anti-PD-1 therapy in a CPI-refractory mouse tumor model.
- Enhanced anti-tumor activity when used in combination with trastuzumab in a mouse tumor model.

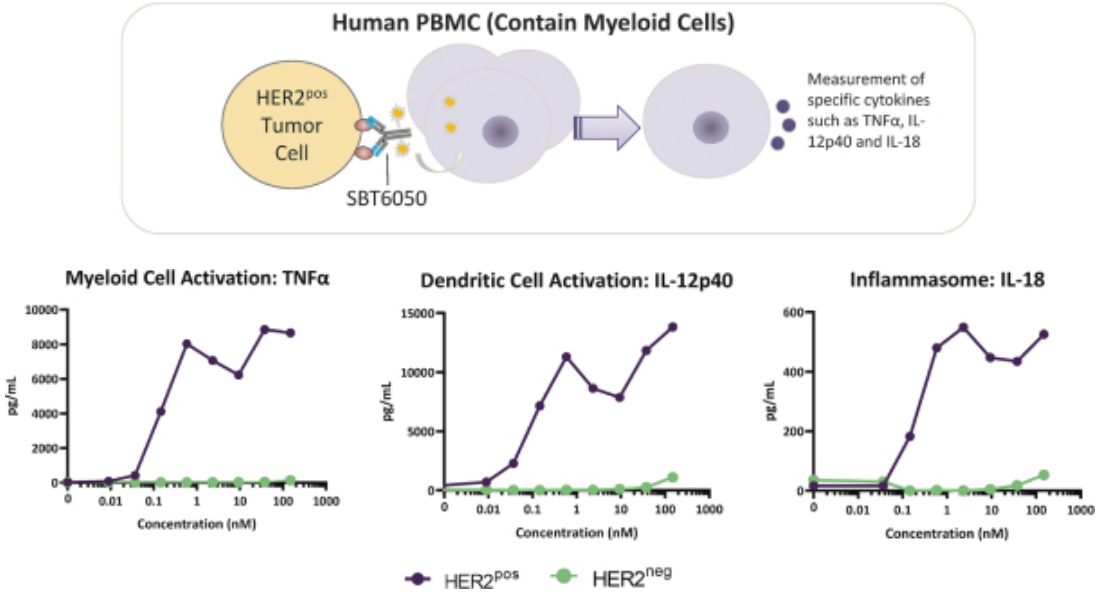
Collectively, these data supported our decision to clinically evaluate the anti-tumor activity of SBT6050 as a single agent and in combination with anti-PD-1 and trastuzumab-based therapeutics in relevant HER2-expressing tumor types.

SBT6050 In Vitro Preclinical Data

In our *in vitro* studies, SBT6050 potently activated human myeloid cell types, including macrophages, dendritic cells, and monocytes. This activation resulted in the induction of multiple myeloid cell effector functions, including the production of cytokines and chemokines that are critical to the generation of anti-tumor immune responses. In addition, SBT6050 activation of myeloid cells *in vitro* resulted in the subsequent, indirect activation of NK cells and T cells. In our *in vitro* studies, SBT6050 also mediated antibody-dependent cellular phagocytosis and antibody-dependent cellular cytotoxicity. Further, TLR8 agonism drove the downmodulation of SIRPa, highlighting the potential to block the CD47-SIRPa pathway, which, in turn, can potentially enable phagocytosis of tumor and red blood cells.

In our *in vitro* studies, human peripheral blood mononuclear cells (PBMC) were co-cultured with HER2^{pos} or HER2^{neg} tumor cell lines in the presence of SBT6050. As shown in the figures below, SBT6050 potently induced multiple anti-tumor immune activities, including general activation of myeloid cells as measured by pro-inflammatory cytokine and chemokine production (TNFa), direct activation of dendritic cells (IL-12p40), and inflammasome activation (IL-18) in the presence of HER2^{pos} tumor cells. No activation was seen when SBT6050 was co-cultured with HER2^{neg} cells.

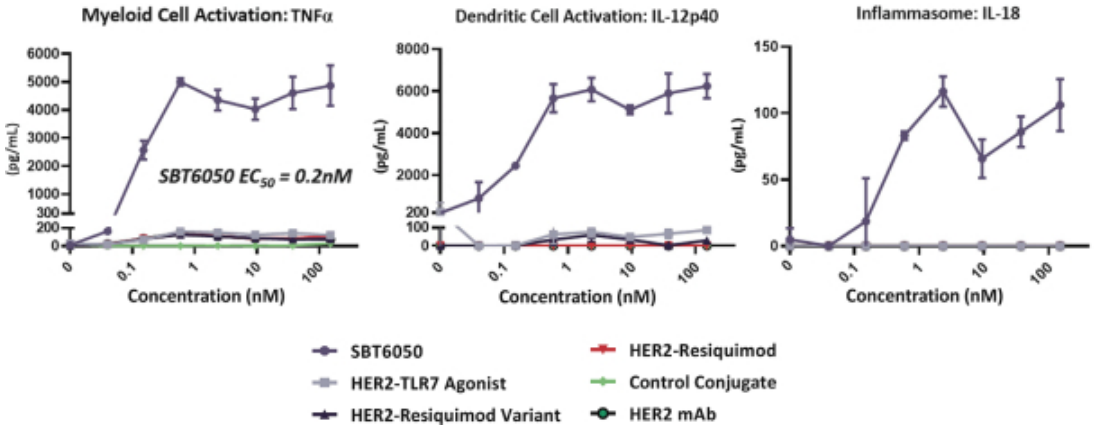
SBT6050 Activated Myeloid Cells in the Presence of HER2^{pos} Tumors



Similar *in vitro* studies using PBMCs were conducted to compare SBT6050 with conjugates that contain a TLR7 agonist, resiquimod or a resiquimod variant payload that were designed to mimic competitor molecules. Of note, the EC_{50} of the free, unconjugated TLR7 small molecule agonist was 9 nM on a TLR7 reporter line and no activity was observed on a TLR8 reporter line. The EC_{50} of unconjugated resiquimod on TLR7 was ~700 nM and >3 µM on TLR8, demonstrating that resiquimod is a weak TLR8 agonist. The resiquimod variant was of slightly better potency compared to resiquimod. As shown in the figures below, in these internal head-to-head studies SBT6050 demonstrated a

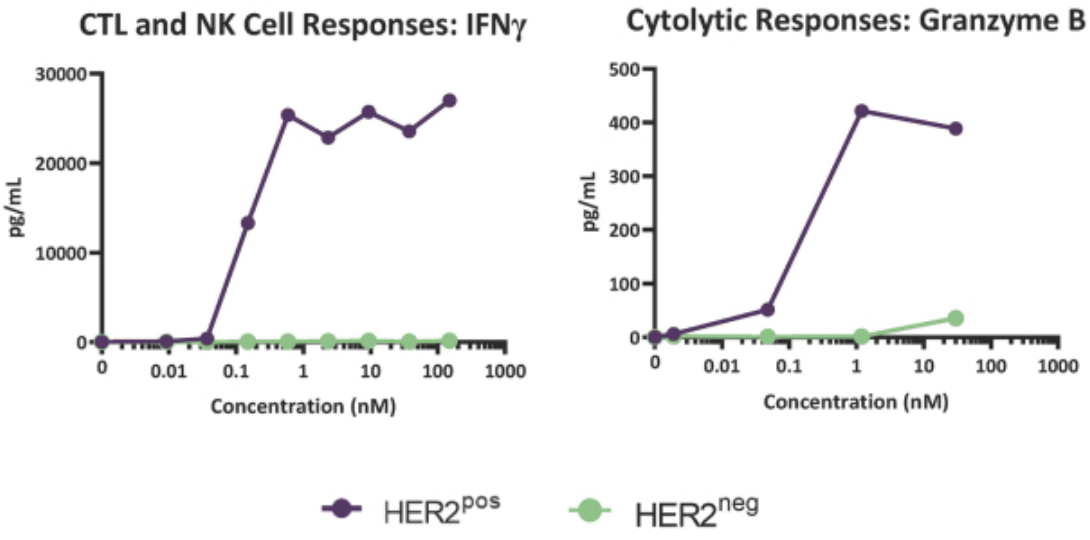
superior ability to induce TNFa, IL-12p40, and IL-18 in the presence of HER2pos tumor cells. This highlights the potential for favorable activity of SBT6050, which we believe is due to efficient engagement of TLR8 in conjugate form. SBT6050's functional profile was not replicated with conjugates comprised of TLR7-specific or resiquimod-derived agonists.

SBT6050 Was Superior at Activating Human Myeloid Cells Compared to HER2 Antibody Conjugates that Use Either a Selective TLR7 Agonist or Resiquimod



Robust activation of the myeloid cell compartment is also known to trigger an adaptive immune cell response. In an additional *in vitro* study using a similar PBMC assay, SBT6050 induced indirect activation of mediators associated with NK cell and T cell responses (IFNg and granzyme B), as shown in the figures below. In a separate *in vitro* study, the induction of IFNg and granzyme B by SBT6050 was shown to be secondary to myeloid cell activation as blockade of IL-12 and/or IL-18 abrogated the IFNg and granzyme B response.

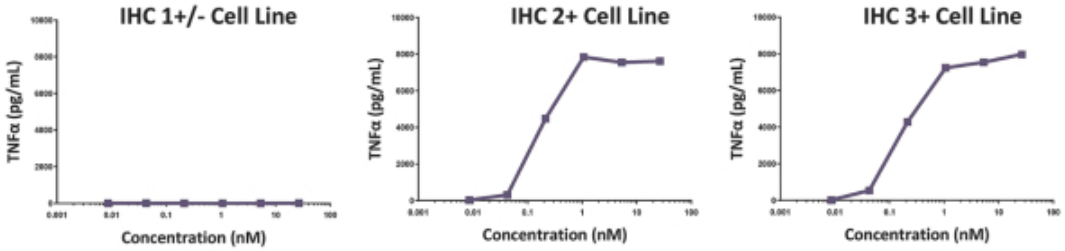
SBT6050 Indirectly Activated Mechanisms Associated with CTL/NK Cell Responses in the Presence of HER2pos Tumors



HER2 expression in tumor cells varies and can be measured by protein expression using immunohistochemistry (IHC) to understand the amount of HER2 in tumor cells. It is also common to determine the gene copy number using fluorescence in situ hybridization (FISH) or other methodologies as another way to understand if the HER2 gene is amplified. Gene amplification typically results in overexpression of the protein usually at the IHC3+ level, but some HER2-amplified tumors express protein at the IHC2+ level. It has become standard practice among pathologists to characterize protein expression using IHC1+, IHC2+ or IHC3+ and also to measure gene copy number because certain FDA-approved therapies, such as Herceptin, are approved in the setting of high HER2 expression levels. High HER2 expression tumors are categorized by either IHC3+ or IHC2+/FISH positive. Low HER2 expression in the industry is categorized as IHC2+/FISH negative and IHC1+. In our preclinical, studies we characterized IHC1+ HER2 tumor cells as expressing less than 25,000 HER2 receptors per cell. SBT6050 has been tuned to work in settings of IHC2+/FISH negative (moderate expression) as well as IHC3+ (high expression) but not IHC1+ (low expression). Targeting tumors with moderate HER2 expression allows us to address a patient population where most current HER2 targeted therapies are not effective. We believe that avoiding some normal tissues that express low levels of HER2 provides the opportunity for an improved safety and tolerability profile.

As shown in the figures below, our *in vitro* studies demonstrated that SBT6050 stimulated myeloid cells in the presence of IHC 2+ and 3+, but not in the presence of IHC 1+/- tumor cell lines.

SBT6050 Activated Myeloid Cells Only in the Presence of IHC 2+ and 3+ Tumor Cell Lines

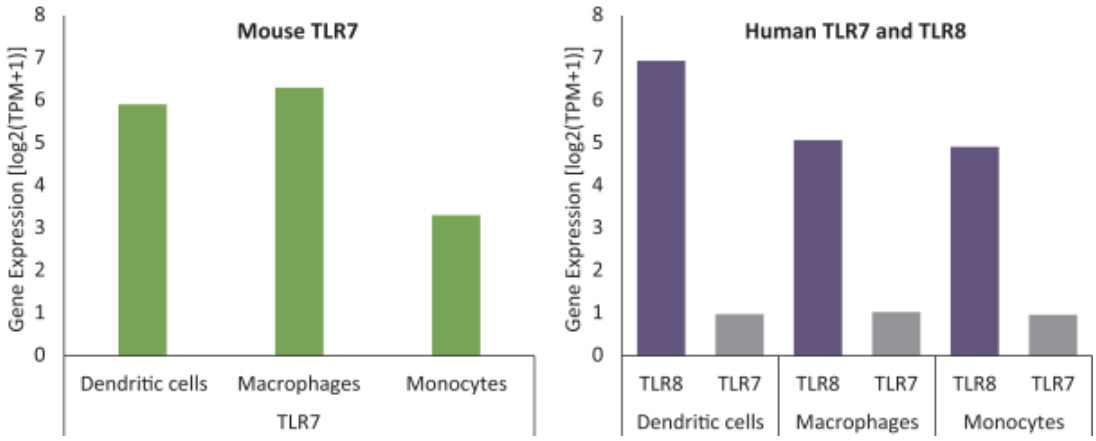


SBT6050 In Vivo Preclinical Data

Background Regarding SBT6050-S

Because mice do not have a functional homologue of human TLR8, we designed SBT6050-S to enable preclinical mouse studies with a molecule that in mice matches the myeloid cell activation profile of SBT6050. TLR7 expression in mouse myeloid cells mirrors that of TLR8 in human myeloid cells. RNA sequencing data published by third parties, as shown in the figures below, highlight the differential expression of TLR8 and TLR7 across mouse and human myeloid cell sub populations. Activation of TLR7 in mouse myeloid cells results in a similar downstream functional profile as TLR8 activation does in human myeloid cells.

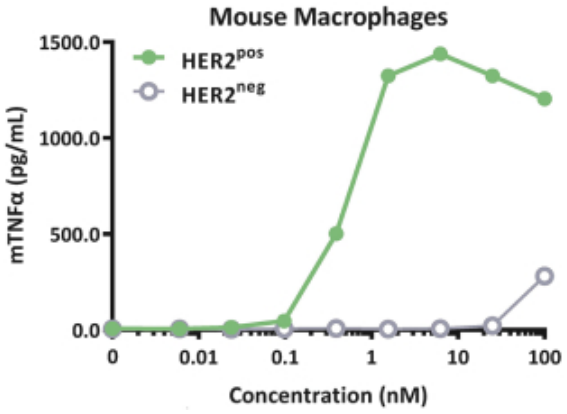
TLR7 Is Highly Expressed in Mouse Myeloid Cells and TLR8 Is Highly Expressed in Human Myeloid Cells, Whereas TLR7 Is Expressed at Low Levels in Human Myeloid Cells



SBT6050-S is a proprietary conjugate that contains a selective TLR7 linker-payload and a mouse IgG2a Fc domain to promote uptake in mouse myeloid cells. Our preclinical data, as shown in the figure below, demonstrated similar *in vitro* potency of SBT6050 on human myeloid cells and SBT6050-S on mouse myeloid cells. In addition, the *in vitro* activity of SBT6050-S is HER2-dependent as is the case for SBT6050 as described earlier.

Functional Results with TLR7 Conjugate, SBT6050-S, on Mouse Myeloid Cells Matched Those of SBT6050 on Human Myeloid Cells In Vitro

ImmunoTAC Conjugate	EC_{50} (nM)
SBT6050	0.2 (on human myeloid cells)
SBT6050-S	0.3 (on mouse myeloid cells)

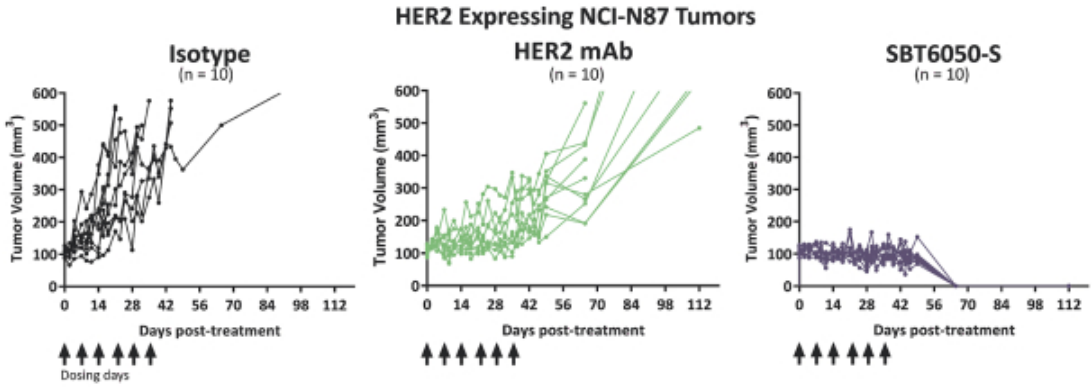


Our SBT6050-S Monotherapy In Vivo Data

Using SBT6050-S in preclinical studies, we have demonstrated that a systemically administered, HER2-directed myeloid cell agonist activated a broad spectrum of anti-tumor mechanisms and led to curative single agent activity in both a human tumor xenograft model lacking T cells and B cells and with defective NK cells as well as a T cell-excluded syngeneic mouse tumor model. In these models, the term “curative effects” describe the complete clearance of tumors (tumor size of 0 mm^3).

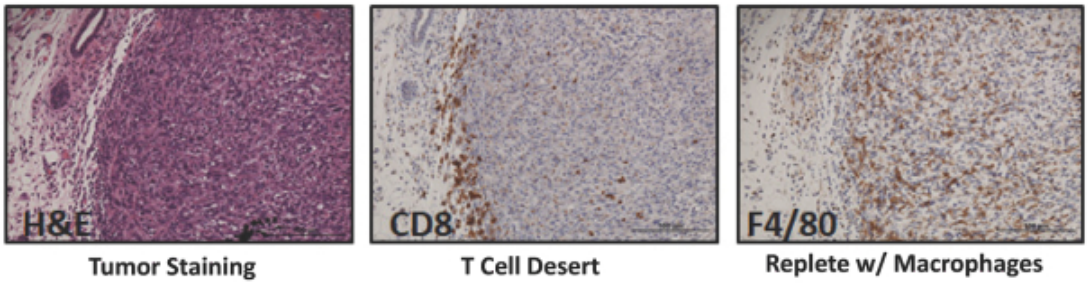
As shown in the figures below, SBT6050-S (at 10 mg/kg) demonstrated curative effects as a monotherapy in a human tumor xenograft (NCI-N87) mouse model that has an absence of T cells along with defective NK cells. This study was powered for statistical significance using survival as a readout which is defined as tumor size remaining below 1,000 mm^3. Treatment with SBT6050-S resulted in a statistically significant increase in survival as compared to the isotype and HER2 mAb control groups (p value<0.0001). We believe that the activity of SBT6050-S in this model is indicative of the potential of myeloid cells to drive tumor eradication. These data indicate that SBT6050 may have activity in tumors with low or no T cell infiltrate, which we believe has important implications regarding the substantial potential benefit of SBT6050 for patients who do not respond to T cell-directed immunotherapy.

SBT6050-S Drove Robust, Curative Single Agent Activity in T Cell, NK Cell-Deficient Mouse Strains



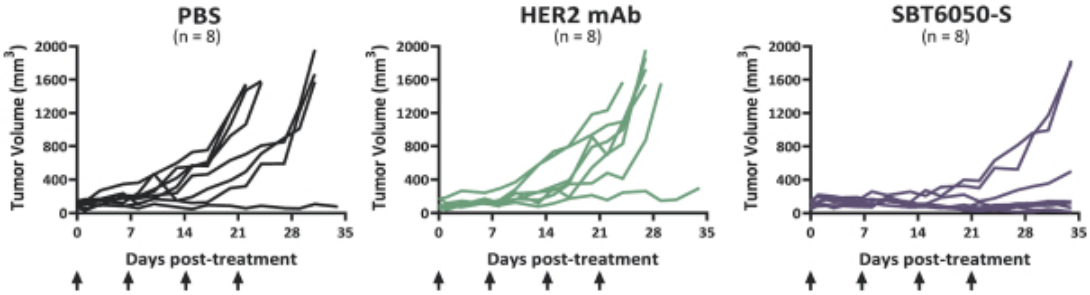
In addition, in our preclinical studies, administration of SBT6050-S as a monotherapy resulted in durable curative effects in a HER2-expressing, T cell excluded EMT6 syngeneic mouse tumor model. EMT6 is a mouse tumor that we engineered to express human HER2. Expression of human HER2 in this model is moderate, heterogenous, and may be lost over time, which is representative of certain HER2^{pos} tumor types such as gastric cancer. While conducted in immunocompetent mice, the EMT6 model is also known to be resistant to anti-PD-1 treatment because T cells are excluded from tumor entry. The left panel in the figure below illustrates tumor cells that were demarcated by H&E staining. The central panel in the figure below illustrates that in the HER2-EMT6 model, CD8 T cells were sequestered on the periphery of the tumor. In contrast, the right panel below illustrates the presence of macrophage infiltrate within this T cell-excluded mouse tumor model.

