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, 2021

OR

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

For the transition period from _____ to

Commission File Number 001-39756

Silverback Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**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 Stock Market LLC**

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

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

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

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

Indicate by check mark whether the registrant 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 ☒

As of March 28, 2022 there were 35,143,186 shares of registrant's common stock, $0.0001 par value per share, outstanding.

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $676.8 million as of June 30, 2021 (the last trading day of the registrant's most recently completed second quarter) based on the closing price of $30.89 as reported on the Nasdaq Global Market on such date. Shares of the registrant's common stock held by executive officers, directors, and their affiliates have been excluded from this calculation. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2022 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, 2021, 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 (this Annual Report) contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our plans to research, develop, and commercialize SBT8230 and any future product candidates;
- our ability to obtain and maintain regulatory approval of product candidates arising from our ImmunoTAC technology platform, including from our SBT8230 program, 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 our planned clinical trials, conduct additional manufacturing and conduct preclinical studies of any of our product candidates, including from our SBT8230 program;
- the success, cost, and timing of our research and development activities, including our preclinical studies and planned clinical trials;
- the size of the markets for our product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our product candidates;
- the rate and degree of market acceptance of our product candidates;
- our ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party service providers, including our contract research organizations (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 Jumpstart Our Business Startups Act of 2012;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing upon the intellectual property rights of others;
- the impact of the COVID-19 pandemic on our business and operations; and
- other risks and uncertainties, including those described under Part I, Item 1A, “Risk Factors” of this Annual Report.

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

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

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

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

- We have a limited operating history, have incurred net losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, may not be able to sustain it.
- The COVID-19 pandemic has had, and could continue to have, an adverse impact on our business, including on our preclinical studies and planned clinical trials, supply chain, and business development activities.
- Preclinical and clinical development is a lengthy, expensive, and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance into clinical trials, including from our SBT8230 program, may not achieve favorable results in later clinical trials, if any, or receive marketing approval.
- 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.
- 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.
- 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 may rely on third parties to conduct, supervise, and monitor our planned 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 contract with third parties for the manufacture and supply of certain of our product candidates for use in preclinical testing and planned clinical trials and will rely on third parties for commercial supply, which supply may become limited or interrupted 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, 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 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 may not realize the benefits of any acquisitions, in-license, or strategic alliances that we enter into.
- 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.
- We face substantial competition, which may result in others discovering, developing, or commercializing products more quickly or marketing them more successfully than us.
- 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 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 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.
- The price of our common stock could be subject to volatility related or unrelated to our operations.

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 biopharmaceutical company focused on leveraging our proprietary ImmunoTAC technology platform to develop systemically delivered, tissue targeted therapeutics for the treatment of chronic viral infections, cancer, and other serious diseases. 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. Our platform enables us to strategically pair proprietary linker-payloads that modulate key disease-modifying pathways with monoclonal antibodies directed to specific disease sites. Many potentially promising systemic therapies fail to maximize their therapeutic potential due to toxicities in healthy tissues. Our approach is designed to expand the therapeutic window and avert unacceptable toxicities by directly targeting specific disease sites where our therapeutics are locally active.

In July of 2020, we initiated clinical development of our first ImmunoTAC product candidate, a TLR8 agonist conjugated to a HER2 antibody, SBT6050. Preclinical data suggested that we would be able to demonstrate a therapeutic window and advance SBT6050 through clinical development as a monotherapy and in combination with standard-of-care agents that had a complementary mechanism-of-action. Our Phase 1/1b program was designed to measure safety and tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and anti-tumor activity as monotherapy and in combination with pembrolizumab. On March 28, 2022, we made the decision to discontinue our clinical development program for SBT6050 due to limited monotherapy activity and dose-limiting adverse events when used in combination with pembrolizumab. SBT6290, comprised of the same linker payload conjugated to a Nectin4 antibody, was expected to show a similar clinical profile and, therefore, we also terminated this program prior to dosing patients. We have prioritized our resources to focus on the development of SBT8230 and early-stage discovery programs.

Our understanding of TLR8 conjugates in preclinical species and in the clinic guides our interpretation of the preclinical characteristics of SBT8230, an ASGR1 antibody conjugated to a TLR8 agonist linker payload for the treatment of chronic hepatitis B virus (cHBV), which is currently in preclinical development. ASGR1 is highly expressed in liver and is restricted in its expression to this organ. Other ASGR1-directed agents, such as those used in RNAi therapies, have shown robust liver localization. SBT8230 shows biodistribution profiles in non-human primates (NHP) consistent with these agents, which is distinct from SBT6050 and SBT6290. We believe that efficient liver targeting of SBT8230 via ASGR1 binding has the potential to lead to markedly lower serum exposures of SBT8230 in patients compared to those observed with SBT6050 in the clinic at any dose evaluated. We believe the preclinical to clinical experience for SBT6050, coupled with the NHP PK, PD, and tolerability data for SBT8230, suggest that the clinical safety, PK and PD profiles for SBT8230 has the potential to be notably different than those for SBT6050, given the large differences in serum exposures and overall conjugate disposition for SBT8230 that are expected in patients due to its efficient liver targeting. SBT8230 is designed to elicit an anti-viral immune response by targeting TLR8 activation to the liver. The anti-viral immune response is achieved through activation of myeloid cells and subsequent activation of immune cells that drive an IFNγ signal, which has been observed in the clinic with SBT6050. This has been shown by others to drive seroconversion, an important determinant of a functional cure. We see a significant opportunity in liver-localized immunotherapies as a potential way of achieving durable responses in these patients. We are focused on advancing SBT8230, our liver-targeted conjugate designed to potently activate human myeloid cells in the liver for the treatment of cHBV.

Further support for investigating TLR8 agonism for the treatment of cHBV comes from selgantolimod (GS-9688), an existing untargeted, orally administered TLR8 agonist being developed by Gilead Sciences. Selgantolimod has 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 cure, which is defined as sustained loss of hepatitis B surface antigen (HBsAg) in the blood, in patients suffering from cHBV. We presented a preclinical update on SBT8230 in the fourth quarter of 2021. In the first quarter of 2022, we began a Phase 1-enabling toxicology study. We plan to complete a Phase 1 regulatory submission in the fourth quarter of 2022 and begin a Phase 1 single ascending dose (SAD) study in healthy volunteers in the first half of 2023. After completing the SAD study, we anticipate initiating a Phase 1 multiple ascending dose (MAD) study in patients with chronic HBV, who are virally suppressed on nucleoside reverse transcriptase inhibitors (NRTI) therapy.

In addition, our internal discovery programs are focused on evaluating and developing new antigen binding domains specific for targets of interest (including antibodies), next-generation linker technologies, and both agonist and antagonist small molecule payloads, that may be combined to create novel tissue-targeted antibody conjugates. The integration of medicinal chemistry, bioconjugation, protein engineering, bioinformatics, pharmacology, and translational medicine expertise focused on developing tissue-targeted therapies allows us to leverage key learnings from our previous clinical program to bring forward the next generation of therapeutics. We anticipate providing an update on our discovery pipeline in the fourth quarter of 2022.

Our ImmunoTAC Platform

Our ImmunoTAC platform is the result of a focused effort 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 localize disease-modifying payloads to specific sites of disease where our therapeutics are locally active.

Our Development Pipeline

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

Program	Target / Payload	Indication(s)	Preclinical Studies	Phase 1	Phase 2	Anticipated Milestones
SBT8230	ASGR1 TLR8 Agonist	cHBV				• 4Q 2022 – Phase 1 regulatory submission • 1H 2023 – Open enrollment for Phase 1 SAD study in healthy volunteers
Discovery Stage Pipeline						
Undisclosed	Undisclosed	Multiple				• 4Q 2022 – Preclinical update

ASGR1 = Asialoglycoprotein Receptor 1 (Liver Localized Protein)
cHBV = Chronic Hepatitis B Virus
SAD = Single Ascending Dose
TLR8 = Toll Like Receptor 8

Our Strategy

Our goal is to transform the treatment of cHBV, 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:

- ***Demonstrate anti-viral properties of TLR8 in cHBV.*** We are applying learnings from our TLR8 agonist oncology programs and clinical experience to maximize the potential of SBT8230. Our understanding of TLR8 conjugates in preclinical species and in the clinic guides our interpretation of the preclinical characteristics of SBT8230, an ASGR1 antibody conjugated to a TLR8 agonist linker payload for the treatment of cHBV that is currently in preclinical development.
- ***Maximize the therapeutic potential of SBT8230.*** The immune activating mechanism of SBT8230 is complimentary to other treatments for cHBV that interfere with components of the viral life cycle such as nucleoside and nucleotide analogs, capsid inhibitors, and RNAi-based therapies. Furthermore, our ASGR1 antibody does not cross block GalNAc, allowing for combinations with RNAi-based therapies.