IHC Staining in EMT6 Tumor Models, Depicting CD8 T Cells and Macrophages (F4/80)



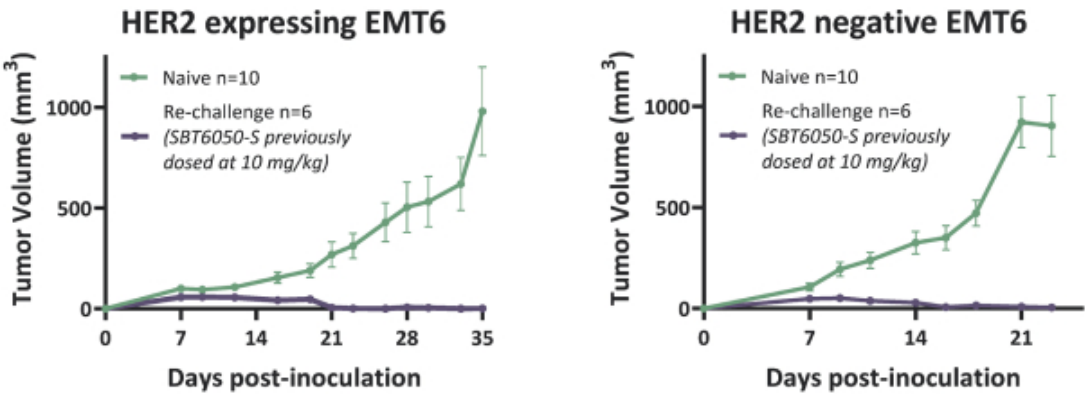
As shown in the figures below, SBT6050-S (at 10 mg/kg) as a monotherapy resulted in a complete response (CR) rate, the percentage of animals with tumors < 30 mm^3 at the end of study, of between 40% and 80% in the HER2-EMT6 model, depending on the study. This study was powered for statistical significance using survival as a readout which is defined as tumor size remaining below 1,000 mm^3. Treatment with SBT6050-S resulted in a statistically significant increase in overall survival when compared to the isotype and HER2 mAb control groups (p value=0.002). Approximately 30-50% of EMT6 tumor cells express human HER2 at the time of dosing initiation. Given the lack of stability of HER2 expression in this model, we believe HER2 expression was lost in the tumors of the mice that did not respond to SBT6050-S in this study.

Treatment with SBT6050-S Monotherapy Resulted in CR Rate of 40-80% in HER2-EMT6 Model



As shown in the figure on the left below, HER2-EMT6 tumor-bearing mice that were cured by SBT6050-S treatment, meaning that no tumor was detectable, were fully protected from an EMT6 tumor re-challenge, indicative of the generation of immunological memory. As shown in the figure on the right below, mice that were re-challenged with EMT6 tumors that did not express HER2 were also shown to have complete protection, indicating SBT6050 engendered activation of an anti-tumor T cell response that was not restricted to HER2. This is consistent with the expansion of T cells reactive to tumor neoantigens observed in the tumors of mice after treatment with SBT6050-S.

SBT6050-S Conferred HER2-Independent Protection in Preclinical Tumor Re-Challenge Studies

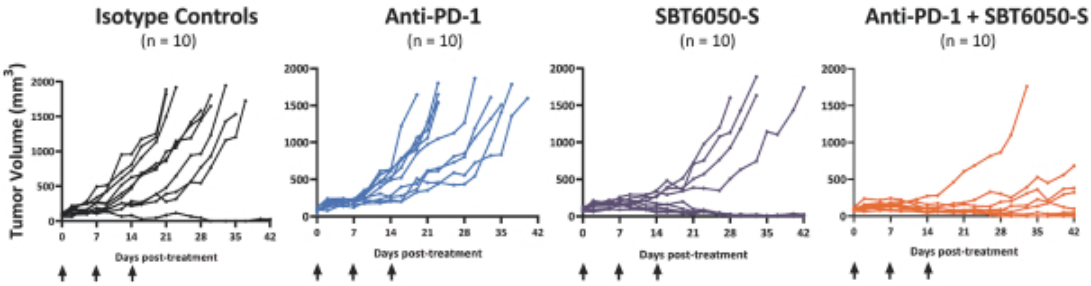


Preclinical Data Supporting the Potential for Combination of SBT6050 with Other Therapies

In our preclinical studies, SBT6050-S drove robust anti-tumor activity as a single agent and in combination with standard of care agents.

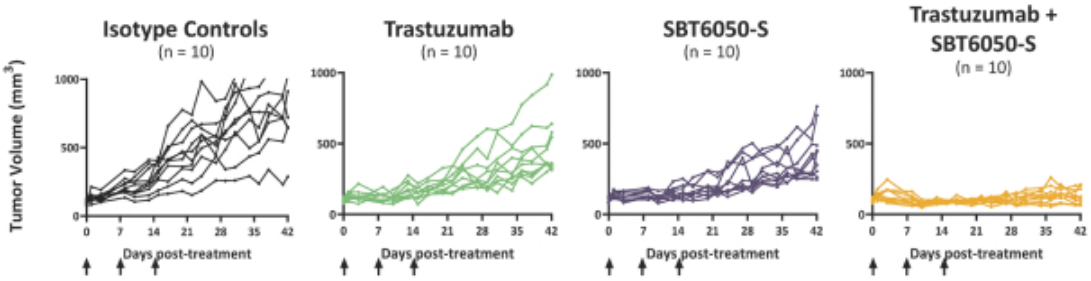
As shown in the figures below, our preclinical data demonstrated that the single agent activity of SBT6050-S in the immune-competent, checkpoint resistant HER2-EMT6 tumor model was further enhanced when combined with an anti-PD-1.

The Combination of SBT6050-S and Anti-PD-1 Drove Robust, Durable Anti-Tumor Activity



In a HER2pos human xenograft mouse model, a combination of low dose SBT6050-S with trastuzumab greatly enhanced the anti-tumor activity observed with either agent alone. As shown in the figures below, our preclinical data demonstrated the potential for enhanced clinical activity with SBT6050 in combination with trastuzumab. In this study, a lower dose of SBT6050-S (1 mg/kg) was used to allow for the combinatorial benefit to be observed. A lower dose of SBT6050-S (1 mg/kg) was used as a monotherapy control. We believe that the potential to combine with trastuzumab-based therapies unlocks the possibility of accessing earlier lines of therapy in breast and gastric cancer, where trastuzumab is a part of the standard of care.

The Combination of SBT6050-S and Trastuzumab Drove Robust, Durable Anti-Tumor Activity



SBT6050 Was Well Tolerated in Non-Human Primates by the Subcutaneous Route of Administration

SBT6050 demonstrated a wide therapeutic window in safety and tolerability studies following repeat subcutaneous administration including in the GLP toxicology study in non-human primates (NHP) that determined our first-in-human (FIH) dose. Forty-one NHPs have been administered repeat SC doses of SBT6050 in three NHP toxicity studies. In two non-GLP studies, 15 NHPs were treated at SC dose levels of 0.1 to 12 mg/kg, with the majority (8 of 15) administered 6 or 12 mg/kg every 2 or 3 weeks (Q2W or Q3W) for 4 doses. In the GLP toxicity study, 26 NHPs received doses of 2, 6 or 12 mg/kg Q2W for 4 doses, with a 4-week recovery period for the higher two dose levels. Across the studies, there was no evidence of injection site reactions or cytokine release syndrome (CRS) in any animal. There were transient, dose-related hematological, clinical chemistry, and cytokine and chemokine changes reflective of the potential mechanism of action of SBT6050. Because of the broad therapeutic

window demonstrated in these studies, our FIH starting dose level of 0.3 mg/kg was selected because of its equivalency to the minimum pharmacologically active dose level in NHP and the projection that this dose level may be pharmacologically active in patients. The FIH dose levels of immune activators, particularly those that are viewed as having a significant risk of CRS, are typically below the projected pharmacologically active dose of the agent, resulting in lengthy dose-escalations to an active dose level. Notably, that is not the case with SBT6050. Based on the totality of our preclinical data, we believe that we have potential to reach the recommended phase 2 dose (RP2D) for SBT6050 between the second and fourth dose levels.

Repeat administration of fully human or humanized proteins, such as that included in SBT6050, to preclinical species, like a NHP, has been extensively evaluated by many organizations over the years and has been found to frequently lead to the generation of anti-drug antibodies (ADA), reflecting the development of immunogenic responses with repetitive challenge of NHP with non-self or foreign proteins. Importantly, the generation of ADA against human or humanized proteins in NHP, even when accompanied by ADA-mediated toxicities such as anaphylaxis, has not been predictive of immunogenicity in humans. ADA developed against SBT6050 in our NHP toxicology studies. The formation of ADA against SBT6050 in NHP was expected given the inherent immunogenicity of humanized proteins in NHP and the potential mechanism of action of SBT6050, which includes the promotion of presentation of foreign antigens by dendritic cells, a mechanism critical to the formation of immune responses to tumor neoantigens. The development of ADA in NHP resulted in decreased exposure following repeat dosing. As has been seen with other immune agonists administered in the presence of ADA in preclinical species, repeat intravenous dosing with SBT6050 resulted in anaphylaxis but anaphylaxis was not seen in NPH studies using subcutaneous dosing of SBT6050. While no animal treated with SBT6050 subcutaneously showed signs of acute anaphylaxis, one animal in the highest dose group was euthanized due to what is believed to be ADA-related immune complex deposits in certain organs. Given the precedent data in the field, we do not believe that neutralizing ADA formation that affected SBT6050 exposure in NHP will translate into the clinic. Nevertheless, a reduction in exposure following repeat dosing of SBT6050 in the Phase 1/1b clinical trial could present a risk for clinical development. Of note, in our ongoing Phase 1/1b clinical trial, we have repeat dose pharmacokinetics (PK) after four doses of 0.3 mg/kg for one patient and reductions in SBT6050 exposure were not observed. Variable ADA titers have been observed across patients ranging from undetectable to low without impact on pharmacodynamic activity.

SBT6050 Clinical Development Plan and Strategy

SBT6050 demonstrated a wide therapeutic window in our GLP toxicology study in NHP, enabling a FIH starting dose of 0.3 mg/kg, which was projected to be pharmacologically active and within 2-3 cohorts of where we could potentially achieve anti-tumor activity. In NHP, 0.5 mg/kg was defined as the minimum pharmacologically active dose as determined by blood-based biomarkers, 6 mg/kg was determined to be the No Adverse Event Level and the highest dose level evaluated was 12 mg/kg. Our FIH starting dose of 0.3 mg/kg is the human equivalent of the minimum pharmacologically active dose level in NHP and projected to be pharmacologically active in patients. Based on the totality of our preclinical data, we believe that the RP2D will be reached between the second and fourth dose levels in our Phase 1 dose-escalation, particularly if 0.3 mg/kg demonstrates pharmacological activity as projected from our preclinical modeling. Additional dose levels may be explored in our Phase 1/1b clinical trial to further characterize the tolerability profile. At the RP2D, we believe there is potential to demonstrate single agent anti-tumor activity in dose expansion cohorts.

Our IND for SBT6050 was cleared in June 2020 with a starting dose of 0.3 mg/kg. In July 2020, we initiated a Phase 1/1b FIH, open-label, multicenter, dose-escalation and expansion clinical trial in patients with HER2-expressing solid tumors that have progressed following standard therapies. The trial is designed to evaluate the safety, tolerability, PK, pharmacodynamics (PD), immunogenicity, and

anti-tumor activity of SBT6050 as a single agent and in combination with pembrolizumab, a PD-1 inhibitor.

In our Phase 1/1b clinical trial, we are monitoring key PD biomarkers in both the blood and the tumor which have been associated with tumor regression in our preclinical mouse studies and was observed in our preclinical NHP studies. Key biomarkers in the blood include elevations in MCP-1, IP-10, and C-reactive protein and induction of additional PD markers indicative of on target mechanism of action such as IFNg. We will be obtaining tumor biopsies at baseline and on treatment to measure biomarkers that correlate with the activation of myeloid cells, T cells and NK cells in cohorts 2 and later.

The trial consists of four parts: monotherapy dose-escalation and expansion (Part 1), monotherapy dose expansion in tumor-specific cohorts (Part 2), pembrolizumab combination dose-escalation (Part 3), and a pembrolizumab combination dose expansion cohort (Part 4).

Part 1: SBT6050 Single Agent Dose-Escalation and Expansion

In Part 1, a standard 3 + 3 dose-escalation of SBT6050 is planned to study safety, tolerability, and PK of SBT6050, and to determine the maximum tolerated dose (MTD) and the RP2D. The MTD is defined as the dose just below the dose level where 2 or more out of 6 patients (^{3}33%) experience dose-limiting toxicities (DLTs). The starting dose of the SBT6050 regimen is 0.3 mg/kg administered via subcutaneous injection once every 14 days. One or two dose levels may be expanded to 12 patients to obtain additional information to select the RP2D. Eligible patients must have HER2-expressing (HER2 IHC 2/3+) or HER2-amplified cancer refractory to or relapsed after standard therapies. We anticipate enrolling approximately 30 participants in Part 1.

Part 2: SBT6050 Single Agent Dose Expansion in Tumor-Specific Cohorts

Patients will be enrolled into parallel expansion cohorts based on tumor type and HER2 expression level. Patients enrolled in the expansion cohorts will receive SBT6050 at the recommended dose and schedule established in Part 1. The purpose of Part 2 is to further characterize the tolerability profile of the RP2D and evaluate the anti-tumor activity and PD effects of SBT6050 as a single agent. Enrollment will follow a Simon 2-stage design. Planned expansion cohorts, which may also be informed by experience in the dose-escalation phase, include the following tumor types:

- Cohort A: HER2^{pos} breast cancer, n=40.
- Cohort B: HER2 low-expressing (IHC2+/amplification negative) breast cancer, n=30.
- Cohort C: HER2^{pos} gastric cancer, n=40.
- Cohort D: HER2-expressing (IHC 2/3+) or HER2-amplified non-small cell lung cancer, n=40.
- Cohort E: HER2-expressing (IHC 2/3+) or HER2-amplified solid tumors, n=30.

Part 3: SBT6050 Plus Pembrolizumab Dose-Escalation Cohort

In Part 3, a standard 3 + 3 dose-escalation of SBT6050 plus the anti-PD-1 CPI, pembrolizumab is planned to determine the MTD and RP2D of SBT6050 when given in combination with pembrolizumab. The MTD is defined as above. SBT6050 will be administered via subcutaneous injection on Days 1, 15, and 29 of 42-day cycles in combination with 400 mg pembrolizumab administered via intravenous injection on Day 1 of each cycle. Eligible patients will have HER2-expressing or HER2-amplified solid tumors. Part 3 of the study will open when changes in PD markers exceeds the pre-defined criteria for pharmacological activity with demonstration of acceptable safety and tolerability in a cohort treated with

single agent SBT6050. The pre-defined threshold is based on changes in peripheral PD markers in preclinical studies, and includes C-reactive protein elevation to ³ 150 mg/L and 3-5x changes from baseline in certain cytokines and chemokines such as IP-10 and/or MCP-1 and induction of additional pharmacodynamic markers indicative of on-target mechanism of action, such as IFNg. We anticipate enrolling approximately 15 participants in Part 3.

Part 4: SBT6050 Plus Pembrolizumab Dose Expansion Cohort

The combination treatment expansion part of the trial will be initiated once the RP2D has been defined by the safety monitoring committee from Part 3. The purpose of Part 4 is to further characterize the tolerability profile of the RP2D and evaluate the anti-tumor activity and PD effects of SBT6050 in combination with pembrolizumab. Approximately 30 patients with HER2-expressing or HER2-amplified tumors of multiple histologies will be enrolled.

Update on SBT6050 Phase 1/1b Clinical Trial

As of November 25, 2020, six patients had been enrolled at 0.3 mg/kg in Part 1 of the study (SBT6050 monotherapy dose-escalation). This first cohort of patients included two patients who had radiological reassessments, one patient with stable disease at her 8 and 16 week reassessments, one patient with a greater than 30% reduction in the diameter of her target lesion at 8 weeks per the investigator's assessment, and two additional patients that had completed the DLT period and remained on study. The most common adverse events included flu-like symptoms (fever, chills, nausea, vomiting, fatigue) and redness and swelling at the injection site. Changes in pharmacodynamic markers consistent with the potential mechanism of action were observed in treated patients. This included increases in plasma levels of CRP (C-reactive protein), a marker of inflammation, increases in MCP-1, IP-10 and IL-6, which are indicative of myeloid cell activation, increases in IFNg, which is a marker for T and NK cell activation, and transient decreases in hemoglobin, which we believe to be due to macrophage phagocytosis.

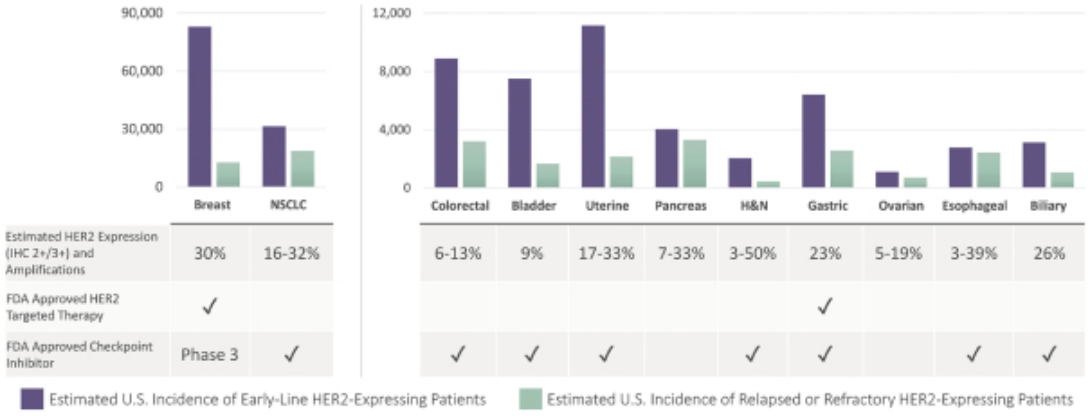
We anticipate providing an update on interim data from the Phase 1 single agent dose-escalation cohorts in the second half of 2021. Enrollment and treatment has been initiated in Part 3 of the study (SBT6050 plus pembrolizumab dose-escalation). We anticipate providing an update on interim data from the Phase 1 SBT6050 plus pembrolizumab combination in the first half of 2022. We anticipate providing a further update on interim data from the Phase 1 monotherapy and combination dose-escalation, as well as a first update of the Phase 1b monotherapy in tumor-specific expansion cohorts and the Phase 1b combination cohort, in the second half of 2022.

SBT6050 Addressable Market

As shown in the figure below, HER2 IHC 2+ and 3+ overexpression and amplification are documented in at least 11 different tumor types including breast (estimated 83,000), gastric (estimated 6,400), non-small cell lung (estimated 31,500), colorectal (estimated 9,000), bladder (estimated 7,500), uterine (estimated 11,000), pancreatic (estimated 4,000), head and neck (estimated 2,000), ovarian (estimated 1,100), esophageal (estimated 3,000), and biliary (estimated 3,000) cancers, providing the potential to address a large HER2-expressing tumor agnostic market estimated to be more than 160,000 newly-diagnosed patients annually in the United States based in part on estimated prevalence rates. HER2 IHC2+ and 3+ overexpression in breast cancer, gastric cancer, and NSCLC are 30.0%, 16.4%, and 23.2%, respectively. Most HER2 targeted therapies require the tumor cells to be dependent on HER2 signaling, often called an oncogenic driver. HER2 oncogenic-driven tumors are limited to subsets of breast and gastric cancer and hence the FDA-approved therapies that require HER2 signaling are limited to these indications as noted in the figure. SBT6050 does not require the tumor cells to be dependent on HER2 signaling for its anti-tumor activity and instead utilizes

the HER2 protein to deliver the conjugate to adjacent myeloid cells. We believe that this expands the market opportunity beyond HER2-driven breast and gastric cancer in which targeted HER2 agents have been approved and are established as standard of care. Because of the rationale to combine SBT6050 with CPI's, which is supported by our preclinical data, we have noted in the figure below those tumor types with an approved CPI.