- ***Leverage our ImmunoTAC platform for promising new antibody-linker-payload combinations.*** We are strategically pairing our disease-modulating payloads with tissue targeted binding domains to create new therapeutic agents with the goal of providing benefits to patients. We plan to continue to leverage our ImmunoTAC platform, discovery of antigen binding domains (including antibodies), new linker technologies and therapeutic discovery infrastructure to discover and develop novel small molecule therapeutics conjugated to antibodies.
- ***Internally and externally source potentially transformative assets and technologies that align with our mission to develop tissue-targeted therapies.*** We have extensive expertise in protein engineering, small molecule linker and payload chemistry, and translational medicine that we apply to the discovery and advancement of new tissue-targeted agents to the clinic. Our clinical development team is a seasoned group with experience in developing antibody-drug conjugates and other therapeutics across all phases of development. While we have robust internal discovery capabilities, we also believe that innovative technologies can be acquired through business development activities. We therefore plan to continue to pursue synergistic, in-licensing opportunities to augment our internal discovery efforts.
- ***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.

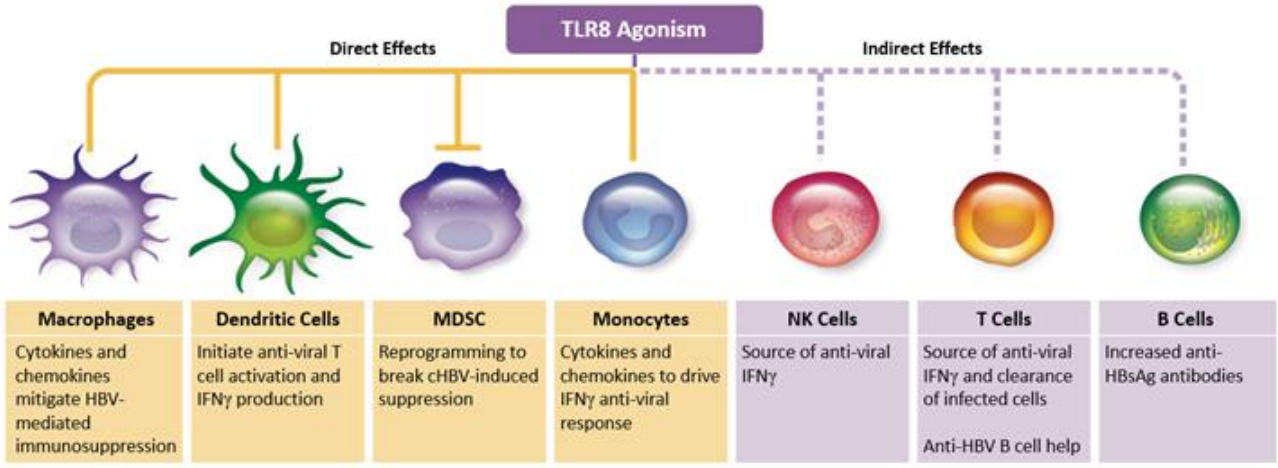
Our Team

We have an accomplished management team with a proven track record of therapeutic research and development expertise and of generating meaningful stockholder value. The members of our team have deep experience in discovering and developing therapeutics, including acalabrutinib, brentuximab vedotin, entrectinib, etanercept, ibrutinib, lisocabtagene maraleucel, sunitinib, tezepelumab, tucatinib, and venetoclax.

Activating the Myeloid Cell Compartment Through Liver-Targeted TLR8 Agonism

As shown in the figure below, TLR8 activation of human myeloid cells plays an important role in the anti-viral immune response in cHBV. HBV-infected liver is highly immunosuppressive and the activation of macrophages and other myeloid cells in the liver can serve to overcome this immunosuppression. We believe TLR8 is the optimal target for activating these myeloid cell types due to its restricted expression and function within these cells. TLR8 is also highly expressed in conventional dendritic cells which promote antigen presentation and the production of cytokines important for the generation of T and B cell responses against hepatitis B virus. TLR8 is not expressed in T or B lymphocytes, but TLR8 activation in human myeloid cells secondarily induces IFNγ production by T cells and antibody production by B cells, both shown to be associated with the generation of functional cure in cHBV.

TLR8 is Highly Expressed in Human Myeloid Cell Types That Drive Anti-Viral Responses when Activated



Silverback's Preclinical and Clinical Development Experience with a HER2-Directed TLR8 Agonist Conjugate, SBT6050

We have gained pre-clinical and clinical experience with TLR8 conjugates through our recently discontinued SBT6050 program. In this program, a HER2-TLR8 agonist conjugate was administered to 58 patients as monotherapy and in combination with a checkpoint inhibitor at dose levels ranging from 0.15 mg/kg through 1.2 mg/kg with the length of patient experience ranging from 2 weeks through 41 weeks. We observed a dose response for adverse events related to immune activation, serum PK, serum pharmacodynamic markers, tumor exposure and intratumoral pharmacodynamic markers inclusive of data that demonstrates activation of immune mechanisms in biopsies collected from patients after treatment. However, antitumor activity was limited in the monotherapy arm, and increased toxicity in combination with checkpoint inhibitors limited dose escalation beyond 0.3 mg/kg. In the 18 patients treated in combination with pembrolizumab, while we observed decreasing volume stable disease in some patients, we did not see responses meeting RECIST criteria. Furthermore, at 0.3 mg/kg in combination with pembrolizumab, although there were no DLTs with additional patients and longer follow-up, it was determined that long-term tolerability was challenging. Several patients experienced grade 3 adverse events in later cycles, including grade 3 hypotension. Finally, PK and PD at 0.3 mg/kg were suboptimal.

On the other hand, there were important learnings from the SBT6050 clinical program that we are applying to SBT8230. In the SBT6050 clinical trial, exposures increased with dose and the data demonstrated that the conjugate was stable in circulation. Free payload was undetectable in ~98% of blood samples evaluated and in the few samples in which payload was detectable, the levels were at least an order of magnitude below the lowest active concentrations of payload. SBT6050 induced PD activity indicative of myeloid and natural killer (NK) and/or T cell activation at all dose levels, confirming the proposed mechanism of action of TLR8 agonism, and PD activity was maintained with repeat dosing.

Our understanding of TLR8 conjugates in preclinical species and in the clinic guides our interpretation of the preclinical characteristics of SBT8230, an ASGR1 antibody conjugated to a TLR8 agonist linker payload for the treatment of cHBV currently in preclinical development. ASGR1 is highly expressed in liver and is restricted in its expression to this organ. Other ASGR1-directed agents, such as those used by RNAi therapies, have shown robust liver localization. SBT8230 shows biodistribution profiles in NHP consistent with these agents and is distinct from SBT6050 and SBT6290 in this regard.

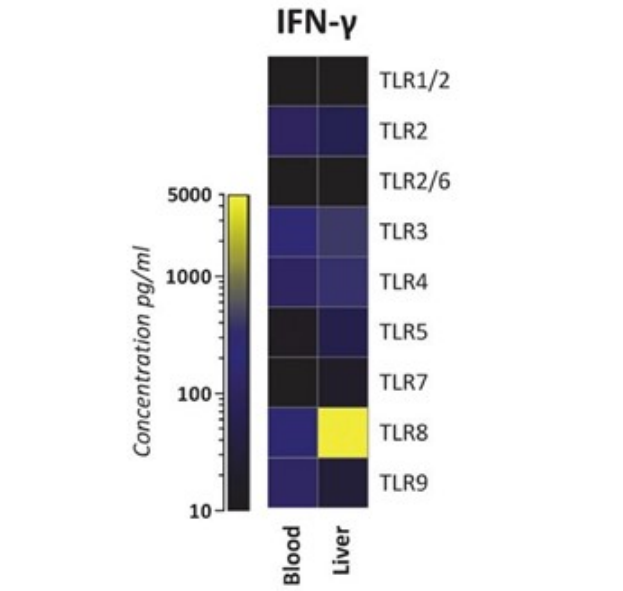
SBT8230: TLR8 Agonist Conjugated to an ASGR1 Antibody

We have engineered SBT8230 to treat cHBV by eliciting an anti-viral immune response through targeting TLR8 activation to the liver. SBT8230 is comprised of an ASGR1 monoclonal antibody conjugated to the same TLR8 linker-payload as SBT6050, but with an average drug antibody ratio (DAR) of about 2 as opposed to the average DAR of about 4 used in SBT6050.