Large Potential Market Opportunity for SBT6050 in Tumors that Express HER2 and in Combination with HER2 Targeted Agents and CPIs

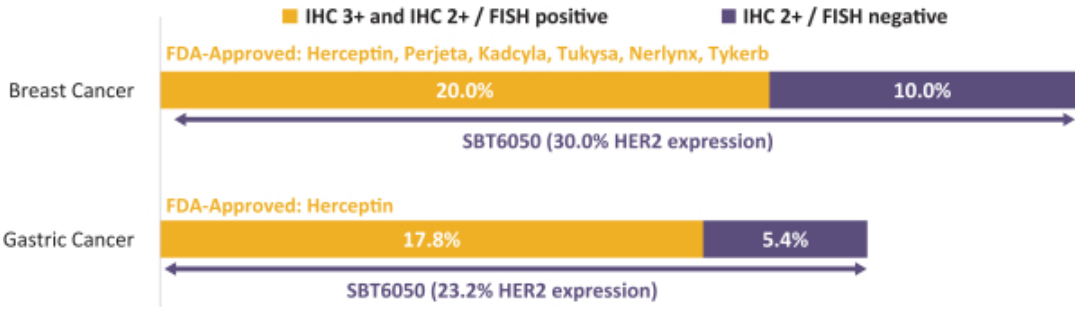


HER2 expression rates are well-understood in tumor types for which there is an FDA-approved HER2 targeted therapy available. Breast and gastric cancer cases are routinely screened for HER2 expression as a part of the standard of care. HER2 overexpression has been reported in other tumor types, but because of the lack of effective therapies targeting cancers outside of breast and gastric, screening is not readily performed. In calculating our potential addressable market for these tumor types, the figure above shows a range of HER2 expression cited in the literature and the lower end of the range was utilized for market considerations. In the United States, we believe that, based in part on estimated prevalence rates as described in the figure above, more than 48,000 patients annually with solid tumors that are refractory to standard of care treatments may benefit from SBT6050 as a single agent or combination therapy, if successfully developed and approved. In the future, if SBT6050 advances to earlier lines of treatment, based in part on estimated prevalence rates as described in the figure above, more than 160,000 patients annually may benefit.

In considering the market for combination treatment, SBT6050 was specifically designed to bind to the HER2 sub-domain II, the pertuzumab epitope, to enable combinations with trastuzumab-based therapies that bind to HER2 sub-domain IV such as Herceptin (trastuzumab), Kadcyla (trastuzumab-DM1), and Enhertu (DS-8201), all of which are FDA-approved HER2 agents. Our preclinical data has demonstrated the potential to use SBT6050 in combination with trastuzumab and CPI's. We believe that SBT6050 may also have the potential to be combined with tyrosine kinase inhibitors such as Tukysa (tucatinib), which is approved for combination with trastuzumab and Xeloda (capecitabine) for the treatment of $HER2^{pos}$ metastatic breast cancer. When considering the market potential for combination therapy, only combinations with trastuzumab and CPI's was utilized in our calculations.

SBT6050 is also active in HER2 IHC 2+ / FISH negative tumors, expanding the market beyond the scope of current approved HER2 targeted therapies indicated for IHC 3+ and IHC 2+ / FISH positive tumors as shown in the figure below. We considered this potential market extension in breast cancer and gastric cancer in calculating the potential addressable market.

SBT6050 Potential Addressable Market in Indications with an FDA-Approved HER2 Targeted Therapy



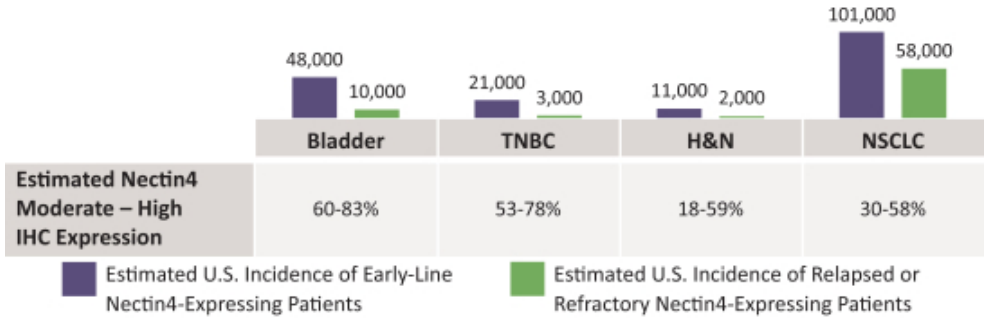
SBT6290: TLR8 Agonist Conjugated to a Nectin4 Antibody

Our second product candidate, SBT6290, is comprised of the same TLR8 linker-payload used in SBT6050 conjugated to a Nectin4-directed monoclonal antibody. Nectin4 has been prioritized as our second target based on differential expression of extracellular proteins on tumor cells in comparison to healthy tissue, as well as the degree of myeloid cell infiltrate in the TME. Nectin4 is overexpressed in cancers including bladder, triple negative breast, head and neck, and NSCLC, among others.

Nectin4 is a target that has been clinically validated by Seagen (formerly Seattle Genetics) through the approval of the Nectin4-directed antibody-drug conjugate Padcev. In 2019, Padcev was approved under the FDA's accelerated approval program indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a PD-1 inhibitor, and a platinum-containing chemotherapy.

Targeting Nectin4 to deliver a TLR8 agonist to adjacent myeloid cells presents a significant therapeutic opportunity across different cancers. As shown in the figure below, the estimated incidence of newly diagnosed patients with bladder, triple negative breast, head and neck cancers, and NSCLC that express Nectin4 represents over 181,000 patients annually in the early line setting. The estimated yearly deaths of patients with bladder, triple negative breast, head and neck cancer, and NSCLC that express Nectin4 represents over 73,000 patients with relapsed or refractory cancer annually in the United States.

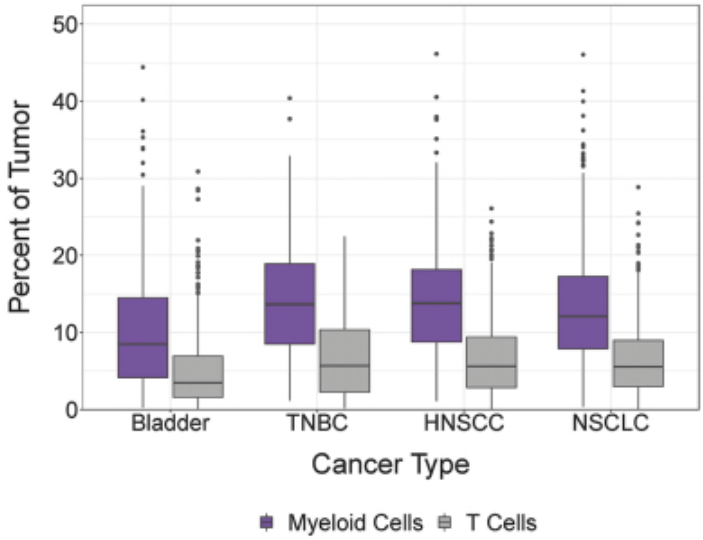
Nectin4 Overexpression Across Select Tumor Types



Bioinformatic analysis of data from The Cancer Genome Atlas (TCGA) database indicates that myeloid cells are present in Nectin4-expressing tumor types, as shown in the figure below. As reported

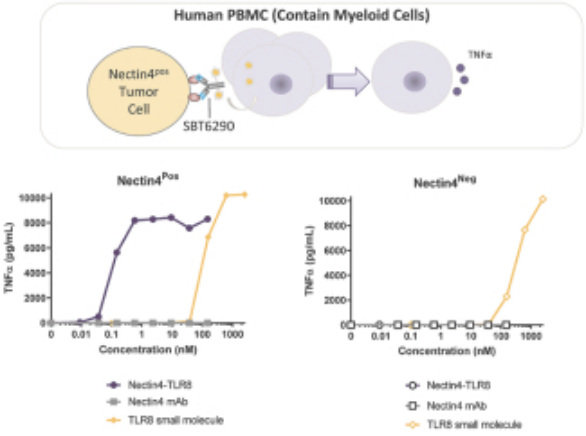
in TCGA, myeloid cells can comprise, on average, between 7% to 14% of the tumor which is higher than the average number of T cells in the same tumor types.

Nectin4-Expressing Tumor Types Are Infiltrated By Myeloid Cells



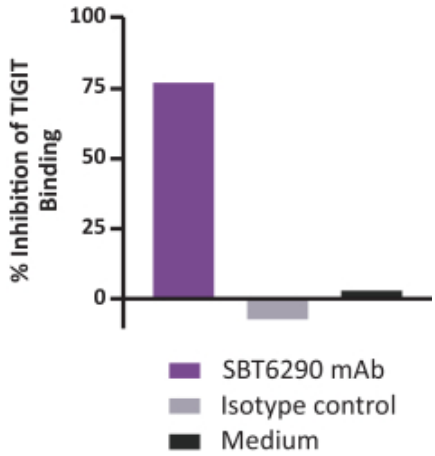
In our *in vitro* studies, human PBMCs were co-cultured with Nectin4^{pos} or Nectin4^{neg} tumor cell lines in the presence of SBT6290. As shown in the figures below, SBT6290 potently activated myeloid cells with an EC_{50} of ~200 pM, in the presence of Nectin4-expressing tumor cells. TNFa production was measured as a marker of myeloid cell activation. The levels of TNFa induced by SBT6290 matched those observed with SBT6050 when tested in a similar *in vitro* assay. Not only did these data highlight the Nectin4-dependent activity of SBT6290, but also demonstrated that the TLR8 linker-payload used in SBT6050 was transferable to antibodies directed to diverse antigens.

SBT6290 Potently Activated Human Myeloid Cells



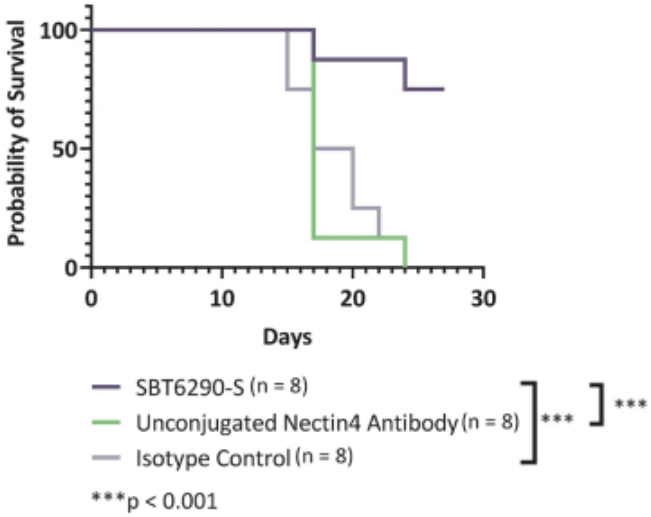
Nectin4 was recently described to be a ligand for T cell immunoglobulin and ITIM domain (TIGIT). TIGIT has emerged as an inhibitor of anti-tumor immune responses and several agents inhibiting this pathway are being tested in clinical trials. In addition to SBT6290's primary mechanism of action through TLR8 activation, the figure below demonstrated that the binding of TIGIT to Nectin4-expressing tumor cells was blocked by the binding domain of SBT6290.

SBT6290 Binding Domain Blocked TIGIT Binding to Nectin4-Expressing Tumor Cells



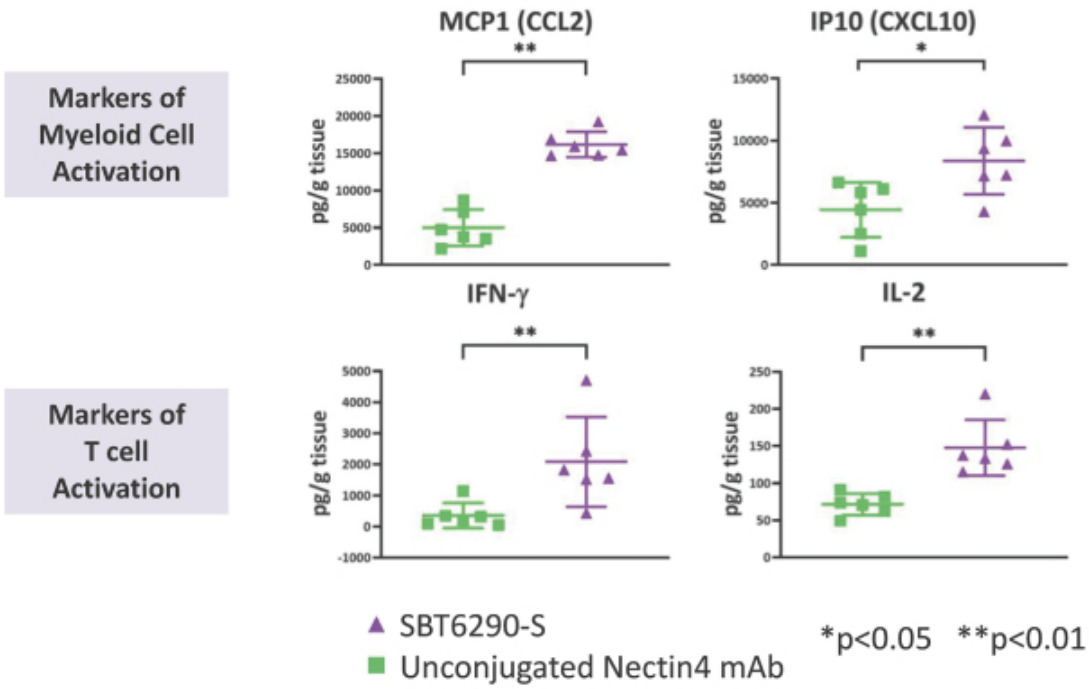
We engineered a mouse surrogate of SBT6290 (SBT6290-S) using a TLR7 agonist conjugated to a Nectin4 monoclonal antibody to account for species differences in our *in vivo* studies, as was described for SBT6050. As shown in the figure below, SBT6290-S improved overall survival in a Nectin4-expressing EMT6 mouse model. This study was powered for statistical significance using survival as a readout which is defined as tumor size remaining below 1,000 mm^3. SBT6290-S demonstrated a statistically significant improvement in survival as compared to the two control groups as noted in the figure below.

Administration of SBT6290-S as Monotherapy Resulted in Improved Overall Survival in a Nectin4-Expressing EMT6 Preclinical Model



As shown in the figure below, subcutaneous administration of SBT6290-S to mice bearing Nectin4-expressing EMT6 tumors induced the production of cytokines and chemokines in the tumors of treated mice. MCP-1 and IP-10 upregulation are indicative of myeloid cell activation and IFNg and IL-2 production are indicative of T cell activation in the treated mice.

Administration of SBT6290-S as Monotherapy Induced the Production of Cytokines and Chemokines in Nectin4-Expressing EMT6Tumors



In a single and repeat dose exploratory safety study, Nectin4-TLR8 conjugate was administered subcutaneously to NHP at a dose level >10-fold of the anticipated, minimum pharmacologically active dose level, a dose that was also evaluated with SBT6050. The overall safety, tolerability, PK and PD findings of the Nectin4-TLR8 conjugate were very similar to those observed with SBT6050 at this dose. A non-GLP toxicology study for SBT6290 has been completed, and we believe the results are supportive of a wide therapeutic window similar to that observed with SBT6050. GLP NHP toxicity studies are expected to commence in first half of 2021. In parallel, we are in the process of creating a master cell bank for GMP production of SBT6290. In our pre-IND interactions with the FDA that took place in February 2021, alignment on SBT6290 preclinical, Chemistry, Manufacturing, and Controls (CMC), and clinical plans was achieved. We anticipate submitting the SBT6290 IND in the fourth quarter of 2021 and initiating a Phase 1 clinical trial in the first quarter of 2022.

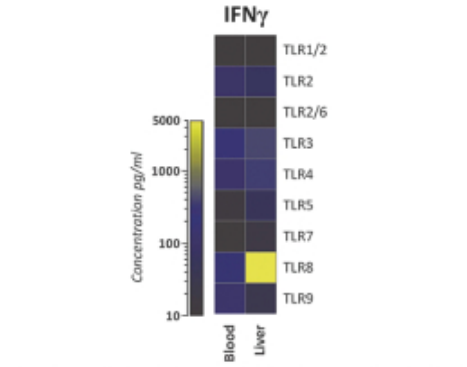
SBT8230: TLR8 Agonist Conjugated to an ASGR1 Antibody

As our lead virology program, we have engineered SBT8230 to treat cHBV using our ImmunoTAC platform. SBT8230 is comprised of an ASGR1 monoclonal antibody conjugated to the same TLR8 linker-payload as SBT6050 and SBT6290 and is designed to elicit an anti-viral immune response by targeting TLR8 activation to the liver.

cHBV infection remains a worldwide problem affecting approximately 257 million people and contributing to an estimated 887,000 deaths in 2015. In the United States alone, approximately 860,000 people suffer from cHBV. cHBV is estimated to be the cause of 60-80% of the world's primary liver cancers. There is a significant unmet need for therapies that can elicit a functional cure for the disease, which is defined as sustained loss of hepatitis B surface antigen (HBsAg) in the blood. Many of the approved therapies for cHBV have low functional cure rates or lack durability over time.

Clinical and preclinical evidence by third parties have demonstrated that IFNg-mediated immune responses, including the activation of IFNg+ T cell and IgG B cell anti-viral responses, can lead to a functional cure in cHBV patients and animal models of HBV. In HBV transgenic mice, HBV-specific CD4 and CD8 T cells have exhibited the ability to inhibit hepatocellular replication by a noncytopathic process that is mediated primarily by IFNg. In acutely infected chimpanzees, viral replication was almost completely abolished soon after CD3 and IFNg mRNA increased in the liver. Evidence by third parties has demonstrated that HBV-specific IFNg producing CD4 T cells were associated with viral clearance in patients with cHBV infection. Additionally, these studies have demonstrated that TLR8 agonists were particularly effective in activation of myeloid cells and the induction of IFNg. The figure below shows IFNg production after human blood or liver-derived mononuclear cells were stimulated with the indicated TLR agonist. TLR8 was unique in its ability to induce IFNg.

TLR8 Drove IFNg Production from Liver Mononuclear Cells in Third Party Preclinical Studies



Supernatants in blood (n=5) or liver- derived mononuclear cells (n=9) stimulated with the indicated TLR agonist

Jo et al, PLOS Pathogens, 2014

In addition, the figures below show concentrations of individual cytokines quantified in the supernatant of purified PBMC or isolated mononuclear cells from the liver after stimulation with either a TLR8 or TLR7 agonist. TLR8 agonism, but not TLR7 agonism, induced IFNg production, along with the production of other cytokines important in the generation of anti-viral immunity such as TNFa, IL-1ß, and IL-6, from both liver and blood immune cells. We believe these data from third parties demonstrate that TLR8 is the agonist of choice for improving the outcome for patients with cHBV.

TLR8 Agonism Drove Cytokine Production

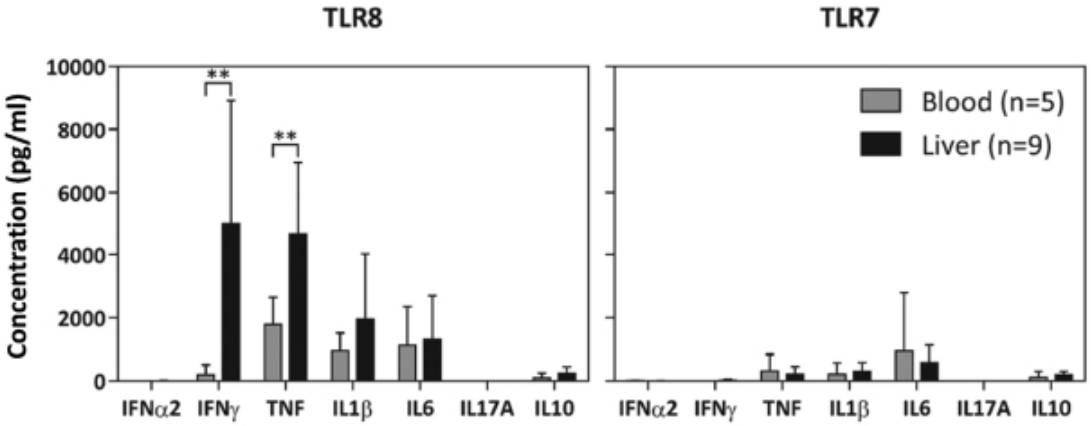


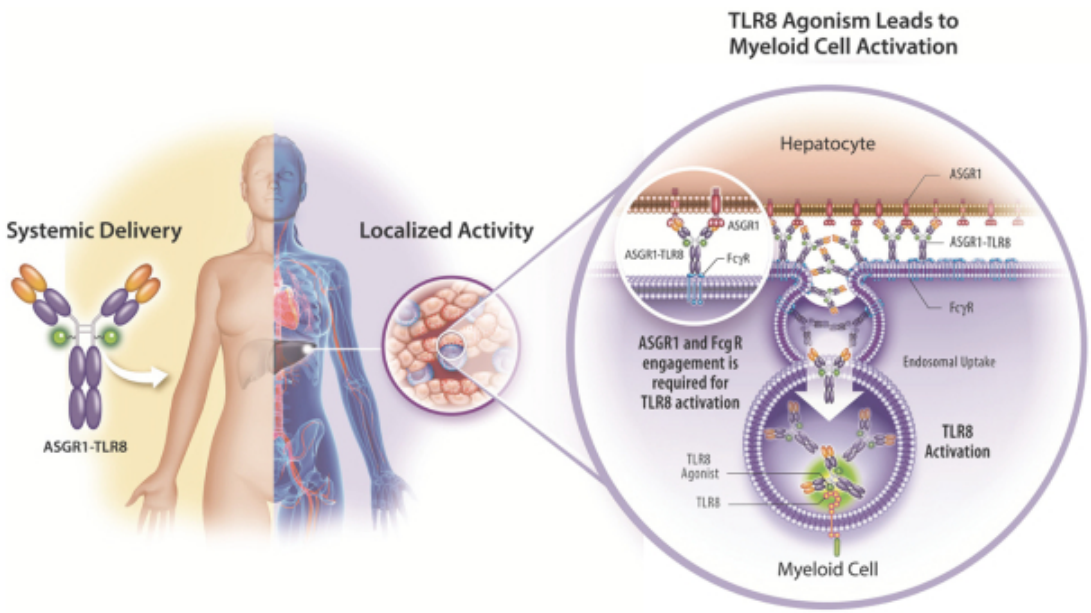
Figure source: Jo et al, PLOS Pathogens, 2014.

In a preclinical woodchuck model of cHBV conducted by a third party, oral administration of a TLR8 agonist small molecule, GS-9688 (selgantolimod), was shown to drive seroconversion and reduce woodchuck hepatitis virus S antigen and woodchuck hepatitis B viral levels. Selgantolimod's effectiveness in cHBV patients has been limited, however. We believe (i) this is due to not achieving necessary exposures because of DLTs associated with activation of myeloid cells outside of the liver and (ii) that systemically delivered but liver localized TLR8 agonism could improve the potential for effective therapy and lead to functional cures in cHBV.

SBT8230 is a Liver-Localized TLR8 Agonist Designed to Achieve Functional Cure in cHBV

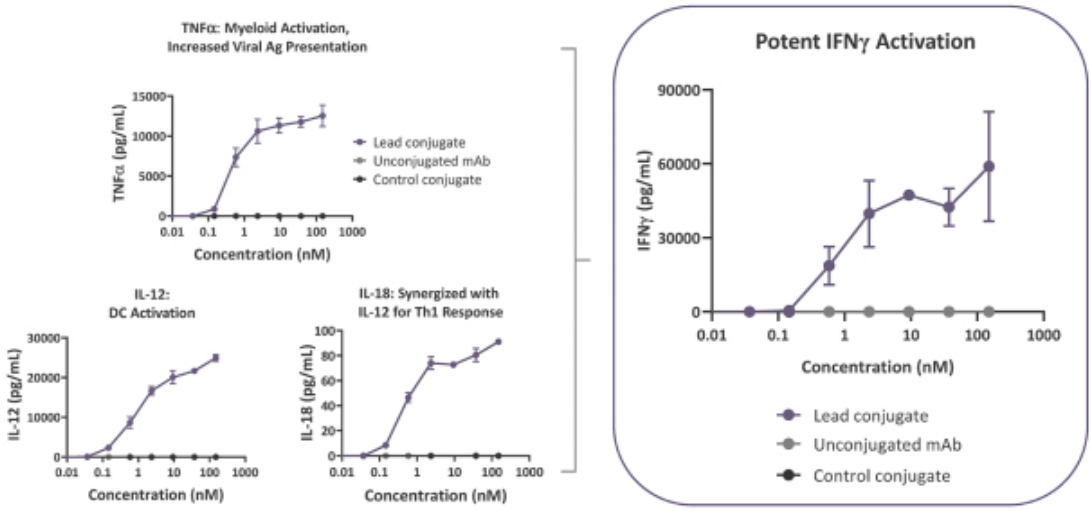
As shown in the figure below, we designed SBT8230 to be comprised of an ASGR1 monoclonal antibody conjugated to a TLR8 linker-payload with the goal of activating the myeloid cell compartment in liver tissue only. The conjugate is designed to be internalized in myeloid cells in an FcR-mediated manner when ASGR1 is present on adjacent liver cells.

Potential Mechanism of Action: SBT8230 is Designed to Localize TLR8 Activation of Myeloid Cells in the Liver Via a Directed ASGR1 Antibody



As shown in the figures below, in our preclinical studies utilizing human PBMCs *ex vivo*, ASGR1-TLR8 induced IFNg-promoting activity through its activation of myeloid cells.

ASGR1-TLR8 Potently Activated Human Myeloid Cells, Resulting in a Robust IFN*g *Response

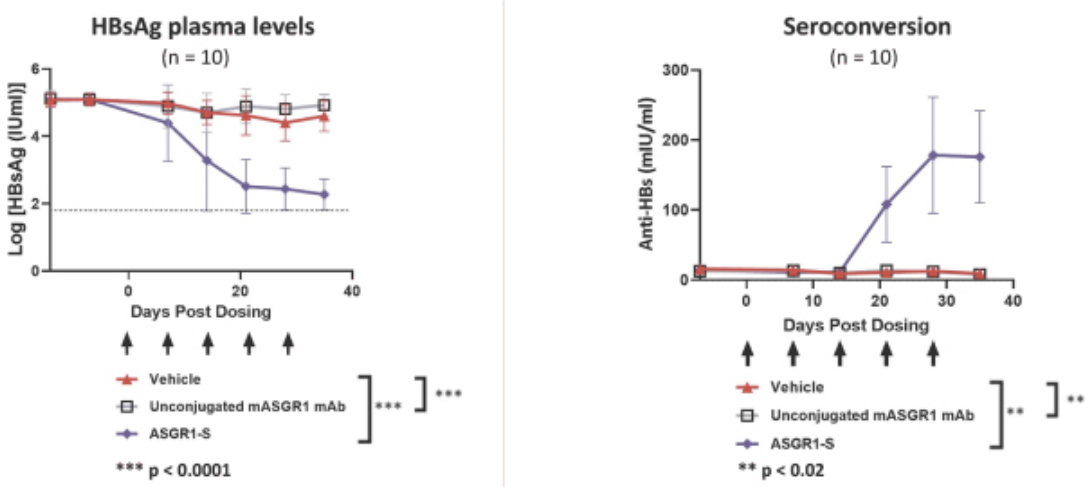


Activation of human myeloid cells by TLR8 was mirrored in mouse myeloid cells by TLR7 as was demonstrated previously in the SBT6050 and SBT6290 programs. Therefore, to evaluate the ability of

a liver-targeted myeloid cell agonist conjugate to drive seroconversion in a mouse model of cHBV, we engineered a surrogate for SBT8230 comprised of an ASGR1 monoclonal antibody conjugated to a TLR7 agonist (ASGR1-S). The antibody contained an IgG2a Fc domain to facilitate uptake into mouse myeloid cells.

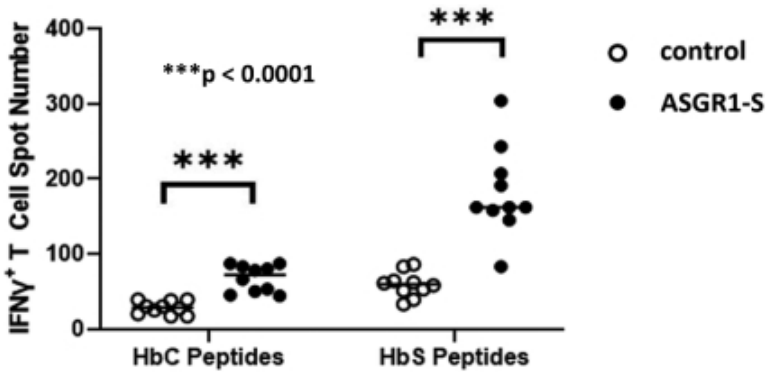
Seroconversion, together with reductions in HBsAg levels and expansion of IFNg-producing anti-viral T cells, is associated with achievement of functional cures in cHBV. The AAV-HBV (adenovirus-hepatis B virus) mouse model is a commonly used preclinical model for cHBV. Paralleling their inability to drive seroconversion in cHBV patients, cHBV standard of care therapies and other agents that target the HBV life cycle such as capsid inhibitors, have not resulted in seroconversion in this or similar models. In contrast, statistically significant increases in seroconversion and reductions in HBsAg was demonstrated with ASGR-S as compared to the vehicle and unconjugated antibody control groups in the AAV-HBV model, as shown in the figures below.

ASGR1-S Reduced HBsAg and Drove Seroconversion in Mouse AAV-HBV Model

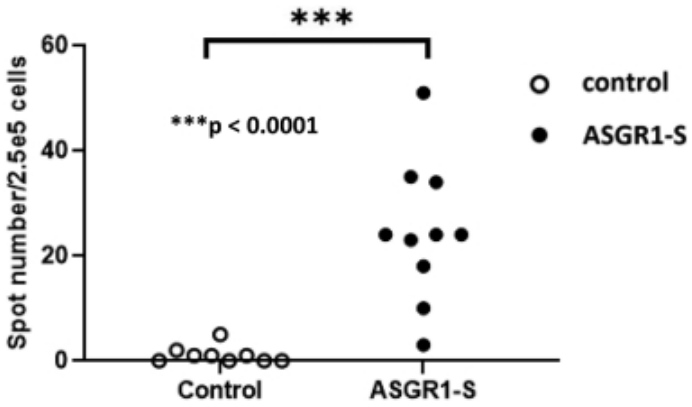


In addition, ASGR1-S treatment generated potent anti-viral T cell and B cell immune responses and significantly increased anti-HBV core and S antigen IFNg+ T cells and anti-HBsAg+ B cells, as shown in the figures below.

ASGR1-S Increased IFNg+ Anti-Viral T Cells

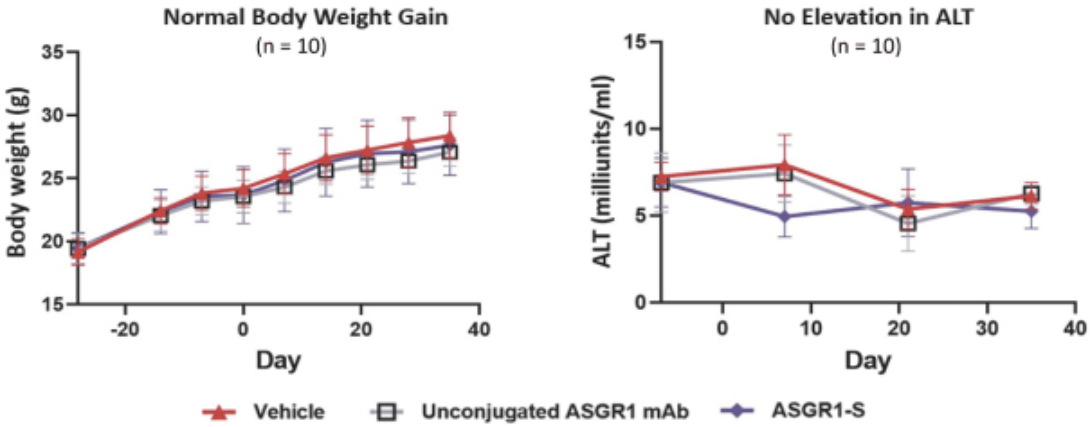


ASGR1-S Increased B Cells Producing Anti-HBs Antigen Antibodies



Importantly, as shown in the figures below, no changes in serum ALT or body weight were noted after treatment with ASGR1-S as compared to controls. In addition, there were no findings in the liver by histopathology after treatment with ASGR1-S. Together, these data indicated that ASGR1-S was well tolerated in the mouse AAV-HBV model.

ASGR1-S Was Well Tolerated in Mice



Initial exploratory NHP toxicology studies demonstrated a wide therapeutic window. Preclinical studies in mice and NHP for our ASGR1-TLR8 ImmunoTAC candidate are ongoing. We selected a development candidate for this program in the fourth quarter of 2020, and we anticipate initiating IND enabling toxicity studies in the first quarter of 2022 and submitting the IND in the second half of 2022.

Other Programs

Additional Immuno-Oncology Programs

In addition to HER2 and Nectin4, we have selected two undisclosed targets that may enable us to address a broader range of solid tumor indications. In these programs, the antibodies have been created and conjugated to the same TLR8 linker-payload utilized in SBT6050 and SBT6290. In addition, our undisclosed product candidates display an *in vitro* activity profile on human immune cells similar to that of SBT6050 and SBT6290. Further, one of these conjugates was evaluated in an exploratory NHP toxicology study with repeat subcutaneous dosing. The dose level evaluated in this

study was previously used in NHP toxicology studies with SBT6050 and SBT6290 to demonstrate a therapeutic window. At this dose level, the undisclosed product candidate was found to have a similar tolerability profile to SBT6050 and SBT6290, indicating that it may have a similar therapeutic window.

Fibrosis Program: TGFßR1 Antagonist Conjugated to an ASGR1 Antibody

We designed our ASGR1-TGFßR1 antagonist conjugate to achieve liver-localized inhibition of TGFß-signaling to treat fibrosis.

Fibrosis is the overgrowth, hardening and scarring of tissue due to accumulation of extracellular matrix molecules, such as collagen, that is produced by fibroblasts. Chronic fibrotic diseases often result in widespread distortion of normal tissue architecture and account for up to 45% of deaths in the United States. Fibrosis can occur in most major tissues, however idiopathic pulmonary fibrosis and hepatic cirrhosis are among the more common fibrotic diseases.

Hepatic cirrhosis and hepatocellular carcinoma (HCC) are leading causes of morbidity and mortality worldwide. Patients with liver cirrhosis are at high risk of deadly hepatic failure and approximately 80%-90% of HCC develop on a cirrhotic background. HCC ranks as the sixth most common cancer and, with over 600,000 deaths per annum, it constitutes a major global health problem. The most common causes of hepatic cirrhosis in the United States are hepatitis C, alcoholic liver disease, and nonalcoholic liver disease.

TGFß Pathway and its Role in Fibrosis

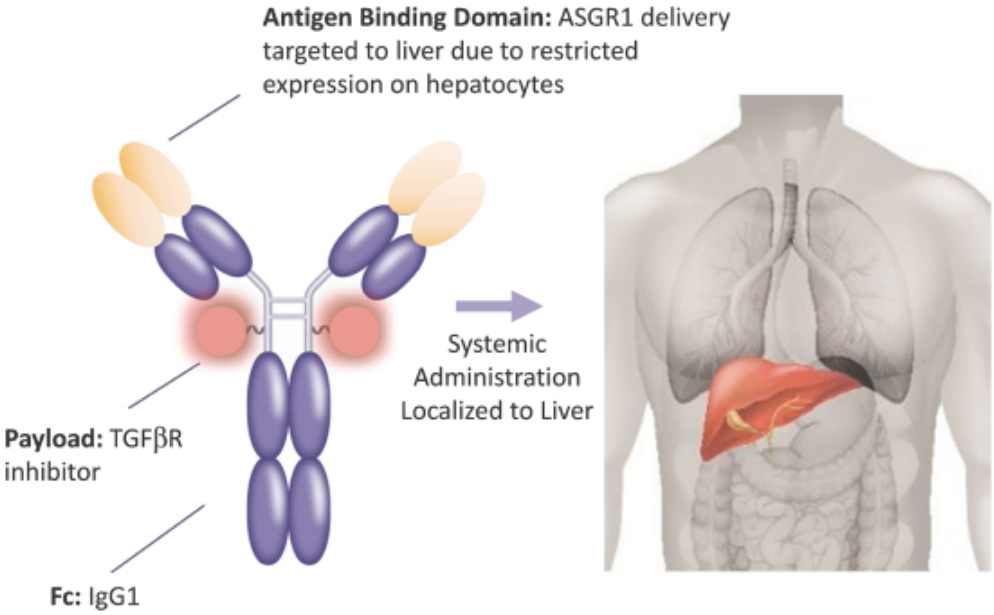
Progress has been made to treat the underlying etiologies initiating liver fibrosis, yet significant needs remain for therapies that slow, halt, or reverse fibrosis and thereby prevent late-stage liver failure and HCC. TGFß signaling is a key mediator of liver fibrosis initiation and progression through multiple mechanisms, including hepatocyte apoptosis, hepatic stellate cell transdifferentiation to myofibroblasts, and pro-fibrotic macrophage activation.

TGFß is secreted by many cell types and is implicated in a wide range of cell functions, critically regulating tissue homeostasis and repair, immune and inflammatory responses, extracellular matrix deposition, and cell differentiation and growth. In healthy tissues, TGFß is expressed at a low level to enable homeostatic mechanisms and is also transiently upregulated in response to tissue injury, which initiates a cascade that results in collagen production and, ultimately, healing of the tissue. In fibrotic tissue, TGFß production and signaling is dysregulated and perpetuated, leading to excess collagen deposition in the absence of acute tissue injury.

While inhibiting the TGFß receptor kinase domains is the most direct way to down-regulate TGFß signaling, systemic availability of TGFß receptor 1 (TGFßR1) antagonists is associated with DLTs due to the homeostatic functions of TGFß in multiple organ systems. Preventing TGFß activity with antibody blockade of ligands or their activation machinery is challenging due to the presence of multiple ligands and activation mechanisms, and TGFß's sequestration in extracellular matrix. We believe a systemically delivered TGFßR1 antagonist with liver-localized activity has the potential to ameliorate liver fibrosis while avoiding the toxicities associated with non-targeted TGFß receptor inhibition.

Using a similar strategy of liver localization that was employed in our cHBV program, as shown in the figure below, we engineered an ASGR1-TGFßR1 antagonist ImmunoTAC intended to inhibit the TGFß pathway to treat liver fibrosis. ASGR1 is a scavenger receptor that is highly expressed exclusively on hepatocytes and internalizes and recycles rapidly upon engagement. Thus, the ASGR1-TGFßR1 antagonist conjugate is designed for systemic administration with liver-localized inhibition of the TGFß receptor.

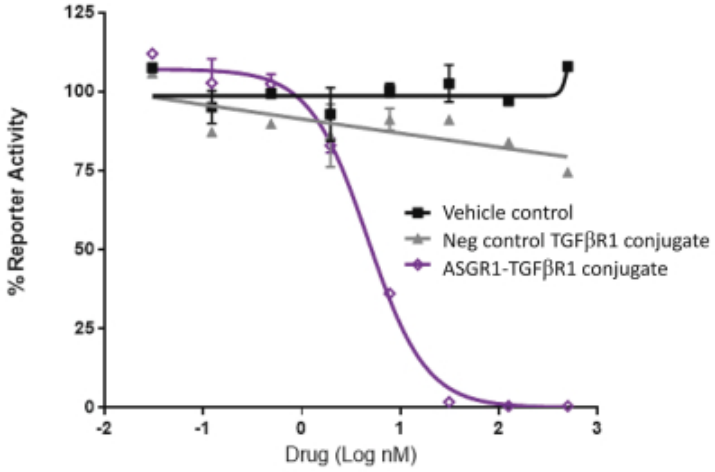
ASGR1-TGFßR1 ImmunoTAC Therapeutic is Designed for Liver-Localized TGFß Signaling Inhibition for Anti-Fibrotic Effects



As shown in the figure below, our initial preclinical studies with ASGR1-TGFßR1 antagonist conjugates demonstrated potent inhibition of TGFß signaling *in vitro*. This activity was dependent on ASGR1 binding as no activity was observed on cells with low or no ASGR1 expression.

ASGR1-TGFßR1 ImmunoTAC Therapeutic: Potent and Complete Inhibition of TGFß Signaling in pSMAD Reporter Assay

ASGR1^{pos} pSMAD Reporter Assay



Preclinical studies in mouse disease models are ongoing for this program.

Competition

The pharmaceutical industry is highly competitive and dynamic, owing to rapidly advancing technologies. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing treatments and new treatments that may become available in the future.

We compete with other companies working to develop immunotherapies and targeted therapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. These companies are developing therapies of many different modalities including small molecules, monoclonal antibodies, antibody-drug conjugates, bi-specific antibodies, cell therapies, oncolytic viruses and vaccines.

Specifically, there are many companies pursuing a variety of approaches to TLR-directed therapies, including Apros Therapeutics, Ascendis, BioNTech, Bolt Biotherapeutics, Bristol Myers Squibb, Checkmate Pharmaceuticals, CureVac, Exicure, Galaderma, Gilead, Idera, Mologen, Nektar, Novartis, Primmune Therapeutics, Roche, Seven&Eight, Shanghai De Novo, Sumitomo Dainippon, 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, Genentech, MacroGenics, Pieris, Puma, Seagen (formerly Seattle Genetics), 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, Celldex, CytomX, Eli Lilly and Company, GlaxoSmithKline, Genmab, ImmunoGen, Immunomedics, Millennium Pharmaceuticals, MorphoSys AG, Novartis, Pfizer, Sanofi, Seagen (formerly Seattle Genetics), Sutro Biopharma, and VelosBio.

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.

Our commercial potential 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 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, 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. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and convenience.

Manufacturing

Our antibody-drug conjugate is produced by chemical conjugation of a non-cytotoxic linker-payload to a monoclonal antibody. We have significant internal expertise in engineering and humanization of antibodies and designing linker-payloads to customize the drug conjugate for a desired target profile. The small molecule linker-payload is chemically synthesized, and the antibody is produced by conventional biological process technology. The manufacturing process involves production of the linker-payload and antibody process intermediates, the conjugation of the intermediates to produce bulk therapeutic substance, and fill/finish of the therapeutic product.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities subject to compliance with current good manufacturing practices (cGMP). We operate on an outsourced model and rely on contracts with third-party development and manufacturing organizations designed to comply with cGMPs to produce and test the intermediates, therapeutic substance and therapeutic product to support clinical development, and commercialization, if any of our product candidates obtain marketing approval. We are working with these manufacturers to scale up our manufacturing capabilities to support our clinical plans. We also rely on third parties to package, label, store and distribute our product candidates, as well as for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest on our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the design and development of our product candidates.