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 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 IFN*g *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 peripheral blood mononuclear cells (PBMC) or isolated mononuclear cells from the liver after stimulation with either a TLR8 or TLR7 agonist. TLR8 agonism, but not TLR7 agonism, induced IFNγ production, along with the production of other cytokines important in the generation of anti-viral immunity such as TNFα, 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

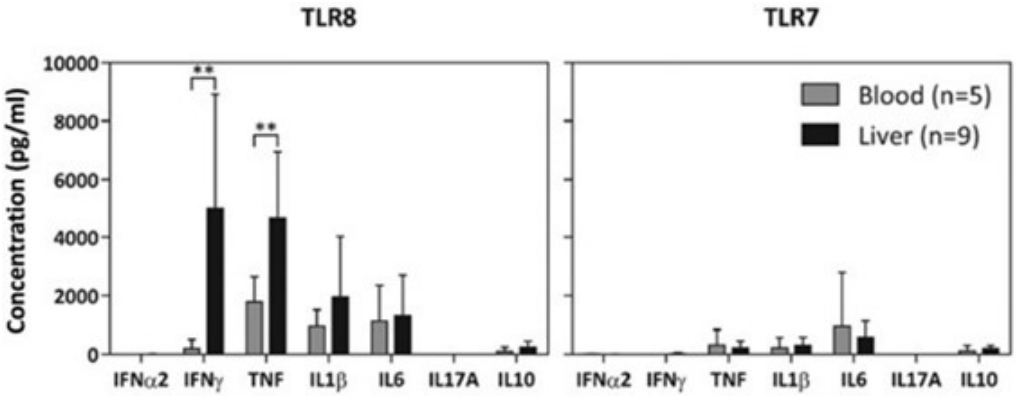


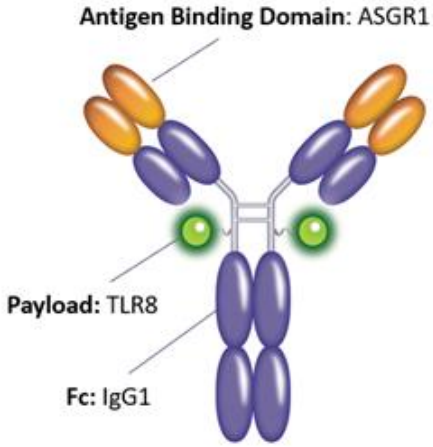
Figure source: Jo et al, PLOS Pathogens, 2014.

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 Combine with other cHBV Drugs 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. In addition, the ASGR1 mAb of SBT8230 was designed to bind to an epitope distinct from that recognized by GalNAc to allow for combination with GalNAc-based therapies.

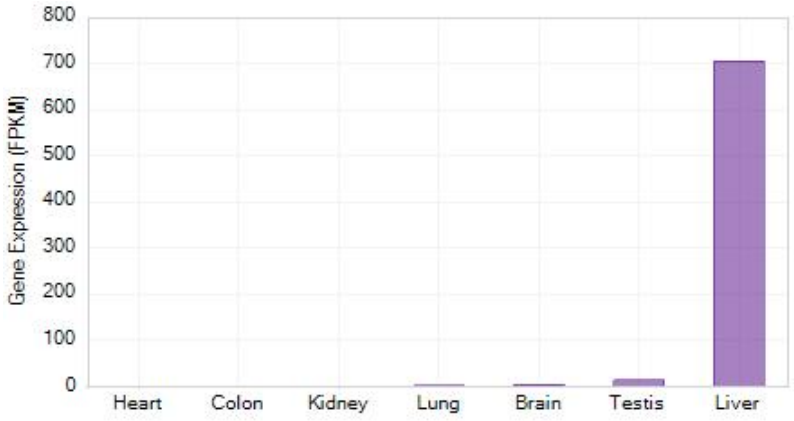
SBT8230 ImmunoTAC is Designed for Liver-localized TLR8 Activation



Background on ASGR1

As with all ADC-based therapeutics, an expression profile differential of the target antigen on healthy tissue relative to target tissues is critical. As shown in the figure below, the expression of ASGR1 is a liver-restricted scavenger receptor that is highly restricted to this organ. Furthermore, it is a clinically validated target that has been successfully targeted by GalNAc-based therapeutics.

ASGR1 Expression is Restricted to the Liver



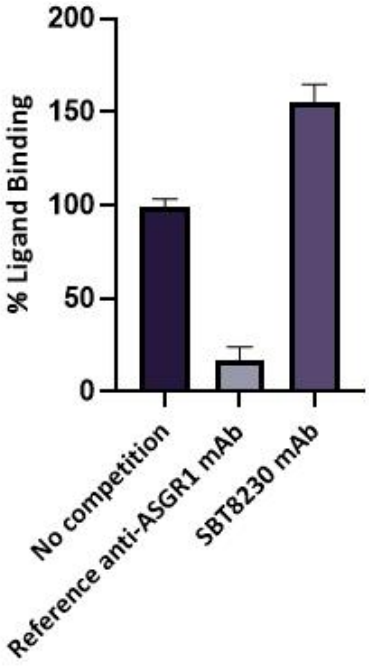
The antibody backbone of SBT8230 has been designed to possess high affinity and specificity for ASGR1 and is not an efficient binder to ASGR2 or CLEC10A. The specificity and binding profile of the SBT8230 antibody is identical between human and monkey (not shown).

SBT8230's Backbone Antibody is Highly Specific to ASGR1

Target	Kd (nM) Octet
huASGR1	3 nM
huASGR2	Non-detected (>>171 nM)
huCLEC10A	Non-detected (>>171 nM)

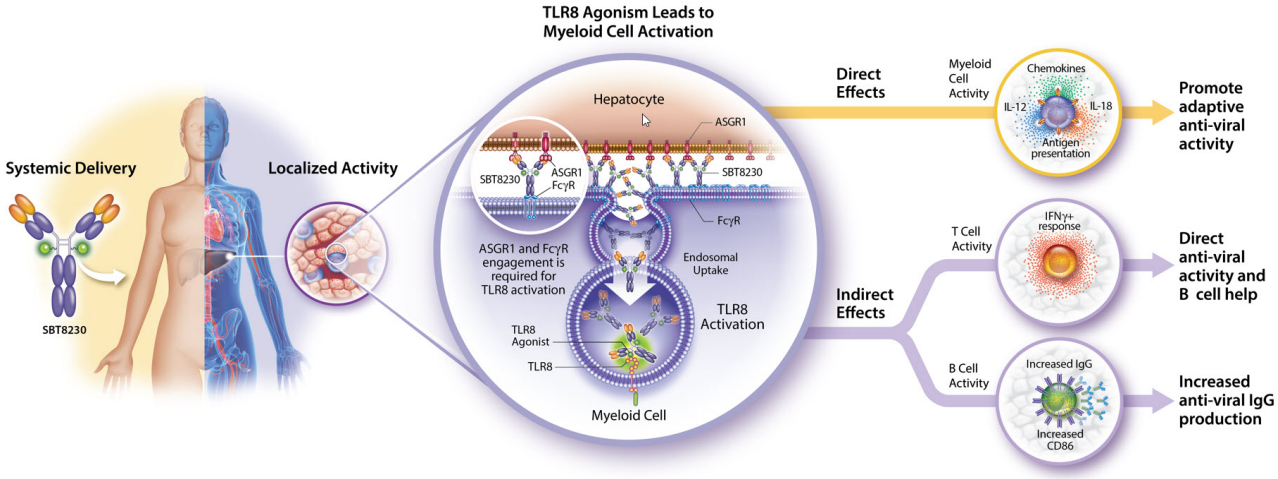
The SBT8230 antibody has also been designed to recognize an epitope distinct from that bound by the ASGR1 ligand, GalNAc, allowing for possible combination of SBT8230 with GalNAc-targeted RNAi therapies currently in development for cHBV.