Commercialization Plan

We intend to retain significant development and commercial rights to our product candidates and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially with a partner, in the United States and other regions. We currently have no sales, marketing or commercial product distribution capabilities and have no experience as a company commercializing products. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of our product candidates. Clinical data, the size of the addressable patient population, the size of the commercial infrastructure and manufacturing needs may all influence or alter our commercialization plans.

License Agreement

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

In October 2019, we entered into a cell line license agreement with WuXi Biologics (Hong Kong) Limited (WuXi Bio), pursuant to which we received a non-exclusive, worldwide, sublicensable license 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 used to manufacture a component of our lead product, SBT6050.

In January 2020, we paid a license fee of $100,000 to WuXi Bio. In December 2020, we incurred an additional license fee of $50,000 to WuXi Bio. Additionally, if we do not engage WuXi Bio to manufacture the WuXi Bio Licensed Products for our clinical and commercial supplies, we are required to make milestone payments to WuXi Bio upon the achievement of certain sales milestones. Under such scenarios, upon achieving certain thresholds for the aggregate annual net sales of a WuXi Bio Licensed Product, we would owe WuXi Bio aggregate milestone payments of up to $10.8 million.

The WuXi Bio Agreement will continue indefinitely unless terminated in accordance with the agreement. The WuXi Bio Agreement may be terminated (i) by us upon six months' written notice provided we pay all amounts due to WuXi Bio through the effective date of termination, (ii) by either party for the other party's material breach that remains uncured for 30 days after written notice, and (iii) by WuXi Bio after 45 days' written notice if we fail to make a payment within 30 days after receiving notice of such failure.

Master Services Agreements

Master Services Agreement with CE3, Inc.

In January 2020, we entered into a master services agreement (MSA) with CE3, Inc. (CE3) pursuant to which CE3 will perform certain clinical research and administrative services in connection with our lead product SBT6050, including trial management, site selection, site management, project management, data collection and analysis, and other related services, in support of certain clinical research and trials. In addition to the fees for these services, we are obligated to pay the fees and expenses incurred in connection with the services provided by CE3.

The CE3 MSA will expire in January 2025, unless earlier terminated in accordance with the MSA. The MSA can be terminated (i) by either party at any time upon 30 days' written notice provided any ongoing work order will continue until the termination date set forth in such work order; (ii) by either party for the other party's material breach that remains uncured for 60 days after written notice; (iii) by either party if the other party becomes insolvent or bankrupt; or (iv) by us if either party is unable to obtain required ongoing review and/or approvals from regulatory agencies in connection with services to be performed under the MSA.

Master Laboratory Services Agreement with Q Squared Solutions LLC

In May 2020, we entered into a Master Laboratory Services Agreement (MLSA) with Q Squared Solutions LLC (Q Squared) pursuant to which Q Squared will perform certain project planning, laboratory design consultation, laboratory analysis, data management and other laboratory services in connection with our lead product SBT6050. In addition to the fees for these services, we are obligated to pay the fees, expenses and pass-through costs incurred in connection with the services provided by Q Squared.

The Q Squared MLSA will continue until May 2025, at which time it will automatically renew annually unless either party elects not to renew by providing 30 days' written notice prior to the date of

an automatic renewal. Additionally, the MLSA can be terminated (i) by either party at any time upon 90 days' written notice; (ii) by either party for the other party's material breach that remains uncured for 30 days after written notice; (iii) by either party if the other party becomes insolvent or files for bankruptcy; or (iv) by Q Squared if its continued performance of services would constitute a potential or actual violation of regulatory or scientific standards of integrity.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We own the issued patents and patent applications relating to our lead product candidate SBT6050. Our policy includes seeking to protect our proprietary position by, among other methods, filing patent applications, in the United States and in jurisdictions outside of the United States, directed to our proprietary technology, inventions, improvements, and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates, continued innovation, and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of immunotherapy. We also plan to rely on data exclusivity, market exclusivity, and patent term extensions when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions, and improvements; to preserve the confidentiality of our trade secrets and know-how; to obtain and maintain licenses to use intellectual property owned by third parties; to defend and enforce our proprietary rights, including any patents that we may own in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

As of February 28, 2021, our licensed and owned patent portfolio included four owned U.S. patents, 23 owned U.S. provisional and non-provisional patent applications, 13 owned patent applications filed under the Patent Cooperation Treaty (PCT), 50 owned foreign patent applications filed in 16 different countries or regions, including in Australia, Brazil, Canada, China, European region, Hong Kong, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, Taiwan, and South Africa, directed to TLR8 agonists and conjugates, including SBT6050, TGFßR1 antagonists and conjugates, TGFßR2 antagonists and conjugates, TLR7 agonists and conjugates, and various applications of our proprietary antibody conjugates and antibodies, including antibodies specific for Nectin4 and ASGR, as well as certain of our other proprietary antibodies, compounds, conjugates, formulations, technology, inventions, improvements, and other product candidates. Any patents that issue from these pending patent applications will expire between March 2038 and October 2041, absent any patent term adjustments or extensions. We also possess and/or in-license substantial know-how and trade secrets relating to the development and commercialization of our product candidates, including related manufacturing processes and technology.

Specifically, our patent portfolio includes the following families and/or groups of families:

- **TLR8 Agonists and Conjugates.** We have four issued U.S. patents with composition of matter and method of treatment claims directed to our lead product candidate, SBT6050, and composition of matter, method of treatment, and method of making claims to TLR8 agonist payloads, linker-payloads and conjugates, including conjugates to HER2-directed antibodies. The issued U.S. patents expire in March 2038, absent any patent term extensions. As of December 31, 2020, we have eight pending U.S. patent applications, six pending PCT applications, and 24 pending foreign patent applications filed in 16 different countries or regions, including in Australia, Brazil, Canada, China, European region, Hong Kong, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, Taiwan and South Africa,

with composition of matter claims directed to SBT6050, formulations of SBT6050, and other TLR8 agonists and conjugates, including capped and substituted TLR8 agonist variants and conjugates, as well as claims to methods of administering SBT6050, and other TLR8 agonists and conjugates, and to methods for treating oncology indications. Any patents that issue from these pending patent applications will expire between March 2038 and July 2041, absent any patent term adjustments or extensions. We own all the issued U.S. patents and all the pending patent applications in these patent families.

With respect to our product candidates and processes, we intend to develop and commercialize in the normal course of business, and we intend to pursue patent protection directed to, when possible, compositions, methods of use, methods of making, dosing, and formulations. We may also pursue patent protection with respect to manufacturing, therapeutic development processes and technologies, and therapeutic delivery technologies.

Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued U.S. patent that is directed to or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its claims, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of immunotherapy has emerged in the United States. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and enforce the patent rights that we license, and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions, and improvements. With respect to both licensed and company-owned intellectual property, we cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even the issued patents that we license do not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and the issued patents that we in-license and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology.

Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents that we own or exclusively in-license. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, such as our investigational medicines and any future investigational medicines. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

Regulatory Approval in the United States

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The FDCA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post- approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Biological products used for the prevention, treatment or cure of a disease or condition of a human being are subject to regulation under the FDCA, except the section of the FDCA that governs the approval of new drug applications, NDAs. Biological products, such as our ImmunoTAC product candidates, are approved for marketing under provisions of the Public Health Service Act (PHSA), via a BLA. However, the application process and requirements for approval of BLAs are very similar to those for NDAs, and biologics are associated with similar approval risks and costs as drugs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending NDAs or BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Our investigational medicines and any future investigational medicines must be approved by the FDA pursuant to a BLA before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical laboratory and animal studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an IRB or independent ethics committee at each clinical trial site before each clinical trial may be commenced;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, GCP requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of a BLA;

- payment of any user fees for FDA review of the BLA;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the biologic, or components thereof, will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- satisfactory completion of any potential FDA audits of the clinical trial sites that generated the data in support of the BLA to assure compliance with GCPs and integrity of the clinical data;
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee; and
- compliance with any post-approval requirements, including REMS, where applicable, and post- approval studies required by the FDA as a condition of approval.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, or at all.

Preclinical Studies

Before testing any biological product candidates in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product candidates and formulations, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated in the trial. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website. Information related to the product, patient population, phase of investigation, clinical trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Disclosure of the results of these clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well- designed and well-conducted foreign clinical trial not conducted under an IND if the clinical trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacokinetics, pharmacologic action, side effect tolerability, safety of the product candidate, and, if possible, early evidence of effectiveness.
- Phase 2 clinical trials generally involve studies in disease-affected patients to evaluate proof of concept and/or determine the dosing regimen(s) for subsequent investigations. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the biologic.

These Phases may overlap or be combined. For example, a Phase 1/2 clinical trial may contain both a dose-escalation stage and a dose expansion stage, the latter of which may confirm tolerability at the recommended dose for expansion in future clinical trials (as in traditional Phase 1 clinical trials) and provide insight into the anti-tumor effects of the investigational therapy in selected subpopulation(s).

Typically, during the development of oncology therapies, all subjects enrolled in Phase 1 clinical trials are disease-affected patients and, as a result, considerably more information on clinical activity may be collected during such trials than during Phase 1 clinical trials for non-oncology therapies. A single Phase 3 or Phase 2 trial with other confirmatory evidence may be sufficient in rare instances to provide substantial evidence of effectiveness (generally subject to the requirement of additional post-approval studies).

Phase 1, Phase 2, Phase 3 and other types of clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including non-compliance with regulatory requirements or a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can

suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the investigational medicines do not undergo unacceptable deterioration over their shelf life.

FDA Review Process

Following completion of the clinical trials, the results of preclinical studies and clinical trials are submitted to the FDA as part of a BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic or drug may be marketed in the United States. The cost of preparing and submitting a BLA is substantial. Under the PDUFA, each BLA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved BLA is also subject to an annual program fee.

The FDA reviews all submitted BLAs before it accepts them for filing and may request additional information. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of an original BLA for a new molecular entity and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process can be extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

The FDA also may audit data from clinical trials to ensure compliance with GCP requirements and the integrity of the data supporting safety and efficacy. Additionally, the FDA may refer applications

for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it generally follows such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process.

After the FDA evaluates a BLA, it will issue either an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter generally outlines the deficiencies in the BLA and may require additional clinical data, additional pivotal clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing in order for FDA to reconsider the application. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. The FDA has committed to reviewing such resubmissions in two or six months, depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

As a condition of BLA approval, the FDA may require a REMS to help ensure that the benefits of the biologic outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals and elements to assure a product's safe use (ETASU). An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation on its own does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication. In the latter case, because healthcare

professionals are free to prescribe products for off-label uses, the competitor's product could be used for the orphan indication despite another product's orphan exclusivity.

FDA's determination of whether two ADCs are the same product for purposes of orphan drug exclusivity is based on a determination of sameness of the monoclonal antibody element and the functional element of the conjugated molecule. Two ADCs are deemed to be the same product if the complementarity determining region sequences of the antibody and the functional element of the conjugated molecule are the same. A difference in either of those two elements can result in a determination that the molecules are different.

Expedited Development and Review Programs

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition.

Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor of a new biologic candidate can request the FDA to designate the candidate for a specific indication for fast track status concurrent with, or after, the submission of the IND for the candidate. The FDA must determine if the biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's BLA before the application is complete. This "rolling review" is available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval.

Breakthrough therapy designation may be granted for products that are intended, alone or in combination with one or more other products, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new biologic candidate may request that the FDA designate the candidate for a specific indication as a breakthrough therapy concurrent with, or after, the submission of the IND for the biologic candidate. The FDA must determine if the biological product qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team and taking other steps to design the clinical studies in an efficient manner.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

Accelerated approval may be granted for products that are intended to treat a serious or life-threatening condition and that generally provide a meaningful therapeutic advantage to patients over

existing treatments. A product eligible for accelerated approval may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large studies to demonstrate a clinical or survival benefit. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval, but may expedite the development or approval process.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Pediatric Information

Under the Pediatric Research Equity Act (PREA), BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. PREA generally does not apply to any biological product for an indication for which orphan designation has been granted but does apply to BLAs for orphan-designated biologics if the biologic is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA has determined is substantially relevant to the growth or progression of a pediatric cancer.

The Best Pharmaceuticals for Children Act (the BPCA) provides a six-month extension of any exclusivity—patent or non-patent—for a biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new biologic in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Post-Approval Requirements

Once a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Biologics may be marketed only for the approved indications and in a manner consistent with the provisions of the 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.

Adverse event reporting and submission of periodic safety summary reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects a biologic product's manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with required regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of

unanticipated severity or frequency, or with manufacturing processes or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning or other enforcement-related letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act. The Hatch Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent term extension (PTE), however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The PTE period is generally one half the time between the effective date of an IND and the submission date of a BLA, plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for such an extension, only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any PTE or restoration. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, we or our licensors may apply for PTE for our owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA. However, an extension might not be granted because of, for example, our or our licensors' failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines, failure to apply prior to expiration of relevant patents or any other failure to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested. There is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether any extensions should be granted, and if granted, the length of such extensions.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009 (the BPCIA) created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be

biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency.

The BPCIA is complex and only recently implemented by the FDA. Recent government proposals have sought to reduce the twelve-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to significant uncertainty.

Regulatory Approval in the European Union

The EMA is a decentralized scientific agency of the European Union. It coordinates the evaluation and monitoring of centrally authorized medicinal products. It is responsible for the scientific evaluation of applications for EU marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors. The EMA decentralizes its scientific assessment of medicines by working through a network of about 4,500 experts throughout the European Union, nominated by the member states. The EMA draws on resources of over 40 National Competent Authorities of European Union member states.

The process regarding approval of medicinal products in the European Union follows roughly the same lines as in the United States and likewise generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU Good Laboratory Practice regulations;
- submission to the relevant national authorities of a clinical trial application (CTA) for each trial in humans, which must be approved before the trial may begin in each country where patient enrollment is planned;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced cGMP;

- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical Studies

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the quality and potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant international, EU and national legislation, regulations and guidelines. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

Clinical Trials

Pursuant to the Clinical Trials Directive 2001/20/EC, as amended (the Clinical Trials Directive), a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, approval must be obtained from the competent national authority of each European Union member state in which a clinical trial is planned to be conducted. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier and further supporting information prescribed by the Clinical Trials Directive and other applicable guidance documents including but not being limited to the clinical trial protocol. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

Directive 2001/20/EC will be replaced by Regulation (EU) No. 536/2014, which entered into force on June 16, 2014 and is due to fully apply from late 2021. The Regulation introduces an authorization procedure based on a single submission via a single EU portal, an assessment procedure leading to a single decision, as well as transparency requirements (the proactive publication of clinical trial data in the EU database). Since October 2016, based on its Policy 0070, the EMA has been publishing clinical data submitted by pharmaceutical companies to support their MAA for human medicines under this centralized procedure.

Manufacturing and import into the EU of investigational medicinal products is subject to the holding of appropriate authorizations and must be carried out in accordance with cGMP.

Review and Approval

Authorization to market a product in the European Union member states proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure. Since our products by their virtue of being antibody-based biologics fall under the centralized procedure, only this procedure will be described here.

Certain drugs, including medicinal products developed by means of biotechnological processes, must be approved via the centralized authorization procedure for marketing authorization. A successful application under the centralized authorization procedure results in a marketing authorization from the European Commission, which is automatically valid in all European Union member states. The other European Economic Area member states (namely Norway, Iceland and Liechtenstein) are also obligated to recognize the European Commission decision. The EMA and the European Commission administer the centralized authorization procedure.

Under the centralized authorization procedure, the Committee for Medicinal Products for Human Use (the CHMP), serves as the scientific committee that renders opinions about the safety, efficacy and quality of human products on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national drug authority, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the CHMP acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP is required to issue an opinion within 210 days of receipt of a valid application, though the clock is stopped if it is necessary to ask the applicant for clarification or further supporting data. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. Once the procedure is completed, a European Public Assessment Report is produced. If the CHMP concludes that the quality, safety and efficacy of the medicinal product is sufficiently proven, it adopts a positive opinion. The CHMP's opinion is sent to the European Commission, which uses the opinion as the basis for its decision whether or not to grant a marketing authorization. If the opinion is negative, information is given as to the grounds on which this conclusion was reached.

After a drug has been authorized and launched, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review. Sanctions may be imposed for failure to adhere to the conditions of the marketing authorization. In extreme cases, the authorization may be revoked, resulting in withdrawal of the product from sale.

Conditional Approval and Accelerated Assessment

As per Article 14(7) of Regulation (EC) 726/2004, a medicine that would fulfill an unmet medical need may, if its immediate availability is in the interest of public health, be granted a conditional marketing authorization on the basis of less complete clinical data than are normally required, subject to specific obligations being imposed on the authorization holder. These specific obligations are to be reviewed annually by the EMA. The list of these obligations shall be made publicly accessible. Such an authorization shall be valid for 12 months, on a renewable basis.

When an application is submitted for a marketing authorization in respect of a drug for human use which is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure pursuant to Article 14(9) of Regulation (EC) 726/2004. Under the accelerated assessment procedure, the CHMP is required to issue an opinion within 150 days of receipt of a valid application, subject to clock stops. We believe that some of the disease indications in which our product candidates are currently being or may be developed in the future qualify for this provision, and we will take advantage of this provision as appropriate.

Period of Authorization and Renewals

A marketing authorization is initially valid for five years and may then be renewed on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder shall provide the EMA or the competent authority with a version of the file in respect of quality, safety and efficacy, including all variants introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization shall be valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization shall cease to be valid (the so-called "sunset clause").

Without prejudice to the law on the protection of industrial and commercial property, marketing authorizations for new medicinal products benefit from an 8+2+1 year period of regulatory protection. This regime consists of a regulatory data protection period of eight years plus a concurrent market exclusivity of 10 years plus an additional market exclusivity of one further year if, during the first eight years of those 10 years, the marketing approval holder obtains an approval for one or more new therapeutic indications which, during the scientific evaluation prior to their approval, are determined to bring a significant clinical benefit in comparison with existing therapies. Under the current rules, a third party may reference the preclinical and clinical data of the reference product beginning eight years after first approval, but the third party may market a generic version of the reference product after only 10 (or 11) years have lapsed.

Orphan Drug Designation

Regulation (EC) 141/2000 states that a drug shall be designated as an orphan drug if its sponsor can establish (i) that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment; and (ii) that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation (EC) 847/2000 sets out criteria for the designation of orphan drugs. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a 10-year period of market exclusivity, which means that no similar medicinal product can be authorized in the same indication. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify continued market exclusivity. In addition, derogation from market exclusivity may be granted on an individual basis in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product or demonstration of “clinically relevant superiority” by a similar medicinal product. Medicinal products designated as orphan drugs pursuant to Regulation (EC) 141/2000 are eligible for incentives made available by the European Union and by the member states to support research into, and the development and availability of, orphan drugs.

If the MAA of a medicinal product designated as an orphan drug pursuant to Regulation (EC) 141/2000 includes the results of all studies conducted in compliance with an agreed PIP, and a corresponding statement is subsequently included in the marketing authorization granted, the 10-year period of market exclusivity will be extended to 12 years.

Data Privacy and Security Laws

Numerous state, federal and foreign laws govern the collection, dissemination, use, access to, confidentiality and security of health-related information. In the United States, numerous federal and state laws and regulations, including the federal Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal

information could apply to our operations or the operations of our partners. State laws may be more stringent, broader in scope or offer greater individual rights with respect to protected health information (PHI) than HIPAA, and state laws may differ from each other, which may complicate compliance efforts. Entities that are found to be in violation of HIPAA, as the result of a breach of unsecured PHI, a complaint about privacy practices, an audit by the U.S. Department of Health and Human Services (HHS), or other instances of non-compliance, may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

Even when HIPAA does not apply, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. For example, California enacted the CCPA, on June 28, 2018, which went into effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. 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.

Further, the collection, transfer, processing and other use of personal data, including health data of individuals within the EEA and the United Kingdom, is governed by the GDPR, which came into effect in May 2018. The GDPR imposes strict requirements on controllers and processors of personal data of individuals within the EEA and the United Kingdom, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, 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. The GDPR prohibits the transfer of personal data to countries outside the EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA member states and the United Kingdom may result in substantial fines and other administrative penalties. The GDPR and related data protection laws may impose additional responsibility and liability in relation to personal data that we collect and process and we may be required to put in place additional mechanisms ensuring compliance with such rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

Marketing

Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union member states, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians and other healthcare professionals in certain European Union member states must be publicly disclosed. Moreover, agreements with physicians and other healthcare professionals often must be the subject of prior notification and approval by the relevant individual's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

International Regulation

In addition to regulations in the United States and Europe, a variety of foreign regulations govern clinical trials, commercial sales and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA or European Commission approval.

Other Healthcare Laws and Regulations and Legislative Reform

Healthcare and Privacy Laws and Regulations

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our operations, including any arrangements with healthcare providers, physicians, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. Our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to CMS, HHS (including the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice (DOJ) and individual U.S. Attorney offices within the DOJ, and state and local governments. The healthcare laws that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, 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, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection.
- Federal civil and criminal false claims laws, such as the FCA, which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the FCA in connection with

their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims.

- HIPAA, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, as amended by HITECH, 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.
- Federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- The federal transparency requirements under the Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act (the Affordable Care Act), which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician’s immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners.
- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- State and foreign laws that are analogous to each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers, and state laws that require manufacturers to report information related to

payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

- State and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare providers; state laws that require the reporting of marketing expenditures or drug pricing, including information pertaining to and justifying price increases; state and local laws that require the registration of pharmaceutical sales representatives; and state laws that prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals; state laws that require the posting of information relating to clinical trials and their outcomes.

Legislative Reform

We operate in a highly regulated industry, and new laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, related to healthcare availability, the method of delivery and payment for healthcare products and services could negatively affect our business, financial condition and prospects. There is significant interest in promoting healthcare reforms, and it is likely that federal and state legislatures within the United States and the governments of other countries will continue to consider changes to existing healthcare legislation.

For example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In 2010, the U.S. Congress enacted the Affordable Care Act, which included changes to the coverage and reimbursement of drug products under government healthcare programs such as:

- increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program;
- established a branded prescription drug fee that pharmaceutical manufacturers of certain branded prescription drugs must pay to the federal government;
- expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program;
- established a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- established a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- created a licensure framework for follow-on biologic products.

There have been executive, judicial and congressional challenges to certain aspects of the Affordable Care Act. For example, in 2017, the U.S. Congress enacted legislation informally titled the Tax Cuts and Jobs Act (the Tax Act), which eliminated the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, the U.S. District Court for the Northern District of Texas held that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed by the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the Affordable Care Act, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs 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 unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the Affordable Care Act. It is difficult to predict the future legislative landscape in healthcare and the effect on our business, results of operations, financial condition and prospects.

In addition, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. In 2011, the U.S. Congress enacted the Budget Control Act, which included provisions intended to reduce the federal deficit. The Budget Control Act resulted in the imposition of 2% reductions in Medicare payments to providers beginning in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, absent additional Congressional action. In addition, in 2012, the U.S. Congress enacted the American Taxpayer Relief Act, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If government spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA, to continue to function at current levels, which may impact the ability of relevant agencies to timely review and approve research and development, manufacturing and marketing activities, which may delay our ability to develop, market and sell any product candidates we may develop. Moreover, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our anticipated product revenues.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several congressional

inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. At the federal level, the 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 pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic.

Environmental, Health and Safety Laws and Regulations

We and our third-party contractors are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In particular, our product candidates use PBDs, which are highly potent cytotoxins that require special handling by our and our contractors' staff. In the event of contamination or injury, or failure to comply with environmental, health and safety laws and regulations, we could be held liable for any resulting damages, fines and penalties associated with such liability could exceed our assets and resources. Environmental, health and safety laws and regulations are becoming increasingly more stringent. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations.

Pharmaceutical Coverage, Pricing and Reimbursement

The availability and extent of coverage and adequate reimbursement by governmental and private third-party payors are essential for most patients to be able to afford expensive medical

treatments. In both domestic and foreign markets, sales of our product candidates will depend substantially on the extent to which the costs of our product candidates will be covered by third-party payors, such as government health programs, commercial insurance, and managed healthcare organizations. These third-party payors decide which products will be covered and establish reimbursement levels for those products.

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.

Obtaining coverage approval and reimbursement for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost- effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement at a satisfactory level. If coverage and adequate reimbursement of our future products, if any, are unavailable or limited in scope or amount, such as may result where alternative or generic treatments are available, we may be unable to achieve or sustain profitability. Adverse coverage and reimbursement limitations may hinder our ability to recoup our investment in our product candidates, even if such product candidates obtain regulatory approval. 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 products. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. There is no uniform policy for coverage and reimbursement in the United States and, as a result, coverage and reimbursement can differ significantly from payor to payor. In the United States, private payors often, but not always, follow Medicare coverage and reimbursement policies with respect to newly approved products. It is difficult to predict what third- party payors will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Further, one payor's determination to provide coverage and adequate reimbursement for a product does not assure that other payors will also provide coverage and adequate reimbursement for that product. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates. There can be no assurance that our product candidates will be considered medically necessary or cost-effective. In addition to third-party payors, professional organizations and patient advocacy groups such as the National Comprehensive Cancer Network and the American Society of Clinical Oncology can influence decisions about reimbursement for new medicines by determining standards for care. Therefore, it is possible that any of our product candidates, even if approved, may not be covered by third-party payors or the reimbursement limit may be so restrictive that we cannot commercialize the product candidates profitably.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or

biological products, will apply to companion diagnostics. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for our product candidates, if approved.

Reimbursement agencies in Europe may be more restrictive than payors in the United States. For example, a number of cancer products have been approved for reimbursement in the United States but not in certain European countries. In Europe, pricing and reimbursement schemes vary widely from country to country. For example, some countries provide that products may be marketed only after an agreement on reimbursement price has been reached. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Other countries require the completion of additional health technology assessments that compare the cost-effectiveness of a particular product candidate to currently available therapies. Within the European Union legislation relating to and regulation of the reimbursement of medicinal products, and to control the prices of such products, is a matter for individual member states. European Union member states may approve a specific price for a product, may adopt a system of direct or indirect controls on the profitability of the company placing the product on the market or monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. Furthermore, many countries in the European Union have increased the amount of discounts required on pharmaceutical products, and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, and prescription products in particular, has become increasingly intense. As a result, there are increasingly higher barriers to entry for new products. There can be no assurance that any country that has reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. Accordingly, the reimbursement for any products in Europe may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Furthermore, the containment of healthcare costs has become a priority of foreign and domestic governments as well as private third-party payors. The prices of drugs have been a focus in this effort. Governments and private third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. We also expect to experience pricing pressures due to the trend towards managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. These and other cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower-than-anticipated product revenues. In addition, the publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if coverage and adequate reimbursement of our products is unavailable or limited in scope or amount, our revenues and the potential profitability of our product candidates in those countries would be negatively affected.

Corporate Information

We were incorporated under the laws of the State of Delaware on January 4, 2016. Our principal executive offices are located at 500 Fairview Ave N, Suite 600, Seattle, Washington 98109, and our telephone number is (206) 456-2900. Our corporate website address is www.silverbacktx.com.

Information contained on, or accessible through, our website shall not be deemed incorporated into and is not a part of this Annual Report on Form 10-K. We have included our website in this Annual Report on Form 10-K solely as an inactive textual reference.

“Silverback Therapeutics,” “Silverback,” the Silverback logo, “ImmunoTAC,” and other trademarks, trade names or service marks of Silverback Therapeutics, Inc. appearing in this Annual Report on Form 10-K are the property of Silverback Therapeutics, Inc. All other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.

Employees and Human Capital Resources

As of December 31, 2020, we had 54 full-time employees. Of these employees, 20 held Ph.D., Pharm.D. or M.D. degrees, and 43 were engaged in research, development and technical operations. As of such date, we had 51 employees based at our headquarters in Seattle, Washington. Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

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 Annual Report on Form 10-K 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.

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 years ended December 31, 2020 and 2019, our net losses were $32.9 million and $24.0 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, have 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.

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 December 31, 2020, we had $386.6 million in cash and cash equivalents. Based upon our current operating plan, we estimate that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 24 months. However, we believe that our existing cash and cash equivalents 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, 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.

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 potentially grants, 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 potentially grants, 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. Additional debt financing, if available, may involve agreements that include covenants further limiting or restricting our ability to take specific actions beyond those contained in our existing loan agreement, 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 terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

As of December 31, 2020, we had an outstanding term loan including principal and final payment fee of $0.8 million under our loan and security agreement, as amended, with Silicon Valley Bank (SVB). The loan is secured by a lien covering substantially all of our personal property, rights and assets, excluding intellectual property. The loan agreement contains customary affirmative and negative covenants and events of default applicable to us and any subsidiaries. The affirmative covenants include, among others, covenants requiring us (and us to cause our subsidiaries, if any) to maintain governmental approvals, deliver certain financial reports, maintain insurance coverage, and protect material intellectual property. The negative covenants include, among others, restrictions on us and our subsidiaries transferring collateral, changing our business, engaging in mergers or acquisitions, incurring additional indebtedness, paying cash dividends or making other distributions, making investments, creating liens, selling assets and making any payment on subordinated debt, in each case subject to certain exceptions. The restrictive covenants of the loan agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial. In addition, SVB could declare a default upon the occurrence of any event that it interprets as a material adverse change as defined under the loan agreement. If we default under the loan agreement, SVB may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, SVB's right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Any declaration by SVB of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

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 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 immuno-oncology agents, monoclonal antibodies or other protein-based drugs or small molecule anti-cancer agent 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. 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 Australia 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 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 ADA 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, undesirable side effects or other unexpected properties of our product candidates may be identified 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, serious adverse events (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, a significant risk observed with systemic administration of motolimod, an unconjugated TLR8 small molecule agonist, was the induction of significant injection site reactions (ISR), and cytokine-induced flu-like symptoms that prevented dose-escalation. Should we observe severe cases of ISR and cytokine release syndrome 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 anti-drug antibodies (ADA) could develop that neutralize the effects of SBT6050 by reducing exposure. The development of ADA could also trigger hypersensitivity reactions that manifest as serious adverse events. For example, as has been described with other immune agonists administered in the presence of ADA 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 (AEs), 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 ADA 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. 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 serious adverse events 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 serious adverse events 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 risk evaluation and mitigation strategy, or 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 test 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, 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. 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 manufacturing 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, 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, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

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 Industry and Business Operations

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 Unites 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 stop further enrollment of new patients in clinical trials, denied access to site monitors 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.

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. 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 December 31, 2020, we had 56 employees which represents an increase of 33 employees since January 1, 2019. 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 Apros Therapeutics, Ascendis, BioNTech, Bolt Biotherapeutics, Bristol Myers Squibb, Checkmate Pharmaceuticals, CureVac, Exicure, Galaderma, Gilead, Idera, Mologen, Nektar, Novartis, Primmune Therapeutics, Roche, Seven&Eight, Shanghai De Novo, Sumitomo Dainippon, 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, Genentech, MacroGenics, Pieris, Puma, Seagen (formerly Seattle Genetics), 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, Celldex, CytomX, Eli Lilly and Company, GlaxoSmithKline, Genmab, ImmunoGen, Immunomedics, Millennium Pharmaceuticals, MorphoSys AG, Novartis, Pfizer, Sanofi, Seagen (formerly Seattle Genetics), Sutro Biopharma, and VelosBio.

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 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 (the Code), 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 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 and the Physician Payments Sunshine Act and 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 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. federal legislation commonly referred to as 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. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the Affordable Care Act, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs 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 unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the Affordable Care Act. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on 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 March 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 pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives.

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.

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.

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.

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 Leathy-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. If such securities litigation were instituted against us, it 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 February 28, 2021, we had 34,894,423 outstanding shares of our common stock. Of these shares, approximately 13.1 million shares are freely tradable and substantially all of the remaining shares of common stock will be available for sale in the public market beginning in June 2021 following the scheduled expiration of lock-up agreements that certain of our stockholders and the underwriters entered into in connection with our initial public offering.

Goldman Sachs & Co. LLC, SVB Leerink LLC and Stifel, Nicolaus & Company, Incorporated may release these stockholders from their lock-up agreements with the underwriters at any time and without notice, which would allow for earlier sales of shares in the public market.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

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, starting on January 1, 2021 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 public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or 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 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. If we face such litigation, it 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 last day of the fiscal year in 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.

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 of 1933, as amended (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

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 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.

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.

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.

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.

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 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 throughout the world and on all of our product candidates 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.

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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters is located in Seattle, Washington, where we lease approximately 19,829 square feet of office, laboratory and storage space pursuant to a lease agreement that commenced on November 1, 2016 and expires on October 31, 2026. We believe that our existing facilities are adequate for the foreseeable future. As we expand, we believe that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been listed on the Nasdaq Global Market under the symbol "SBTX" since December 4, 2020. Prior to that date, there was no public market for our common stock.

Holders of Common Stock

As of February 28, 2021, there were 34,894,423 shares of common stock issued and held by approximately 61 stockholders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Securities

During the year ended December 31, 2020, we issued and sold the following unregistered securities:

(1) In March 2020, we entered into a Series B Preferred Stock Purchase Agreement with various investors, pursuant to which we issued and sold to such investors an aggregate of 10,027,666 shares of our Series B redeemable convertible preferred stock at a purchase price of $2.16 per share, and received gross proceeds of $21.5 million and 4,673,388 shares upon conversion of then outstanding convertible notes.

(2) In July 2020, pursuant to the March 2020 Series B Preferred Stock Purchase Agreement with various investors, we issued and sold to such investors an aggregate of 10,669,834 shares of our Series B redeemable convertible preferred stock at a purchase price of $2.16 per share, and received gross proceeds of $23.0 million.

(3) In September 2020, pursuant to the March 2020 Series B Preferred Stock Purchase Agreement with various investors, we issued and sold to such investors an aggregate of 11,063,028 shares of our Series B redeemable convertible preferred stock at a purchase price of $2.16 per share, and received gross proceeds of $23.9 million.

(4) In September 2020, we entered into a Series C Preferred Stock Purchase Agreement with various investors, pursuant to which we issued and sold to such investors an aggregate of 24,926,685 shares of our Series C redeemable convertible preferred stock at a purchase price of $3.41 per share, and received gross proceeds of $84.9 million.

(5) From January 1, 2020 through December 2, 2020, which is the day before we priced our initial public offering, we granted stock options to purchase an aggregate of 3,213,541 shares of our common stock at a weighted average exercise price of $3.67 per share, to certain of our employees and directors in connection with services provided to us by such persons. Of these, 131,266 options have been exercised and 5,772 options have been cancelled through December 31, 2020.

The issuance of securities described above in paragraphs (1) through (4) were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) (or Regulation D promulgated thereunder) in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D. No underwriters were involved in these transactions.

The issuance of securities described above in paragraph (5) was deemed to be exempt from registration under the Securities Act in reliance on either Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or Section 4(a)(2) in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of such securities were our employees and directors and received the securities under our 2016 Equity Incentive Plan.

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 IPO were held in cash and cash equivalents, primarily in treasury money market accounts. Through December 31, 2020, we have not used any 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.

Issuer Purchases of Equity Securities

Not applicable.

Item 6. Selected Financial Data.

Not applicable.

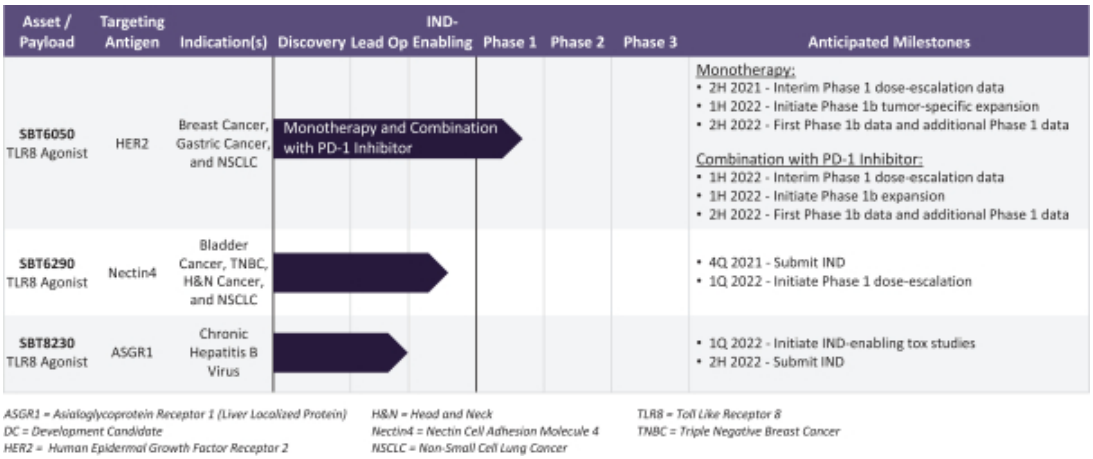
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis together with our financial statements and related notes included in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. For a complete discussion of forward-looking statements, see the section above entitled "Forward Looking Statements." Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption "Item 1A. Risk Factors."

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 immuno-oncology 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 tumors such as certain breast, gastric and non-small cell lung cancers. SBT6050 is currently 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 this trial, we have observed changes in pharmacodynamic markers in the first dose cohort, and we anticipate providing an update on interim data from the Phase 1 single agent dose-escalation cohorts in the second half of 2021. SBT6290 is our second product candidate, expanding 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 anticipate submitting an investigational new drug application for SBT6290 in the fourth quarter of 2021. Our third TLR8 program, SBT8230, is comprised of a TLR8 linker-payload conjugated to an ASGR1 monoclonal antibody that is under development for the treatment of cHBV. 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 December 31, 2020, we had an accumulated deficit of $96.7 million. Our net losses were $32.9 million and $24.0 million for the years ended December 31, 2020 and 2019, 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 public or private equity offerings, debt financings, collaborations and licensing arrangements or other capital sources.

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.

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 Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		Dollar Change	% Change
	2020	2019		
	(in thousands)			
Operating expenses:				
Research and development	$ 24,577	$ 21,505	$ 3,072	14%
General and administrative	8,341	2,562	5,779	*
Total operating expenses	32,918	24,067	8,851	37
Loss from operations	(32,918)	(24,067)	(8,851)	37
Interest income (expense), net	(29)	100	(129)	(129)
Net loss and comprehensive loss	$(32,947)	$(23,967)	$(8,980)	37%

* *Not meaningful*

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		Dollar Change	% Change
	2020	2019		
	(in thousands)			
Direct costs:				
SBT6050	$ 4,710	$ 8,723	$(4,013)	(46)%
Preclinical programs	6,108	2,297	3,811	166
Total direct costs	10,818	11,020	(202)	(2)
Indirect costs:				
Personnel-related expenses, including stock-based compensation	9,657	6,571	3,086	47
Facility and equipment related expenses	2,426	2,250	176	8
Other unallocated research and development expenses	1,676	1,664	12	1
Total research and development expenses	$24,577	$21,505	$ 3,180	14%

Research and development expenses were $24.6 million and $21.5 million for the years ended December 31, 2020 and 2019, respectively. The increase of $3.2 million was due primarily to an increase in preclinical programs of $3.8 million as we began advancing certain pipeline programs, including SBT6290 and SBT8230, into preclinical development. The increase was also due to increases in personnel-related expenses of $3.1 million, and facility and equipment related expenses of $0.2 million. These increases were partially offset by a decrease of $4.0 million in research and manufacturing expenses related to the development of SBT6050 as the program completed manufacturing activities and initiated a Phase 1/1b clinical trial in the second half of 2020.

General and Administrative Expenses

General and administrative expenses were $8.3 million and $2.6 million for the years ended December 31, 2020 and 2019, respectively. The increase of $5.8 million was due primarily to an increase of $3.9 million in personnel-related expenses due to increased headcount in 2020, including new executives, as well as increases in salaries, bonuses, and stock-based compensation. To a lesser extent, the increase in general and administrative expenses was due to an increase in legal fees of $0.8 million, professional fees of $0.7 million, and $0.4 million in other various general and administrative expenses as we prepared to become a public company.

Interest Income (Expense), Net

Interest income (expense), net was ($29,000) and $0.1 million for the years ended December 31, 2020 and 2019, respectively. The change of $0.1 million was primarily due to a decrease in interest earned on our cash and cash equivalents due to changes in interest rates.

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 debt financings. We will need to raise substantial

additional capital in the future. In 2020, we raised net proceeds, after deducting underwriting discounts and commissions and offering costs, of $255.3 million from our initial public offering in December 2020 and net proceeds of $153.3 million from the sale of our redeemable convertible preferred stock in March, July, and September 2020.

As of December 31, 2020, we had $386.6 million in cash and cash equivalents. The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (31,196)	$(18,898)
Investing activities	(917)	(96)
Financing activities	408,506	8,610
Net increase (decrease) in cash, cash equivalents, and restricted cash	$376,393	$(10,384)

Operating Activities

During the year ended December 31, 2020, net cash used in operating activities was $31.2 million. This consisted primarily of a net loss of $32.9 million and an increase in our operating assets and liabilities of $2.6 million, partially offset by non-cash charges of $4.4 million. The non-cash charges primarily consisted of stock-based compensation expense of $2.6 million, non-cash lease expense of $1.1 million, and depreciation expense of $0.6 million. The increase in our operating assets and liabilities was primarily due to an increase in prepaid expenses and other assets of $3.5 million and a decrease in our lease liability of $0.9 million, partially offset by an increase in accounts payable and accrued expenses of $1.8 million after adjusting for non-cash items. The increase in prepaid expenses and other assets was primarily due to the purchase of $2.6 million in prepaid insurance.