SBT8230's Backbone Antibody Does Not Block Ligand Binding Allowing for Combination Therapy with GalNAc Targeted Molecules



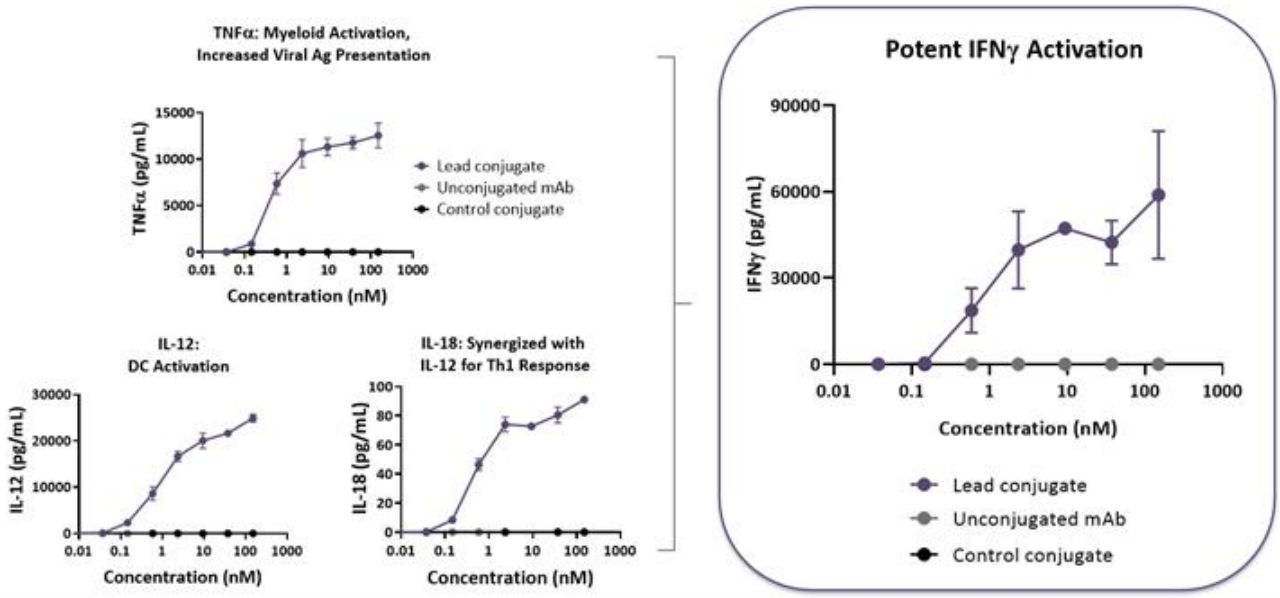
Potential Mechanism of Action: SBT8230 is Designed to Localize TLR8 Activation of Myeloid Cells in the Liver Via a Directed ASGR1 Antibody

The diagram below walks through the potential mechanism of action of SBT8230. SBT8230 is designed to be administered subcutaneously. In the liver, the ASGR1 binding domain engages hepatocytes and the Fc domain of the conjugate binds to the FcgR receptors on myeloid cells. The increase in FcgR binding avidity is a result of ASGR co-binding and results in the internalization of the conjugate into the endo-lysosome where TLR8 resides. SBT8230 directly activates myeloid cells, and these cells in turn activate anti-viral IFNg+ T cell and anti-viral B cell immune responses.



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

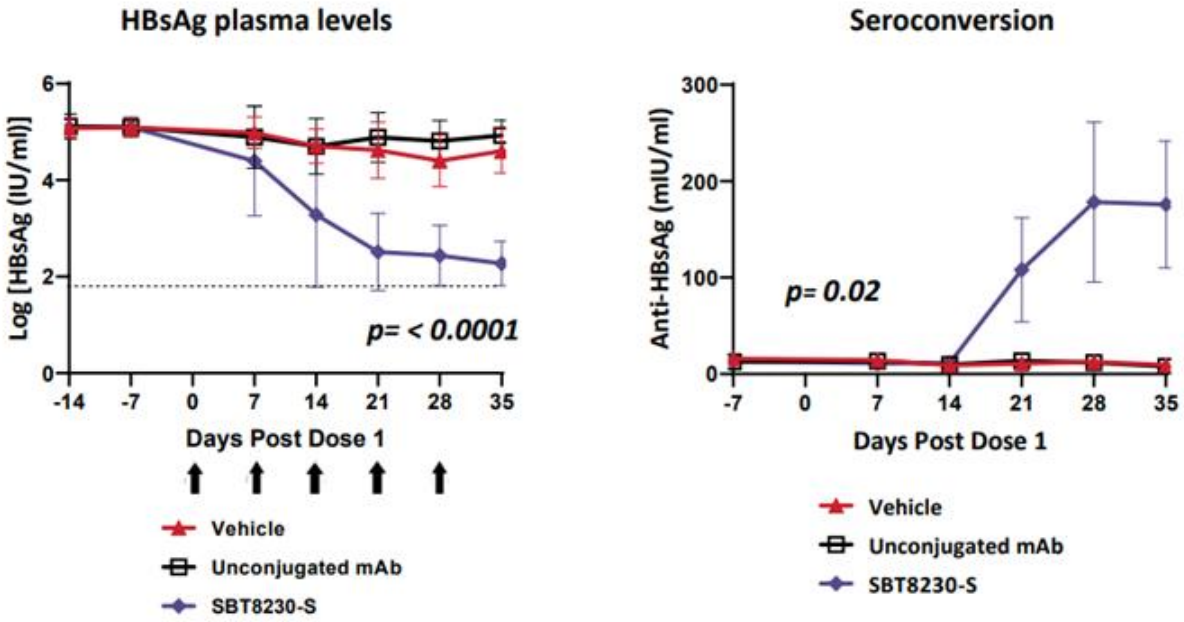
ASGR1-TLR8 Potently Activated Human Myeloid Cells, Resulting in a Robust IFN*g *Response



Activation of human myeloid cells by TLR8 was mirrored in mouse myeloid cells by TLR7 as was previously demonstrated in our SBT6050 program. 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 anti-mouse ASGR1 monoclonal antibody conjugated to a TLR7 agonist (SBT8230-S). The antibody contained an IgG2a Fc domain to facilitate uptake into mouse myeloid cells.

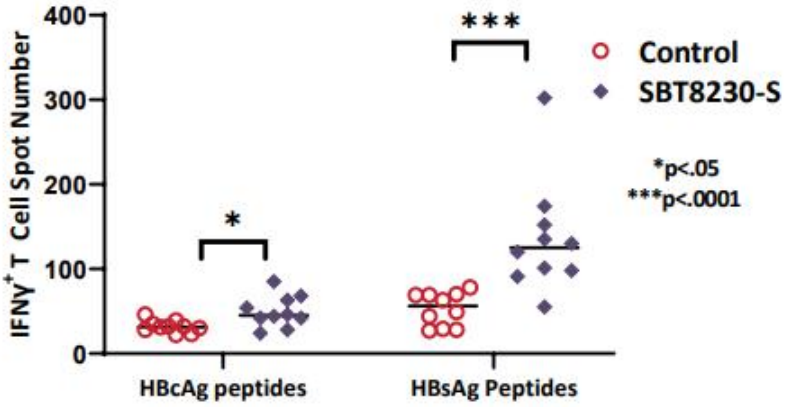
Seroconversion, together with reductions in HBsAg levels and expansion of IFNg-producing anti-viral T cells, is associated with achievement of functional cures in cHBV. The AAV-HBV (adenovirus-hepatis B virus) mouse model is a commonly used preclinical model for cHBV. Paralleling their inability to drive 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 were demonstrated with SBT8230-S as compared to the vehicle and unconjugated antibody control groups in the AAV-HBV model, as shown in the figures below.

SBT8230-S Reduced HBsAg and Drove Seroconversion in Mouse AAV-HBV Model

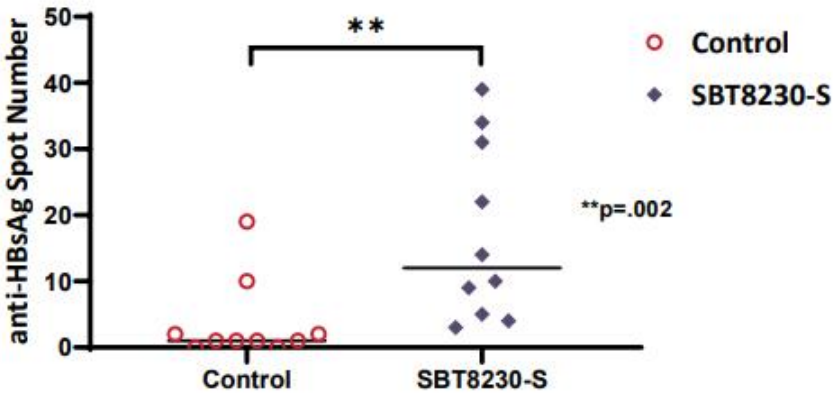


In addition, SBT8230-S treatment generated potent anti-viral T cell and B cell immune responses, as indicated by the significantly increased anti-HBV core and S antigen IFNg+ T cells and anti-HBsAg+ B cells, as shown in the figures below.