During the year ended December 31, 2019, net cash used in operating activities was $18.9 million. This consisted primarily of a net loss of $24.0 million, partially offset by a decrease in our operating assets and liabilities of $3.3 million and non-cash charges of $1.8 million. The non-cash charges primarily consisted of non-cash lease expense of $1.0 million, depreciation expense of $0.5 million, stock-based compensation expense of $0.2 million, and amortization of debt issuance costs of $0.1 million. The decrease in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses of $4.0 million and a decrease in prepaid expenses and other assets of $0.1 million, partially offset by a decrease in our lease liability of $0.8 million.

Investing Activities

During the year ended December 31, 2020, cash used in investing activities was $0.9 million due to purchases of property and equipment.

During the year ended December 31, 2019, cash used in investing activities was $0.1 million due to purchases of property and equipment.

Financing Activities

During the year ended December 31, 2020, cash provided by financing activities was $408.5 million. This consisted primarily of net proceeds received from the issuance of our common

stock in connection with our initial public offering of $255.7 million, 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 term loan payable of $0.7 million.

During the year ended December 31, 2019, cash provided by financing activities was $8.6 million. This consisted primarily of net proceeds received from the issuance of our convertible notes of $10.0 million, which was partially offset by principal payments on term loan payable of $1.4 million.

Future Funding Requirements

We believe that our cash and cash equivalents of $386.6 million at December 31, 2020 will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 24 months. 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, 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 public or private equity offerings, debt financings, or other capital sources which may include strategic collaborations, licensing arrangements or other arrangements with third parties. 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

The following table summarizes our contractual obligations and commitments at December 31, 2020:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations[1]	$3,586	$ 1,132	$2,454	$ —	$ —
Term loan payable[1][2]	848	848	—	—	—
Total	$4,434	$ 1,980	$2,454	$ —	$ —

(1) Refer to Notes 6 and 7 to our financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

(2) Payments due for the term loan include both principal and interest portions calculated using the interest rate at December 31, 2020 of 1.75%.

Under our license agreements, we have payment obligations that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and are required to make royalty payments in connection with the sales of products developed under those agreements. As of December 31, 2020 and 2019, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales and, therefore, any related payments are not included in the table above. For additional details regarding these agreements, see Part I, Item 1 of this Annual Report on Form 10-K under the section titled “License Agreement”.

In November 2016, we entered into a loan and security agreement with SVB that allowed borrowings up to $5.0 million in two tranches, the first that was immediately drawn and the second to be drawn before December 31, 2017 if certain financing milestones were met. We drew $3.5 million in the first tranche, and the second tranche expired undrawn. The outstanding principal amount of the term loan accrues interest at an annual rate of 1.75% per annum. At closing, we 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 our term loan is 5.14%. In April 2020, SVB amended our term loan to defer principal payments for six months and extend the maturity date to May 1, 2021, which we determined to be a debt modification.

In October 2019, we entered into a cell line license agreement with WuXi Biologics (Hong Kong) Limited (WuXi Bio), pursuant to which we received a non-exclusive, worldwide, sublicensable license under certain of WuXi Bio’s intellectual property rights, know-how and biological materials (the WuXi Bio Licensed Technology) to make, use, sell, offer for sale and import developed through the use of the WuXi Bio Licensed Technology (the WuXi Bio Licensed Product). In consideration for the license, we paid a license fee of $100,000 to WuXi Bio which was recorded in research and development expense in 2019. In 2020 we incurred an additional license fee of $50,000 to WuXi Bio which was recorded in research and development expense in 2020. Additionally, if we do not engage WuXi Bio to manufacture the WuXi Bio Licensed Products for our clinical and commercial supplies, we are required to make aggregate milestone payments of up to $10.8 million to WuXi Bio upon the achievement of certain sales milestones. To date, other than the license fee, no payments have been made under this agreement.

We enter into contracts in the normal course of business with clinical supply manufacturers and with vendors for preclinical studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included in the table above.

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.

While our significant accounting policies are described in more detail in Note 2 to our audited financial statements appearing in Part II, Item 8 of this Annual Report on Form 10-K, we believe the following accounting policies and estimates to be most critical to the preparation of our financial statements.

Research and Development Expenses

All research and development costs are expensed in the period incurred. 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 we do not expect the goods to be delivered or services to be performed. We estimate 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, we will adjust the amounts recorded accordingly. We have not experienced any material differences between accrued or prepaid costs and actual costs since our inception.

Stock-Based Compensation

We recognize stock-based compensation expense for stock options on a straight-line basis over the requisite service period and account for forfeitures as a reduction of stock-based compensation expense as they occur. Our stock-based compensation costs are based upon the grant date fair value of options estimated using the Black-Scholes option pricing model.

The Black-Scholes option pricing model utilizes inputs which are highly subjective assumptions and generally require significant judgment. These assumptions include:

- *Fair Value of Common Stock*. For all periods prior to our initial public offering, the fair value of the shares of common stock underlying our share-based awards was estimated on each grant date by our board of directors. To determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, input from management, valuations of our common stock prepared by unrelated third-party valuation firms in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the Practice Aid). Following the closing of our initial public offering, the fair market value of our common stock is based on its closing price as reported on the primary stock exchange on which our common stock is traded.
- *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 we have concluded that our stock option exercise history does not provide a reasonable basis upon which to estimate expected term.
- *Expected Volatility*. Given our limited historical stock price volatility data, we derived the expected volatility from the average historical volatilities over a period approximately equal to the expected term of comparable publicly traded companies within our peer group that were deemed to be representative of future stock price trends as we have limited trading history for our common stock. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

- *Risk-Free Interest Rate*. The risk-free interest rate is based on the U.S. Treasury zero-coupon issues in effect at the time of grant for periods corresponding with the expected term of the options.
- *Expected Dividend Yield*. We have never paid dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. Therefore, we used an expected dividend yield of zero.

Income Taxes

We recognize deferred income taxes for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. In evaluating our valuation allowance, we consider all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, and recent financial performance. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance.

As of December 31, 2020, we had net operating loss carryforwards for income tax purposes of approximately $89.7 million. If not used, $18.2 million of this carryforward will begin to expire in 2036 and $71.5 million has no expiration. We also have research and development tax credits of approximately $1.5 million which will begin to expire in 2037 if left unused.

Under Sections 382 and 383 of the Code, substantial changes in our ownership may limit the amount of NOL and research and development credit carryforwards that could be used annually in the future to offset taxable income. The tax benefits related to future utilization of federal and state NOL carryforwards, credit carryforwards, and other deferred tax assets may be limited or lost if cumulative changes in ownership exceeds 50% within any three-year period. We have not completed a Section 382/383 analysis under the Code regarding the limitation of NOL and credit carryforwards. If a change in ownership were to have occurred, the annual limitation may result in the expiration of NOL carryforwards and credits before utilization.

As of December 31, 2020, we did not have any liabilities for unrecognized income tax benefits associated with uncertain tax positions, including any interest and penalties.

Recent Accounting Pronouncements

See Note 2 to our audited financial statements appearing in Part II, Item 8 of this Annual Report on Form 10-K 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 last day of the fiscal year in 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.

Item 7A. 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.

Item 8. Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Silverback Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Silverback Therapeutics Inc. (the Company) as of December 31, 2020 and 2019, the related statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements'). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2020.

Seattle, Washington
March 29, 2021

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$386,569	$ 9,976
Prepaid expenses and other current assets	4,087	552
Total current assets	390,656	10,528
Property and equipment, net	1,618	1,316
Restricted cash	350	550
Right-of-use asset	2,180	3,253
Total assets	$394,804	$ 15,647
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,583	$ 3,518
Accrued expenses	5,278	2,112
Term loan payable, net	844	1,522
Convertible notes, net	—	9,991
Current portion of lease liability	896	783
Total current liabilities	9,601	17,926
Lease liability, net of current portion	2,326	3,324
Total liabilities	11,927	21,250
Commitments and contingencies (Note 12)		
Redeemable convertible preferred stock, $0.0001 par value per share; no shares and 17,142,854 shares authorized, no shares and 15,714,283 shares issued and outstanding with aggregate liquidation preference of $0 and $55,000 at December 31, 2020 and 2019, respectively	—	53,174
Stockholders' equity (deficit):		
Preferred Stock, $0.0001 par value per share; 10,000,000 and no shares authorized at December 31, 2020 and 2019, respectively; no shares issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, $0.0001 par value per share; 200,000,000 and 23,500,000 shares authorized, 34,801,537 and 670,477 shares issued, and 34,701,274 and 664,431 shares outstanding at December 31, 2020 and 2019, respectively	3	—
Additional paid-in capital	479,608	5,010
Accumulated deficit	(96,734)	(63,787)
Total stockholders' equity (deficit)	382,877	(58,777)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$394,804	$ 15,647

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

Silverback Therapeutics, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Years ended December 31,	
	2020	2019
Operating expenses:		
Research and development	$ 24,577	$ 21,505
General and administrative	8,341	2,562
Total operating expenses	32,918	24,067
Loss from operations	(32,918)	(24,067)
Interest income (expense), net	(29)	100
Net loss and comprehensive loss	$ (32,947)	$ (23,967)
Net loss per share applicable to common stockholders, basic and diluted	$ (11.33)	$ (36.27)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	2,907,542	660,893

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

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

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance as of December 31, 2018	15,714,283	$ 53,174	656,820	$ —	$ 4,843	$ (39,820)	$ (34,977)
Exercise of common stock options and vesting of early exercised common stock options	—	—	7,611	—	19	—	19
Stock-based compensation	—	—	—	—	148	—	148
Net loss and comprehensive loss	—	—	—	—	—	(23,967)	(23,967)
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	31,760,528	68,401	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock upon conversion of convertible notes	4,673,388	10,095	—	—	—	—	—
Issuance of Series C redeemable convertible preferred stock for cash, net of $53 in issuance costs	24,926,685	84,897	—	—	—	—	—
Redeemable convertible preferred stock converted into shares of common stock	(77,074,884)	(216,567)	20,758,098	2	216,565	—	216,567
Initial public offering of common stock, net of $22,386 in issuance costs	—	—	13,225,000	1	255,338	—	255,339
Exercise of common stock options and warrants and vesting of early exercised common stock options	—	—	53,745	—	55	—	55
Stock-based compensation	—	—	—	—	2,640	—	2,640
Net loss and comprehensive loss	—	—	—	—	—	(32,947)	(32,947)
Balance as of December 31, 2020	—	$ —	34,701,274	$ 3	$ 479,608	$ (96,734)	$ 382,877

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

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

	Year ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (32,947)	$(23,967)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	637	544
Amortization of debt issuance costs	31	75
Stock-based compensation expense	2,640	148
Non-cash lease expense	1,073	1,002
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,535)	66
Accounts payable and accrued expenses	1,790	4,014
Lease liability	(885)	(780)
Net cash used in operating activities	(31,196)	(18,898)
Cash flows from investing activities:		
Purchase of property and equipment	(917)	(96)
Net cash used in investing activities	(917)	(96)
Cash flows from financing activities:		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	153,351	—
Proceeds from issuance of common stock upon initial public offering, net of underwriting discounts and commissions	258,284	—
Payment of deferred offering costs	(2,606)	
Proceeds from issuance of convertible notes	—	10,000
Payment of convertible notes issuance costs		(9)
Principal payments on term loan payable	(700)	(1,400)
Proceeds from exercise of common stock options	177	19
Net cash (used in) provided by financing activities	408,506	8,610
Change in cash, cash equivalents, and restricted cash	376,393	(10,384)
Cash, cash equivalents, and restricted cash at beginning of period	10,526	20,910
Cash, cash equivalents, and restricted cash at end of period	$386,919	$ 10,526
Supplemental disclosure of cash flow information:		
Unpaid initial public offering costs included in accounts payable and accrued expenses	$ 339	$ —
Change in early exercise liability included in accounts payable and accrued expenses	$ 122	$ —
Issuance of Series B redeemable convertible preferred stock upon conversion of convertible notes	$ 10,095	$ —
Conversion of redeemable convertible preferred stock upon closing of initial public offering	$216,567	$ —

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

Silverback Therapeutics, Inc.

Notes to 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 us 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.

Reverse Stock Split

In November 2020, the Company's Board of Directors approved an amendment to the Company's certificate of incorporation to effect a reverse split of shares of the Company's common stock on a one-for-3.713 basis, which was effected on November 30, 2020 (the "Reverse Stock Split"). The number of authorized shares and the par values of the common stock and redeemable convertible preferred stock were not adjusted as a result of the Reverse Stock Split. In connection with the Reverse Stock Split, the conversion ratio for the Company's outstanding redeemable convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was decreased in proportion to the Reverse Stock Split. All references to common stock and options to purchase common stock share data, per share data, and related information contained in the financial statements have been retroactively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

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.

Silverback Therapeutics, Inc.

Notes to Financial Statements

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 $96.7 million as of December 31, 2020. The Company had cash and cash equivalents of $386.6 million as of December 31, 2020 and has not generated positive cash flows from operations. To date, the Company has been able to fund its operations primarily through the issuance of redeemable convertible preferred stock and convertible notes. During 2020, the Company has received an aggregate of $68.4 million in gross proceeds from the issuance of shares of its Series B redeemable convertible preferred stock and an aggregate of $84.9 million in gross proceeds from the issuance of shares of its Series C redeemable convertible preferred stock. In December 2020, the Company completed an initial public offering in which it sold 13,225,000 shares of common stock at $21.00 per share and received net proceeds, after underwriting discounts and offering costs, of $255.3 million. The Company's currently available cash and cash equivalents as of December 31, 2020 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 preclinical manufacturing, and clinical 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").

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, future expectations, 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.

Silverback Therapeutics, Inc.

Notes to Financial Statements

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.

Segments

The Company has determined that it operates and manages one operating segment, which is the business of developing and commercializing tissue targeted therapeutics. The Company's chief operating decision maker, its chief executive officer, reviews financial information on an aggregate basis for the purpose of allocating resources.

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. As of December 31, 2020 and 2019, 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 balance sheets that sum to the amounts shown in the statements of cash flows (in thousands):

	December 31,	
	2020	2019
Cash and cash equivalents	$ 386,569	$ 9,976
Restricted cash	350	550
Total cash and cash equivalents and restricted cash	$ 386,919	$ 10,526

Concentrations of Credit Risk

The Company is subject to credit risk from holding its cash and cash equivalents at one commercial bank. The Company limits its exposure to credit losses by investing in money market funds through a U.S. bank with high credit ratings. 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.

Silverback Therapeutics, Inc.

Notes to Financial Statements

Prepaid Expenses and Other Current Assets

Prepaid expenses consist primarily of operating expenses paid in advance.

Property and Equipment, Net

Property and equipment, net consists of furniture and fixtures and laboratory equipment and is stated at cost, less accumulated depreciation. Furniture and fixtures and laboratory equipment are depreciated over the estimated useful lives of the assets (each three to five years) using the straight-line method. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations in the period realized. Repairs and maintenance costs are charged to expense as incurred.

Leases

Leases consist of the Company's operating lease. 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. The operating lease ROU asset also includes any prepaid lease payments, lease incentives received, and costs which will be incurred in exiting a lease. The Company's lease includes options to extend or terminate the lease. Periods covered by an option to extend the 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 the lease are included in the lease term when it is reasonably certain that the Company will not exercise that option. At the inception of the lease and as of December 31, 2020, the Company was not reasonably certain that it will exercise its option to extend the lease and was not reasonably certain that it will not exercise its option to terminate the lease, therefore, the periods covered by the options are not included within the lease term. 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.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment and ROU assets. These assets are reviewed for impairment whenever facts or circumstances either internally or externally may suggest that the carrying value of an asset or asset group may not be recoverable. An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. The Company has not recognized any impairment losses through December 31, 2020.

Silverback Therapeutics, Inc.

Notes to Financial Statements

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. 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 use.

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.

General and Administrative Expenses

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. General and administrative costs are expensed as incurred.

Stock-Based Compensation

The Company has stock-based compensation plans that are described in Note 9. As of December 31, 2020, the Company had issued stock options and permitted eligible employees to participate in an employee stock purchase plan whereby shares of the Company's common stock may be purchased at a discount. Further discussion of the measurement and expense methodology related to these programs is described below:

Silverback Therapeutics, Inc.

Notes to Financial Statements

Stock Option Awards

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.

Employee Stock Purchase Plan

In December 2020, the Company's Employee Stock Purchase Plan ("ESPP") became effective, pursuant to which eligible employees can purchase shares of the Company's common stock at a discount to the fair market value at semi-annual intervals. In determining the grant date fair value of shares expected to be purchased under the ESPP, the Company uses the Black-Scholes option pricing model. Black-Scholes inputs are determined in the same manner as for stock option awards. The estimated grant date fair value of shares expected to be purchased is recognized into expense on a straight-line basis over the requisite service period.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company is more likely than not able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes in the period in which the adjustment is made.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on

the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability. The Company did not have any uncertain tax positions as of December 31, 2020 and 2019.

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's comprehensive loss was equal to net loss for the years ended December 31, 2020 and 2019.

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 Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted ASU 2018-13 on January 1, 2020 and the standard did not have a material impact on its financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes, eliminates certain

exceptions within ASC 740, *Income Taxes*, and clarifies certain aspects of the current guidance to promote consistency among reporting entities. The guidance is effective for fiscal years beginning after December 15, 2021, with early adoption permitted. The Company adopted ASU 2019-12 on January 1, 2020 and the standard did not have a material impact on its financial statements and related disclosures.

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. The Company's Level 1 assets consist of money market funds.

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 1	Level 2	Level 3
December 31, 2020			
Assets:			
Money market funds	$386,369	$ —	$ —
December 31, 2019			
Assets:			
Money market funds	$ 9,976	$ —	$ —

There were no transfers between the Level 1 and Level 2 categories or into or out of the Level 3 category during the years ended December 31, 2020 and 2019.

Silverback Therapeutics, Inc.

Notes to Financial Statements

4. Property and Equipment, Net

Property and equipment are summarized as follows (in thousands):

	December 31, 2020	December 31, 2019
Furniture and fixtures	$ 269	$ 156
Laboratory equipment	3,401	2,610
Property and equipment, gross	3,670	2,766
Less accumulated depreciation and amortization	(2,052)	(1,450)
Property and equipment, net	$ 1,618	$ 1,316

Depreciation and amortization expense was $0.6 million and $0.5 million for the years ended December 31, 2020 and 2019, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Research and development expenses	$ 2,063	$ 827
Employee compensation and benefits	2,634	1,024
Professional services and other	581	261
Total accrued expenses	$ 5,278	$ 2,112

6. Leases

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

	Year Ended December 31, 2020	Year Ended December 31, 2019
Lease expense		
Operating lease expense	$1,388	$1,388
Variable lease expense	386	334
Total lease expense	$1,774	$1,722
Operating cash outflows from operating leases	$1,591	$1,522

The remaining term on the Company's lease was 1.8 years and 2.8 years as of December 31, 2020 and 2019, respectively. To compute the present value of the lease liability, the Company used a discount rate of 8.5%.

Silverback Therapeutics, Inc.

Notes to Financial Statements

Future minimum commitments due under the operating lease agreement as of December 31, 2020 are as follows (in thousands):

Year Ending December 31,	Amount
2021	$1,132
2022	2,454
Thereafter	—
Total undiscounted lease payments	3,586
Present value adjustment	(364)
Total present value of lease payments	$3,222

7. Convertible Notes and Other Debt

Convertible Notes

In October 2019, the Company issued convertible promissory notes for proceeds of $10.0 million. The notes were unsecured, bore an interest rate of 3% per year, and had a maturity date of March 31, 2020. On March 4, 2020, these notes and accrued interest of $0.1 million converted into 4,673,388 shares of the Company's Series B redeemable convertible preferred stock at the Series B redeemable convertible preferred stock issuance price of $2.16 per share.

Term Loan Payable

In November 2016, the Company entered into a loan and security agreement with Silicon Valley Bank (SVB) that allowed borrowings up to $5.0 million in two tranches. $3.5 million was immediately drawn as a term loan by the Company. In conjunction with the term loan, SVB received a warrant to purchase 7,601 shares of the Company's common stock with an exercise price of $2.31 per share. The warrant was recorded as a discount to the loan and an increase in additional paid-in capital. In December 2020, the warrant was exercised in full.

Under the terms of the agreement, the Company was able to draw an additional $1.5 million through a second tranche before December 31, 2017 if it met certain financing milestones. SVB was eligible to receive an additional warrant contingent upon the Company's draw of this additional tranche. However, in December 2017, the Company amended the loan and security agreement to extend the second tranche draw window to March 31, 2018. This tranche expired undrawn. In exchange for the extension, SVB received an additional warrant to purchase 1,553 shares of the Company's common stock with an exercise price of $2.42 per share and, because the tranche expired undrawn, an unused term loan fee. Neither the additional warrant to purchase common stock or the unused term loan fee were material to the financial statements. In December 2020, the warrant was exercised in full.