SBT8230-S Increased IFN*g+ *Anti-Viral T Cells

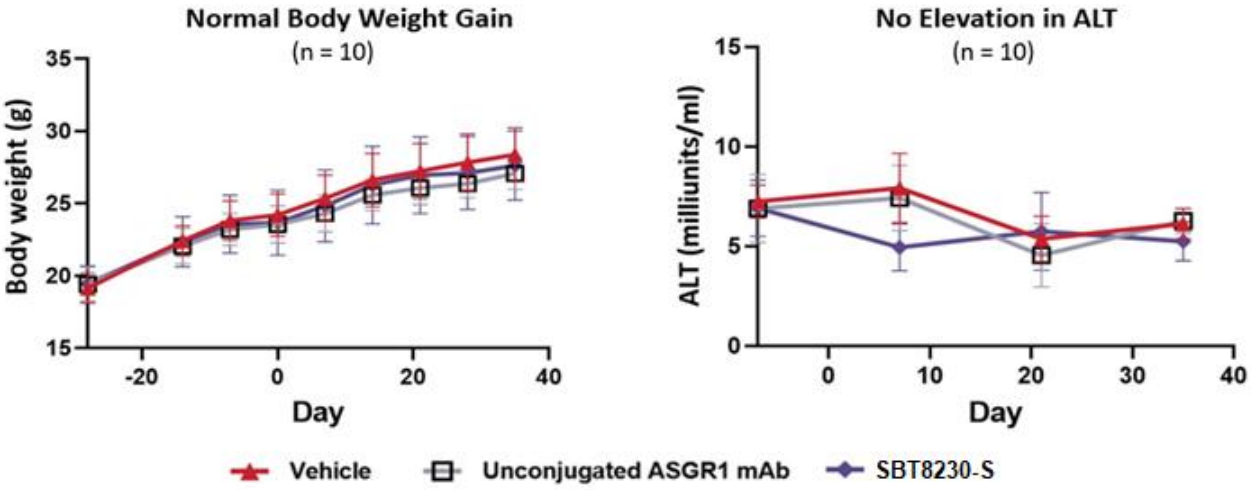


SBT8230-S Increased B Cells Producing Anti-HBs Antigen Antibodies



Importantly, as shown in the figures below, no changes in serum ALT or body weight were noted after treatment with SBT8230-S as compared to controls. In addition, there were no findings in the liver by histopathology after treatment with SBT8230-S. Together, these data indicated that SBT8230-S was well tolerated in the mouse AAV-HBV model.

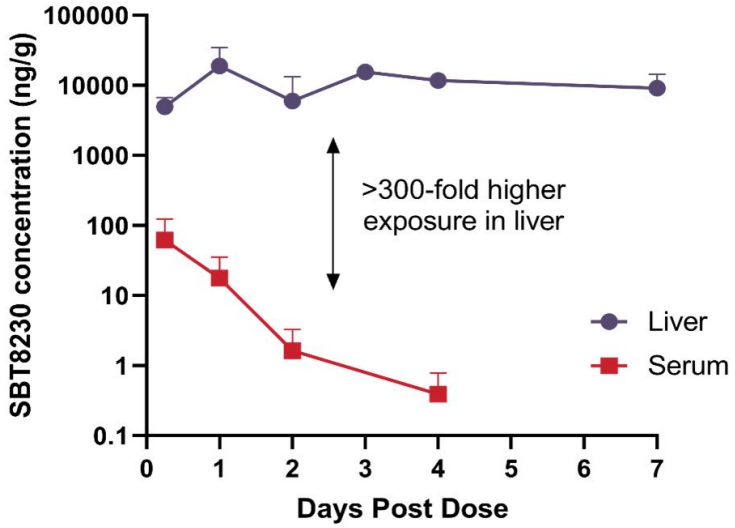
SBT8230-S was Well Tolerated in Mice



SBT8230 is Highly Localized to the Liver in Non-Human Primates, Suggestive of Pharmacological Activity at Low Doses in the Clinic

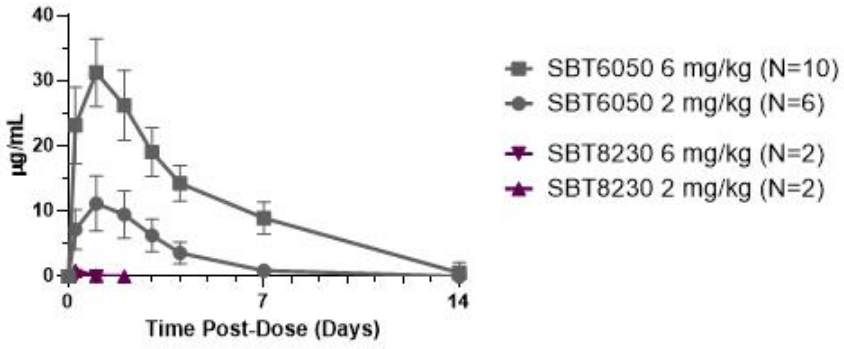
SBT8230 demonstrates comparable activity on NHP immune cells, supporting the use of NHP to characterize its tolerability, efficiency of liver uptake, and ability to produce robust and localized PD effects. As shown in the figure below, SBT8230 was targeted to the liver with high efficiency in NHP. SBT8230 liver exposures (area under the curve, AUC) were over 300 times greater than serum exposures, the latter of which also displayed a very short half-life.

SBT8230 concentration in NHP liver vs serum



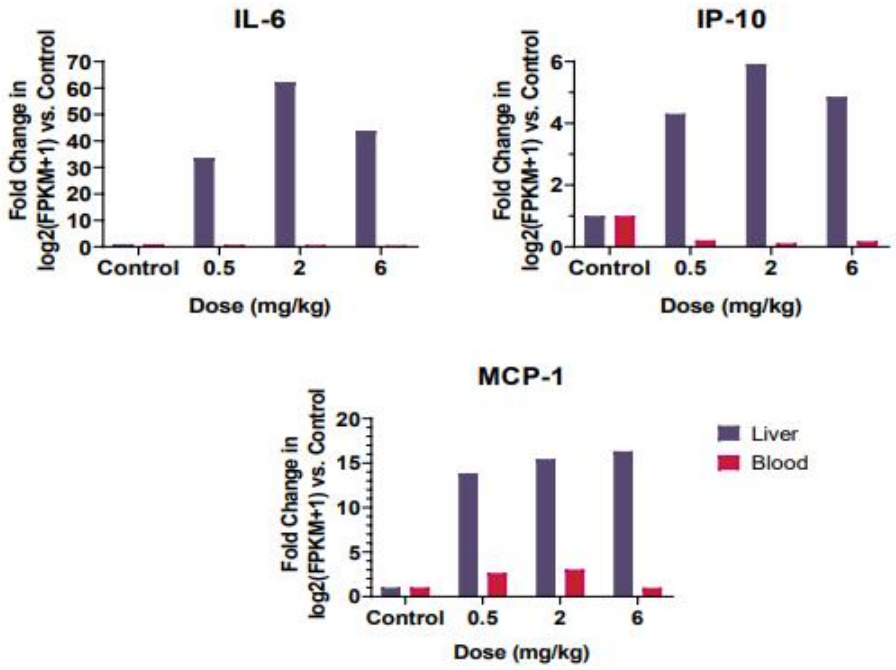
Because of the robust liver-localization of SBT8230, the systemic (serum) exposure of SBT8230 is distinct from SBT6050. As shown in the figure below, when SBT8230 and SBT6050 are dosed at equivalent dose levels, SBT8230 has far lower serum exposure than SBT6050 due to its efficient localization to liver. The mean estimated liver SBT8230 concentration at this dose in NHP was ~300-fold the maximum serum exposure, which is consistent with the reported liver to plasma exposure ratio of ~260 in NHP for the approved GalNAc-siRNA givosiran (US FDA Pharmacology Review, Givlaari).

Serum exposures of SBT8230 vs SBT6050 in NHP



Liver PD assessments demonstrate that the highly efficient liver uptake of SBT8230 in NHP leads to robust liver-localized PD effects. The figures below illustrate that RNA levels for multiple markers of myeloid cell activation in liver are markedly increased with SBT8230 treatment. Of note, PD effects at 0.5 mg/kg are similar overall to those at higher doses, indicating that maximal liver PD effects are achieved at this dose level. Based on the totality of our preclinical data, we believe that SBT8230 has the potential to induce pharmacological effects in the liver at doses as low as 0.03 mg/kg. This is below the lowest dose level evaluated for SBT6050, 0.15 mg/kg, that was found to be well-tolerated in patients.

SBT8230 Induced Cytokine mRNA in the Liver but not in Serum



The non-clinical safety and tolerability of SBT8230 has been assessed in two NHP toxicity studies. In a dose range finding non-GLP study, dose levels of 6, 12 and 25 mg/kg were administered every 2 weeks (Q2W) for 4 doses. The 6 and 12 mg/kg dose levels were well-tolerated. At the 25 mg/kg dose level the first dose was well tolerated, but the second or third doses were associated with toxicities that included injection site reactions. This dose level is >800-fold higher than the dose noted above (0.03 mg/kg) that is expected to be pharmacologically active in patients with HBV. Across all dose levels, there were transient, dose-related hematological, clinical chemistry, and cytokine and chemokine changes reflective of the potential mechanism of action of SBT8230. There was no evidence of cytokine release syndrome (CRS) or liver enzyme elevations observed at any dose level.

SBT8230 Phase 1-Enabling Study Update

We initiated a Phase 1-enabling GLP toxicology study in the first quarter of 2022. Dose levels of 6, 12 and 18 mg/kg were evaluated on a Q2W schedule for 4 doses. The in-life portion has recently completed, and bioanalytical assessments are now in progress. SBT8230 was generally well-tolerated. Two animals out of 26, one in the 12 mg/kg group and one in the 18 mg/kg group, displayed clinical signs consistent with ADA-mediated toxicity after the fourth and third doses, respectively, and were euthanized. Repeat administration of fully human or humanized proteins, such as the mAb in SBT8230, to NHP can frequently lead to the generation of ADA and development of associated toxicities, which have been extensively investigated over the years and found to generally not be predictive of toxicities in humans (van Meer 2013; Kronenberg 2017). Similar toxicities were also observed with SBT6050 in NHP studies (at 12 mg/kg dose level), but acute ADA-mediated toxicities were not observed in patients dosed with SBT6050.

As noted above, we believe that SBT8230 has the potential to be pharmacologically active in the liver at doses as low as 0.03 mg/kg in humans. Additional assessments (e.g., histopathology, PK, PD) are ongoing in the GLP toxicology study, and we believe that overall results of the study has the potential to provide favorable safety margins in support of the first-in-human study.

SBT8230 Next Steps

Upon completion of the GLP toxicology studies and GMP manufacturing of SBT8230, we plan to complete a Phase 1 regulatory submission in the fourth quarter of 2022, which includes an umbrella trial with a Phase 1 SAD study in healthy volunteers anticipated to start in the first half of 2023. GMP manufacturing of the antibody intermediate and ADC drug substance have been completed, with release testing in progress. Manufacturing and release of lyophilized SBT8230 drug product is on track to be completed in the third quarter of 2022. After completing the SAD study, we anticipate initiating a Phase 1 MAD study in patients with chronic HBV, who are virally suppressed on NRTI therapy.

Additional ImmunoTAC conjugates

In addition, our internal discovery programs are focused on evaluating and developing new antigen binding domains specific for targets of interest (including antibodies), next-generation linker technologies, and both agonist and antagonist small molecule payloads, that may be combined to create novel tissue-targeted antibody conjugates. The integration of medicinal chemistry, bioconjugation, protein engineering, bioinformatics, pharmacology, and translational medicine expertise focused on developing tissue-targeted therapies allows us to leverage key learnings from our previous clinical program to bring forward the next generation of therapeutics. We anticipate providing an update on our discovery pipeline in the fourth quarter of 2022.

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 tissue targeted therapies for the treatment of hepatitis B virus infections, cancer, and other serious diseases, 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 immune modulation and more specifically TLR-directed therapies. Companies engaging in TLR-directed therapies include Ambrx, Apros Therapeutics, Ascendis, BioNTech, Bolt Biotherapeutics, Bristol Myers Squibb, Checkmate Pharmaceuticals, CureVac, Exicure, Galderma, Gilead, Idera, Mologen, Nektar, Novartis, Primmune Therapeutics, Roche, Seven&Eight Biopharmaceuticals, Shanghai De Novo, Sumitomo Dainippon, Tallac Therapeutics, TriSalus, and UroGen. Other companies using antibody-drug conjugates to target innate immune receptors include Actym Therapeutics, Mersana, and Takeda Pharmaceuticals. Immunotherapy and validated pathway approaches are further being pursued by many smaller biotechnology companies as well as larger pharmaceutical companies. We also face competition from (i) validated pathway therapy treatments offered by companies such as AstraZeneca, Byondis, Daiichi Sankyo, Klus Pharma, MacroGenics, Pieris, Puma, RemeGen, Seagen, Spectrum Pharmaceuticals, and Zymeworks; (ii) companies that continue to invest in innovation in the antibody-drug conjugate field, including but not limited to AbbVie, ADC Therapeutics, Astellas, BioAtla, Bicycle Therapeutics, Celldex, CytomX, Eli Lilly and Company, GlaxoSmithKline, Genmab, ImmunoGen, Millennium Pharmaceuticals, MorphoSys AG, Novartis, Pfizer, Sanofi, Seagen, and Sutro Biopharma; and (iii) companies that are developing assets for the treatment of chronic HBV infection, which include 3SBio, AICuris, Albireo, Aligos, Allovir, Alnylam, Altimmune, Antios, Arbutus, Arcus, Arrowhead, Ascentage, Assembly Biosciences, Blue Jay Therapeutics, Bristol Myers Squibb, Door Pharmaceuticals, Enanta, ENYO Pharma, Excision Bio, Finch Therapeutics, GC Pharma, Gilead, GlaxoSmithKline, Golden Biotechnology Group, Grifols, HEC Pharm, Hepion, Immunocore, ISA pharmaceuticals, Johnson & Johnson, Kineta, Lupin Limited, Merck, Nucorion, Replicor, Roche, SciClone Pharma, Shanghai Henlius Group, Spring Bank, Tasly, TeneoTen, TRACON, Vaccitech, VBI Vaccines, VenatoRx, Vir, VLP Biotech, and Zydus Cadila.

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 we obtain marketing approval, 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 ImmunoTAC platform.

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.

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 ImmunoTAC platform and SBT8230. 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, 2022, our licensed and owned patent portfolio included five owned U.S. patents, 30 owned U.S. provisional and non-provisional patent applications, eight owned patent applications filed under the Patent Cooperation Treaty (PCT), 19 owned foreign patents, 118 owned foreign patent applications filed in a number of different foreign jurisdictions, 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 SBT8230, 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 ASGR1, 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 November 2042, 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 and Combination Therapies.** We have four issued U.S. patents with composition of matter, method of treatment, and method of making claims to TLR8 agonist payloads, linker-payloads and conjugates. The issued U.S. patents are projected to expire in March 2038, absent any patent term extensions. As of February 28, 2022, we have eight pending U.S. patent applications, one pending PCT application, 19 granted foreign patents, and 56 pending foreign patent applications filed in a number of different foreign jurisdictions, including 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 TLR8 agonists, conjugates and formulations, including substituted TLR8 agonist variants and conjugates, as well as claims to methods of administering TLR8 agonists and conjugates, to methods of treatment with TLR8 agonists and conjugates, in combination with other therapies. Any patents that issue from these pending patent applications are projected to expire between March 2038 and October 2040, 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.
- **Anti-ASGR1 Antibodies and Conjugates in Viral Infections.** As of February 28, 2022, we have five pending U.S. patent applications, one pending PCT application, and 37 pending foreign patent applications filed in a number of different foreign jurisdictions, including Australia, Brazil, Canada, China, European region, Hong Kong, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, and South Africa, with composition of matter claims and method of treatment claims directed to our product candidate, SBT8230, including claims directed to anti-ASGR1 antibodies, anti-ASGR1 antibody conjugates to TLR8 or TLR7 agonists, as well as to methods for treating viral infection, such as chronic HBV infections. Any patents that issue from these pending patent applications will expire between December 2038 and July 2041, absent any patent term adjustments or extensions. We own 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, which 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. Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including imposition of a clinical hold, refusal to approve marketing applications, withdrawal of an approval, import/export delays, issuance of warning letters and other types of enforcement letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal investigations and penalties.

Regulatory Approval in the United States

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (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 biologics license application (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 investigational new drug application (IND), which must become effective before human clinical trials may begin;
- approval by an institutional review board (IRB) or independent ethics committee at each clinical trial site before each clinical trial may be commenced;
- completion 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).

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 diseases 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.

International Regulation

In addition to regulations in the United States, 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 approval.