The outstanding principal amount of the term loan accrues 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 is 5.14%. Interest expense under the term loan was not material to the financial statements for the year ended December 31, 2020 and totaled $0.1 million for the year ended December 31, 2019.

Silverback Therapeutics, Inc.

Notes to Financial Statements

The term loan is collateralized by the Company's tangible and intangible assets, excluding intellectual property. The proceeds are to be used as working capital and to fund general business requirements. The agreement includes customary nonfinancial covenants and events of default that include, among other things, non-payment, inaccuracy of representations and warranties, covenant breaches, cross default to material indebtedness or material agreements, bankruptcy and insolvency, material judgments, a change of control, or any material adverse event. The Company was in compliance with all related covenants as of December 31, 2020 and 2019. Given the existence of a subjective acceleration clause, all amounts due to SVB are classified as a current liability at December 31, 2020 and 2019, though SVB has not accelerated any amounts due under the debt agreement.

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 is amortizing the remaining debt discount over the remaining term.

8. Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

Authorized Shares

In connection with the completion of the Company's IPO in December 2020, the Company amended its Certificate of Incorporation to authorize 200,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

Redeemable Convertible Preferred Stock

Prior to its conversion to common stock, 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 years ended December 31, 2020 and 2019 as a deemed liquidation event was not considered probable.

The Company did not issue any redeemable convertible preferred stock during the year ended December 31, 2019. During the year ended December 31, 2020, the Company issued convertible preferred stock as follows:

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 provides that the Company will issue, and the Series B holders will 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 are achieved or the preferred majority approves their closing. The future 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.

Silverback Therapeutics, Inc.

Notes to Financial Statements

In July 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.

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.

Common Stock

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

	December 31,	
	2020	2019
Conversion of outstanding redeemable convertible preferred stock	—	4,232,232
Shares underlying outstanding equity awards	6,316,569	555,636
Shares available for future equity award grants	1,506,806	433,729
Shares underlying early exercised equity awards	100,263	6,046
Exercise of common stock warrants	—	9,154
Shares underlying ESPP withholdings	4,393	—
Total	7,928,031	5,236,797

9. 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):

	Year Ended December 31,	
	2020	2019
Research and development expense	$ 1,180	$ 131
General and administrative expense	1,460	17
Total stock-based compensation expense	$ 2,640	$ 148

As of December 31, 2020, the total unrecognized stock-based compensation expense was $60.8 million, which is expected to be recognized over a remaining weighted-average period of approximately 3.4 years.

Stock-based compensation expense includes October 2020 and November 2020 grants that were originally granted with a strike price based upon the estimated grant date fair market value of our common stock as a private company; however, when determining the Black-Scholes value of these stock options, we utilized the public offering price of $21.00 per share as the estimated grant date fair market value of common stock.

Silverback Therapeutics, Inc.

Notes to Financial Statements

Stock Option Awards

In November 2020, the Company's board of directors and stockholders approved the 2020 Equity Incentive Plan (the "2020 Plan"). The 2020 Plan became effective upon the date of the underwriting agreement related to the IPO. Upon adoption of the 2020 Plan, the Company restricted future grants from its 2016 Equity Incentive Plan, as amended (the "2016 Plan").

Under the 2020 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock awards, performance cash awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of the Company's affiliates. A total of 4,132,681 new shares of common stock were initially reserved for issuance under the 2020 Plan. The number of shares reserved under the 2020 Plan also includes 67,319 shares of common stock that remained available for issuance under the 2016 Plan at the time the 2020 Plan became effective and will be increased by the number of shares under the 2016 Plan that are repurchased, forfeited, expired or cancelled on or after the effective date of the 2020 Plan. In addition, the number of shares of common stock available for issuance under the 2020 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2021 through January 1, 2030, in an amount equal to 5% of the total number of shares of Common Stock outstanding on December 31 of the preceding year, or a lesser number of shares determined by the Company's board of directors.

As of December 31, 2020, the Company's plans authorized a total of 7,824,721 shares, of which 1,506,806 shares are available for future grant, and 6,316,569 shares are outstanding. Not included in the outstanding option balance are 100,263 shares pursuant to stock options that were early exercised and subject to repurchase under the 2016 Plan that remain unvested as of December 31, 2020.

As of December 31, 2020, the Company has granted stock options under its equity incentive plans. Stock options granted under these plans expire no later than 10 years from the date of grant and generally vest over a four year period, with vesting either occurring at a rate of 25% at the end of the first and thereafter in 36 equal monthly installments or on a monthly basis. In the case of awards granted to our non-employee board members, vesting generally occurs on a monthly basis over three years. The Company issues new shares of common stock upon the exercise of stock options.

A summary of the Company's stock option activity for the year ended December 31, 2020 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, 2019	555,636	$ 1.61	8.5	$ 154
Granted	5,906,735	$ 11.57		
Exercised	(139,478)	$ 1.27		$ 6,285
Canceled	(6,324)	$ 1.29		
Balance at December 31, 2020	6,316,569	$ 10.93	9.5	$223,647
Vested at December 31, 2020	449,290	$ 2.20	7.5	$ 19,832

Silverback Therapeutics, Inc.

Notes to Financial Statements

The total fair value of shares vested during the years ended December 31, 2020 and 2019 was $1.1 million and $0.1 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 December 31, 2020. The weighted-average grant date fair value per share of option grants for the years ended December 31, 2020 and 2019 was $10.50 and $0.96, respectively.

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

	Year Ended December 31,	
	2020	2019
Expected term (in years)	6.0	6.1
Expected volatility	81%	80%
Risk-free interest rate	0.51%	2.08%
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 our 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.

Silverback Therapeutics, Inc.

Notes to Financial Statements

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.

Employee Stock Purchase Plan

In November 2020, the Company's board of directors and stockholders approved and adopted the 2020 ESPP. The ESPP became effective immediately prior to the date of the underwriting agreement related to the IPO. The ESPP permits eligible employees who elect to participate in an offering under the ESPP to have up to 15% of their eligible earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the ESPP. The price of common stock purchased under the ESPP is equal to 85 percent of the lower of the fair market value of the common stock at the commencement date of each offering period or the relevant date of purchase. A total of 350,000 shares of common stock were initially reserved for issuance under the ESPP. In addition, the number of shares of common stock available for issuance under the ESPP will automatically increase on January 1 of each calendar year, starting on January 1, 2021 through January 1, 2030, in an amount equal to the lesser of (i) 1% of the total number of shares of the Company's common stock outstanding on December 31st of the preceding calendar year, and (ii) 700,000 shares of the Company's common stock, or a lesser number of shares determined by the Company's board of directors.

As of December 31, 2020, no shares were issued under the ESPP. The weighted average per share fair value rights granted during the year ended December 31, 2020 was $10.28.

In determining the grant date fair value of shares to be issued under the ESPP, the Company uses the Black-Scholes option pricing model. The Black-Scholes inputs are determined in the same manner as for stock option awards. The weighted average inputs used for the ESPP for the year ended December 31, 2020, were as follows:

	Year Ended December 31, 2020
Expected term (in years)	1.2
Expected volatility	82%
Risk-free interest rate	0.11%
Expected dividend yield	—

Silverback Therapeutics, Inc.

Notes to Financial Statements

10. Income Taxes

The Company's effective tax rates for the years ended December 31, 2020 and 2019 differ from the U.S. federal statutory rate as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Tax at the federal statutory rate	$(6,919)	$(5,033)
Benefit from R&D tax credits	(586)	(561)
Stock-based compensation	331	—
Other temporary and permanent differences	21	(3)
Change in valuation allowance	7,153	5,597
Total provision for income taxes	$ —	$ —

The significant components of the Company's deferred tax assets and liabilities were as follows (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforward	$ 18,832	$ 12,575
Lease liability	677	862
R&D tax credit carryforward	1,502	941
Other deferred tax assets	336	41
Total deferred tax assets	21,347	14,419
Deferred tax liabilities—Right of use asset	(458)	(683)
Valuation allowance	(20,889)	(13,736)
Net deferred tax assets	$ —	$ —

At December 31, 2020, the Company had net operating loss carryforwards for income tax purposes of approximately $89.7 million. If not used, $18.2 million of this carryforward will begin to expire in 2036 and $71.5 million has no expiration. At December 31, 2020, the Company also had research and development tax credits of approximately $1.5 million which will begin to expire in 2037 if left unused. The Company did not have any foreign tax provision and did not generate material net operating losses in any states with an income tax.

FASB ASC 740 requires that the tax benefit of net operating losses, temporary differences, and credit carryforwards be recorded as an asset to the extent that management assesses the realization is "more likely than not." Realization of the future tax benefits from the net operating losses or credit carryforwards, if any, is dependent on the Company's ability to generate sufficient taxable income within the applicable carryforward period. Because of the Company's recent history of operating losses, the Company maintains a full valuation allowance in the amount of $20.9 million and $13.7 million for the years ended December 31, 2020 and 2019, respectively.

The Company may have already experienced one or more ownership changes. Depending on the timing of any future utilization of its carryforwards, the Company may be limited as to the amount that

can be utilized each year as a result of such previous ownership changes. However, the Company does not believe such limitations will cause its carryforwards to expire unutilized.

Future changes in the Company's stock ownership as well as other changes that may be outside the Company's control could potentially result in further limitations on the Company's ability to utilize its net operating loss and tax credit carryforwards.

As of December 31, 2020 and 2019, the Company did not have any liabilities for unrecognized income tax benefits associated with uncertain tax positions, including any interest and penalties.

11. 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.

In consideration for the license, the Company paid WuXi Bio a license fee of $100,000 which was recorded as research and development expense in 2019 accordance with ASC 730. In 2020 we incurred an additional license fee of $50,000 to WuXi Bio which was recorded in research and development expense in 2020. 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.

12. 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.

Silverback Therapeutics, Inc.

Notes to Financial Statements

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. The Company intends to enter 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 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, 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 most 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.

13. Related Party Transactions

The Company reimburses certain travel expenses incurred by one of its investors to support the business. Amounts due to the investor totaled less than $0.1 million as of December 31, 2020 and 2019. Reimbursable travel expenses incurred by the investor totaled less than $0.1 million during each of the years ended December 31, 2020 and 2019.

14. 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.

15. 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:

	Year Ended December 31,	
	2020	2019
Redeemable convertible preferred stock	—	4,232,232
Common stock options	6,316,569	555,636
Unvested common stock	100,263	6,046
Common stock warrants	—	9,154
ESPP withholdings	4,393	—
Total potentially dilutive shares	6,421,225	4,803,068

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None

Item 9A. 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 December 31, 2020. 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 December 31, 2020, 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.

Management’s Report on Internal Control over Financial Reporting

This annual report does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of the company’s registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item and not set forth below will be set forth in the sections headed *Election of Directors* and *Executive Officers* contained in our definitive Proxy Statement to be filed with the Commission within 120 days after the conclusion of our year ended December 31, 2020 (the "Proxy Statement") pursuant to General Instructions G(3) of Form 10-K and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. A current copy of the Code of Business Conduct and Ethics is available on the Corporate Governance section of our website at www.silverbacktx.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K.

Item 11. Executive Compensation.

The information required by this item will be set forth in our Proxy Statement in the sections headed *Executive and Director Compensation* and *Director Compensation* contained in our Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this item will be set forth in the sections headed *Security Ownership of Certain Beneficial Owners and Management* and *Executive and Director Compensation* contained in our Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item will be set forth in the sections headed *Certain Related-Person Transactions* and *Information Regarding the Board of Directors and Corporate Governance* contained in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

Information required by this item will be set forth in the sections headed *Ratification of Selection of Independent Registered Public Accounting Firm* contained in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as part of this report.

(1) *Financial Statements.* The following financial statements of Silverback Therapeutics, Inc., together with the report of Ernst & Young LLP, an independent registered public accounting firm, required to be filed pursuant to Part II, Item 8 of this Annual Report on Form 10-K are included on the following pages:

(2) *Financial Statement Schedules.* None.

(3) *List of exhibits required by Item 601 of Regulation S-K*. See part (b) below.

(b) 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).
4.6	Description of Registrant's Common Stock.

Exhibit Number	Description
10.1+	Form of Indemnity Agreement, by and between the registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.2+	Silverback Therapeutics, Inc. 2016 Equity Incentive Plan, as amended, and Forms of Option Agreement, Notice of Exercise, Notice of Early Exercise, Restricted Stock Grant Notice and Restricted Stock Award Agreement thereunder (incorporated by reference to Exhibit 10.2 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.3+	Silverback Therapeutics, Inc. 2020 Equity Incentive Plan, and Forms of Option Grant Notice, Option Agreement and Notice of Exercise thereunder (incorporated by reference to Exhibit 10.3 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 30, 2020).
10.4+	Silverback Therapeutics, Inc. 2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 30, 2020).
10.5+¥	Letter Agreement, by and between the registrant and Laura Shawver, Ph.D., dated March 6, 2020, as amended (incorporated by reference to Exhibit 10.5 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.6+¥	Letter Agreement, by and between the registrant and Valerie Odegard, Ph.D., dated July 23, 2016 (incorporated by reference to Exhibit 10.6 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.7+¥	Letter Agreement, by and between the registrant and Naomi Hunder, M.D., dated December 22, 2018 (incorporated by reference to Exhibit 10.7 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.8+¥	Letter Agreement, by and between the registrant and Jonathan Piazza, dated November 3, 2020 (incorporated by reference to Exhibit 10.8 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.9¥	Lease, by and between the registrant and BMR-500 Fairview Avenue LLC, dated June 8, 2016 (incorporated by reference to Exhibit 10.9 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.10*¥	Master Laboratory Services Agreement, by and between the registrant and Q Squared Solutions LLC, dated May 25, 2020 (incorporated by reference to Exhibit 10.10 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.11*¥	Master Services Agreement, by and between the registrant and CE3, Inc., dated January 21, 2020 (incorporated by reference to Exhibit 10.11 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.12*¥	Cell Line License Agreement, by and between the registrant and WuXi Biologics (Hong Kong) Limited, dated October 11, 2019 (incorporated by reference to Exhibit 10.12 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).

Exhibit Number	Description
10.13	Loan and Security Agreement, by and between the registrant and Silicon Valley Bank, dated November 21, 2016, as amended (incorporated by reference to Exhibit 10.13 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.14+	Silverback Therapeutics, Inc. 2020 Change in Control and Severance Benefit Plan (incorporated by reference to Exhibit 10.14 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.15+	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.3 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 30, 2020).
10.16**	Amendment No. 1 to Cell Line License Agreement, by and between the registrant and WuXi Biologics (Hong Kong) Limited, dated January 12, 2021.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see signature page).
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.

+ Indicates management contract or compensatory plan.
¥ 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.
* Certain portions of this exhibit are omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.
** Certain information in this exhibit is omitted because it is both not material and is the type that the registrant treats as private or confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Company Name

Date: March 29, 2021

By: /s/ Laura Shawver, Ph.D.
Laura Shawver, Ph.D.
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Laura Shawver and Jonathan Piazza, and each of them, his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Laura Shawver, Ph.D. Laura Shawver, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 29, 2021
/s/ Jonathan Piazza Jonathan Piazza	Chief Financial Officer *(Principal Financial Officer)*	March 29, 2021
/s/ Russ Hawkinson Russ Hawkinson	Senior Vice President of Finance *(Principal Accounting Officer)*	March 29, 2021
/s/ Peter Thompson, M.D. Peter Thompson, M.D.	Chairman of the Board of Directors	March 29, 2021
/s/ Vickie L. Capps Vickie L. Capps	Director	March 29, 2021
/s/ Robert Hershberg, M.D., Ph.D. Robert Hershberg, M.D., Ph.D.	Director	March 29, 2021
/s/ Saqib Islam, J.D. Saqib Islam, J.D.	Director	March 29, 2021
/s/ Andrew Powell, J.D. Andrew Powell, J.D.	Director	March 29, 2021
/s/ Jonathan Root, M.D. Jonathan Root, M.D.	Director	March 29, 2021
/s/ Thilo Schroeder, Ph.D. Thilo Schroeder, Ph.D.	Director	March 29, 2021
/s/ Maria Koehler, M.D., Ph.D. Maria Koehler, M.D., Ph.D.	Director	March 29, 2021

Exhibit 4.6

DESCRIPTION OF COMMON STOCK

The following summary description of the common stock of Silverback Therapeutics, Inc. (we, our or us) is based on the provisions of our amended and restated certificate of incorporation, as well as our amended and restated bylaws, and the applicable provisions of the Delaware General Corporation Law. This information is qualified entirely by reference to the applicable provisions of our amended and restated certificate of incorporation, amended and restated bylaws, and the Delaware General Corporation Law. Our amended and restated certificate of incorporation and amended and restated bylaws have previously been filed as exhibits with the Securities and Exchange Commission.

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. The affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified structure of our board of directors, the size of our board of directors, removal of directors, director liability, vacancies on our board of directors, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

Dividends

Subject to preferences that may apply to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose on a non-cumulative basis.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Anti-Takeover Provisions of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;
- provide that the authorized number of directors may be changed only by resolution of our board of directors;
- provide that our board of directors will be classified into three classes of directors;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least 66 2/3% of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;

- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or president or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors, and not by our stockholders; and
- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require approval by the holders of at least 662/3% of the voting power of all of our then-outstanding common stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our amended and restated certificate of incorporation provides that 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 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 certificate of incorporation or our bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate

of incorporation or our 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. This provision will not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other claim for which the U.S. federal courts have exclusive jurisdiction.

In addition, our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

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, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these provisions. Although we believe these provisions benefit us by providing increased consistency in the application of law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers.

Listing

Our common stock is listed on the Nasdaq Global Market under the trading symbol “SBTX.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent’s address is 6201 15th Avenue, Brooklyn, New York 11219, and its telephone number is (800) 937-5449.

Exhibit 10.16

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

AMENDMENT NO. 1 TO CELL LINE LICENSE AGREEMENT

This Amendment No. 1 (this "Amendment") is entered into between Silverback Therapeutics, Inc. ("Licensee") and WuXi Biologics (Hong Kong) Limited ("WuXi Biologics"), effective as of the date of the last signature hereto, and amends, as set forth herein, the Cell Line License Agreement (the "CLLA"), effective as of 11 October, 2019 entered into between Licensee and WuXi Biologics. Each of WuXi Biologics and Licensee are referred to from time to time as a "Party" and collectively as the "Parties". All terms used, but not otherwise defined, in this Amendment shall have the meanings accorded to them in the CLLA.

1. The Parties hereby agree to amend the Appendix I pursuant to Section 1.2 of the CLLA as follows:

List of Service Agreements for Licensee Products

	Licensee Product Name	Contract(e.g.,MasterService Agreements)	Effective Date
1	[***]	[***]	[***]
2	[***]	[***]	[***]
3			
4			

2. Miscellaneous.

2.1 Ratification of Agreement. The CLLA is in all respects ratified and confirmed by the Parties.

2.2 One Instrument. The CLLA and this Amendment shall be read, taken and construed as one and the same document.

2.3 Counterpart Signatures. This Amendment may be signed by the Parties in multiple, separate counterparts which when taken together shall constitute one and the same

***Certain Information Omitted

document. This Agreement may be signed by electronic signature via a recognized provider (e.g., DocuSign or Adobe) or ".pdf" file and such signature shall be deemed to bind each Party hereto as if they were original.

IN WITNESS WHEREOF, the Parties have signed this Amendment through their duly authorized representatives.

WuXi Biologics (Hong Kong) Limited		**Silverback Therapeutics, Inc.**	
Signature:	/s/ Chris Chen	Signature:	/s/ Jeffrey Pepe
Name:	Chris Chen	Name:	Jeffrey Pepe
Title:	CEO	Title:	General Counsel
Date:	1/12/2021	Date:	1/12/2021

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-251143) pertaining to the 2020 Equity Incentive Plan, the 2020 Employee Stock Purchase Plan, and the 2016 Equity Incentive Plan, as amended, of Silverback Therapeutics, Inc. of our report dated March 29, 2021, with respect to the consolidated financial statements of Silverback Therapeutics, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Seattle, Washington
March 29, 2021

Exhibit 31.1

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 Annual Report on Form 10-K for the fiscal year ended December 31, 2020 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: March 29, 2021

By: /s/ Laura Shawver, Ph.D.
Laura Shawver, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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 Annual Report on Form 10-K for the fiscal year ended December 31, 2020 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 on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant 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: March 29, 2021

By: /s/ Jonathan Piazza

Jonathan Piazza

Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Silverback Therapeutics, Inc. (the "Company") for the period ended December 31, 2020, to which this Certification is attached, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company herby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their knowledge:

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

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 29, 2021 By: /s/ Laura Shawver, Ph.D.
Laura Shawver, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: March 29, 2021 By: /s/ Jonathan Piazza
Jonathan Piazza
Chief Financial Officer
(Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.