Other Healthcare Laws and Regulations and Legislative Reform

Healthcare and Privacy Laws and Regulations

Healthcare providers, including 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, including 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, the U.S. Department of Health and Human Services (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.
- The federal Health Insurance Portability and Accountability Act of 1996, as amended (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 the Health Information Technology for Economic and Clinical Health Act (HITECH), and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them, and their covered subcontractors, that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of such individually identifiable health information.
- 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), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members.
- 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.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to 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, 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 curtailment or restructuring of our operations.

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 June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is possible that the Patient Protection and Affordable Care Act ("PPACA") will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, and the healthcare reform measures of the Biden administration will impact the Affordable Care Act. 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 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, absent additional Congressional action. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. 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. 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 and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January1, 2023. 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 27, 2021, CMS issued a final rule that rescinded the Most Favored Nation interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. Congress is also considering additional health reform measures. 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 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 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. 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. Our periodic and current reports are available on our website, free of charge, as soon as reasonably practicable after filing. 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,” “Seeking Victory for Patients,” 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, 2021, we had 90 full-time employees. Of these employees, 31 held Ph.D., Pharm.D. or M.D. degrees, and 65 were engaged in research, development and technical operations. As of such date, we had 77 employees based at our headquarters and satellite office in Seattle, Washington. On March 28, 2022, our board of directors approved a corporate restructuring plan pursuant to which, among other things, our workforce will be reduced by 27%, with substantially all of the reduction in personnel expected to be completed by July 15, 2022. For further information, see Part II, Item 9B, “Other Information” in this Annual Report. 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. We believe that we have been successful in attracting and retaining talented personnel to support our expanding business, though competition for personnel in our industry is intense. We monitor recruiting efforts using a variety of metrics, including cycle times, cost per hire, information on the retention of business-critical hires (such as medical directors and executives), and the percentage of budgeted openings filled on time and on budget. We also track voluntary and involuntary turnover rates for business-critical talent, time in role, and job level.

We offer competitive pay and benefits designed to attract and retain exceptional talent and drive company performance. In setting appropriate compensation levels, we look at the average base pay rate for each position based on market data. We also offer an annual cash incentive program and long-term equity incentive plans designed to assist in attracting, retaining, and motivating employees and promoting the creation of long-term value for stockholders.

Our standard employee benefits include paid and unpaid leaves, medical, dental and vision insurance coverage, a 401(k) plan, short- and long-term disability, life insurance, flexible spending accounts, and an employee stock purchase plan. We also offer a variety of voluntary benefits that allow employees to select options that meet their needs, including a long-term care plan, telehealth, an employee assistance program, and wellness programs. We benchmark our benefits program against others in our industry on an annual basis.

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, business development, raising capital, developing and optimizing our technology platform, identifying potential product candidates, undertaking research and preclinical studies for our lead program and other development programs, undertaking clinical trials for our now discontinued SBT6050 and SBT6290 programs, establishing and enhancing our intellectual property portfolio, and providing general and administrative support for these operations. All of our 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, 2021 and 2020, our net losses were $89.5 million and $32.9 million, respectively. We expect that it will be several years, if ever, before we have a product candidate ready for regulatory approval and commercialization. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future as we advance our product candidates through clinical development. Our prior losses, combined with expected future losses, had and will continue to have an adverse effect on our stockholders' deficit and working capital.

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

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

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

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

Since our inception, we have used substantial amounts of cash to fund our operations and expect we will continue to incur significant losses for the foreseeable future. The development of biopharmaceutical product candidates is capital intensive. As our product candidates enter and advance through preclinical studies and potential 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, 2021, we had $319.1 million in cash, cash equivalents, restricted cash, and investments. Based upon our current operating plan, we estimate following our corporate restructuring plan approved in March 2022, that our existing cash, cash equivalents, restricted cash, and investments will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2026. However, we believe that our existing cash, cash equivalents, restricted cash, and investments will not be sufficient to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

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

- the initiation, trial design, progress, timing, costs and results of drug discovery, preclinical studies and clinical trials of our product candidates, and in particular future clinical trials for SBT8230;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing, and costs of seeking FDA, EMA and any other regulatory approvals;
- the costs of manufacturing our product candidates and commercial manufacturing activities;
- 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;
- our costs associated with expanding our facilities or building out our laboratory space;
- the effects of the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide from the COVID-19 pandemic; and
- the costs of operating as a public company.

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

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

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

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

The COVID-19 pandemic has had, and could continue to have, an adverse impact on our business, including on our preclinical studies 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 taken 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 were telecommuting, which 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 preclinical studies, future clinical trials 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 planned 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 clinical site initiation due to staff shortages at clinical sites or with our contract research organizations (CROs);
- delays or difficulties in enrolling patients in our planned clinical trials;
- difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our planned clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations and policies as part of a response to the COVID-19 outbreak, which may require us to change the ways in which our planned clinical trials are conducted including slower enrollment, and may result in unexpected costs or the clinical site discontinuing the clinical trial 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 planned 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 prior clinical trials for SBT6050 and SBT6290 were, and our future clinical trials may be, affected by the COVID-19 pandemic. For example, some of our prior clinical trial sites slowed down or stopped further enrollment of new patients in clinical trials, and otherwise curtailed certain operations. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be adversely impacted. Our 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 may need to make certain adjustments to the operation of our planned 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. Many of these adjustments may be 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 planned clinical trials, increase the cost of completing our planned clinical trials and negatively impact the integrity, reliability or robustness of the data from our planned 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 or CROs upon which we rely, or the availability or cost of materials or supplies, which could disrupt the supply chain for our product candidates or for performing preclinical studies. For example, we depend on the availability of various animals, including rodents and non-human primates, to conduct certain preclinical studies that we are required to complete prior to submitting an IND and initiating clinical development or to continue clinical development, including pharmacological and toxicology evaluations. There is currently a global shortage of animals available for drug development, due in part to an increase in demand from companies and other institutions developing vaccines and treatments for COVID-19. This has caused the cost of obtaining animals for our preclinical studies to increase dramatically and, if the shortage continues, could also result in delays to our development timelines. 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.

We face risks related to the health, safety, morale, and productivity of our employees, including the safe occupancy of our sites during the pandemic. In the third quarter of 2021, we transitioned to a return-to-site phase for our non-lab based employees. Our job site enhancements and risk protocols, which include health screenings and COVID-19 testing and vaccine requirements, do not guarantee that we can maintain the continued safe occupancy of our sites and may adversely impact employee recruitment and retention. On-site employees testing positive for COVID-19 could lead to mandatory quarantines and potential site shutdowns. In the fourth quarter of 2021 and continuing to the present, the Omicron variant affected our staff, our clinical sites, our CROs and our third-party manufacturers.

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 has or may continue to impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our preclinical studies and future 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 otherwise 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 planned clinical trials and our financing needs.

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

We are early in our development efforts and all of our product candidates and research programs are in preclinical development or discovery stage.

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. While we performed limited clinical trials for our now discontinued SBT6050 and SBT6290 programs, we have not begun clinical trials for any of our current product candidates or development programs. Our current product candidates remain in the preclinical and discovery stage. As a result, we have limited infrastructure, experience conducting clinical trials as a company and regulatory interactions, and cannot be certain that our 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 with favorable results;
- submission and acceptance of INDs by the FDA or similar regulatory filing by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- 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; 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 from our SBT8230 program, 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. Preclinical and clinical development is expensive and can take many years to complete, and their outcome is inherently 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 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. 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. For example, on March 28, 2022, we made the decision to discontinue our clinical development programs for SBT6050 and SBT6290 due to SBT6050 exhibiting limited monotherapy activity and dose-limiting adverse events when used in combination with pembrolizumab. 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 future clinical trials are inconclusive or if there are safety concerns or other adverse events associated with our product candidates, we may:

- incur unplanned costs;
- be delayed in or prevented from continuing clinical development and obtaining marketing approval for our product candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings including boxed warnings;
- be subject to changes or limitations in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a modified Risk Evaluation and Mitigation Strategy (REMS);
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Treatment of patients with chronic disease, such as HBV infection, with our product candidates may be used in combination with other drugs, such as monoclonal antibodies or other protein-based drugs, small molecule agents, and RNAi therapeutics which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our future clinical trials. Additionally, our product candidates could potentially cause adverse events. 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 planned clinical trials or commercializing any products on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA, EMA and other regulatory agencies 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 cHBV market is also rapidly developing and our competitors may introduce new technologies that effectively target the virus lifecycle or modulate the immune response to the virus that render our technologies obsolete or less attractive. New technology could emerge at any point in the development cycle of our product candidates.

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

If we experience delays or difficulties enrolling in our planned clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.

We may not be able to initiate or continue our planned clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of healthy volunteers or eligible patients to participate in these trials as required by the FDA or other regulatory agencies. Subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment or retention in our planned clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our planned clinical trials may compete with other clinical trials for product candidates 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. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development 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.

As we continue developing our product candidates and initiate any future clinical trials of our 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. Should we observe any SAEs in our planned 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 from our SBT8230 program, activate dendritic cells among other innate immune cells, which can amplify anti-drug antibodies. As a result, significant anti-drug antibodies (ADA) generation could neutralize the effects of SBT8230 by reducing exposure. The development of ADAs could also trigger hypersensitivity reactions that manifest as SAEs. If patients experience adverse events due to ADAs, our preclinical studies and future trials could be delayed or stopped and our development programs may be halted entirely if this is observed during clinical development. Even if ADAs are not detected in the early clinical trials, they may be detected after product launch and may significantly reduce the commercial potential or even result in the product being pulled from the market.

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

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

- regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is administered or conduct additional clinical trials;
- the product may become less competitive, and our reputation may suffer;
- we may decide to remove the product from the marketplace; and
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties.

Interim, topline and preliminary data from our preclinical studies or planned 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 or planned 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 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 planned 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.

The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our ability to generate revenue, our business and our results of operations.

The development, research, testing, manufacturing, labeling, approval, selling, import, export, marketing, promotion and distribution of drug products are subject to extensive and evolving regulation by federal, state and local governmental authorities in the United States, principally the FDA, and by foreign regulatory authorities, which regulations differ from country to country. Neither we nor any current or future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of a BLA from the FDA.

Obtaining regulatory approval of a BLA can be a lengthy, expensive and uncertain process. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate.

Results from preclinical studies and planned clinical trials can be interpreted in different ways. Even if we believe 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. Administering product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a product candidate for any or all indications. The FDA may also require us to conduct additional studies or trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program such as the number of subjects in our future clinical trials from the United States.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or the applicable foreign regulatory agency’s disagreement with the design or implementation of our planned clinical trials;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that our product candidates are safe and effective for the proposed indication;
- the FDA’s or the applicable foreign regulatory agency’s disagreement with the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA’s or the applicable foreign regulatory agency’s requirement for additional preclinical studies or clinical trials;
- the FDA’s or the applicable foreign regulatory agency’s disagreement regarding the formulation, labeling and/or the specifications of our product candidates;
- the FDA’s or the applicable foreign regulatory agency’s failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or other regulatory 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 our planned clinical testing and receive approval of a BLA or foreign marketing application for our product candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or in the case of the FDA, the implementation of a REMS, which may be required to ensure safe use of the drug after approval. The FDA or the applicable foreign regulatory agency also may approve a product candidate for a more limited indication or a narrower patient population than we originally requested, and the FDA or applicable foreign regulatory agency 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 materially adversely impact our business and prospects.

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.

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.

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. For example, on March 28, 2022, we made the decision to discontinue our clinical development programs for SBT6050 and SBT6290 and to prioritize resources on the development of SBT8230 and our early-stage discovery programs.

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 may rely on third parties to conduct, supervise, and monitor our planned 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 planned 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 any future clinical trials of our product candidates. Specifically, CROs that manage preclinical studies, GLP toxicology studies and our planned clinical trials as well as consultants play a significant role in the conduct of our preclinical studies and future clinical studies 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 future clinical trial sites fail to comply with applicable GLP or GCP requirements, the data generated in our preclinical studies and planned clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical or clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

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

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

We contract with third parties for the manufacture and supply of certain of our product candidates for use in preclinical testing and clinical trials and will rely on third parties for commercial supply, 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 from our SBT8230 program, 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 GLP 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 preclinical studies or 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, 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. Our product candidate targets mechanisms for which there are limited or no currently approved products, which may result in slower adoption by physicians, patients and payors. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

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

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

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

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

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

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

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

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

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

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

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 on developing tissue targeted therapeutics for the treatment of chronic viral infections, cancer, and other serious diseases, such as SBT8230 for cHBV. Our projections of addressable patient populations that have the potential to benefit from treatment with a current or future product candidate are based on estimates. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

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

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

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

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

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

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

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

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

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

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

Risks Related to Our In-Licenses and Other Strategic Agreements

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

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

These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in-license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, or if there are materially adverse impacts on our or the counterparty's operations resulting from COVID-19, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

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

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

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

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

Risks Related to Our Business Operations

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

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

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

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

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

We believe our product liability insurance coverage is sufficient in light of our current 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 infectious disease, such as cHBV, 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 and restricted stock units that vest over time. The value to employees of stock options and restricted stock units 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, 2021, we had 90 employees which represents an increase of 34 employees since January 1, 2021. However, on March 28, 2022, we approved a corporate restructuring plan to discontinue our clinical development programs for SBT6050 and SBT6290 and in connection with this plan, our workforce will be reduced by 27%, with substantially all of the reduction in personnel expected to be completed by July 15, 2022. 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 treatments for infectious diseases. 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 immune modulation and more specifically TLR-directed therapies. Companies engaging in TLR-directed therapies include Ambrx, Apros Therapeutics, Ascendis, BioNTech, Bolt Biotherapeutics, Bristol Myers Squibb, Checkmate Pharmaceuticals, CureVac, Exicure, Galderma, Gilead, Idera, Mologen, Nektar, Novartis, Primmune Therapeutics, Roche, Seven&Eight Biopharmaceuticals, Shanghai De Novo, Sumitomo Dainippon, Tallac Therapeutics, TriSalus, and UroGen. Other companies using antibody-drug conjugates to target innate immune receptors include Actym Therapeutics, Mersana, and Takeda Pharmaceuticals. Immunotherapy and validated pathway approaches are further being pursued by many smaller biotechnology companies as well as larger pharmaceutical companies. We also face competition from (i) validated pathway therapy treatments offered by companies such as AstraZeneca, Byondis, Daiichi Sankyo, Klus Pharma, MacroGenics, Pieris, Puma, RemeGen, Seagen, Spectrum Pharmaceuticals, and Zymeworks; (ii) companies that continue to invest in innovation in the antibody-drug conjugate field, including but not limited to AbbVie, ADC Therapeutics, Astellas, BioAtla, Bicycle Therapeutics, Celldex, CytomX, Eli Lilly and Company, GlaxoSmithKline, Genmab, ImmunoGen, Millennium Pharmaceuticals, MorphoSys AG, Novartis, Pfizer, Sanofi, Seagen, and Sutro Biopharma; and (iii) companies that are developing assets for the treatment of chronic HBV infection, which include 3SBio, AICuris, Albireo, Aligos, Allovir, Alnylam, Altimmune, Antios, Arbutus, Arcus, Arrowhead, Ascentage, Assembly Biosciences, Blue Jay Therapeutics, Bristol Myers Squibb, Door Pharmaceuticals, Enanta, ENYO Pharma, Excision Bio, Finch Therapeutics, GC Pharma, Gilead, GlaxoSmithKline, Golden Biotechnology Group, Grifols, HEC Pharm, Hepion, Immunocore, ISA pharmaceuticals, Johnson & Johnson, Kineta, Lupin Limited, Merck, Nucorion, Replicor, Roche, SciClone Pharma, Shanghai Henlius Group, Spring Bank, Tasly, TeneoTen, TRACON, Vaccitech, VBI Vaccines, VenatoRx, Vir, VLP Biotech, and Zydus Cadila.

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 current law, 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.

As of December 31, 2021, we had $160.3 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 $142.1 million can be carried forward indefinitely under current law. As of December 31, 2021, we also had aggregate U.S. federal research and development (R&D) credits of approximately $2.7 million. Our NOL carryforwards and R&D credits are subject to review and possible adjustment by the U.S. and state tax authorities.

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

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims, including the False Claims Act, which can be enforced through whistleblower actions, and Civil Monetary Penalties Laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them, and their covered subcontractors, that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of such individually identifiable health information;
- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

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

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

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

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

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2031, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless Congress takes additional action. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

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 and guidance in September 2020, providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation (MFN) executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the MFN model, on December 27, 2021, CMS published a final rule that rescinded the MFN interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of other health reform 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.

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

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

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

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

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

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

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

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation, and/or adverse publicity and could negatively affect our operating results and business.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. For example, we may obtain clinical trial data from research institutions. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, numerous federal, state, and local 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. For example, HIPAA as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information.

The California Consumer Privacy Act (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 allows for statutory fines for noncompliance (up to $7,500 per violation). Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, it is anticipated that the California Privacy Rights Act of 2020 (the CPRA), effective January 1, 2023, will expand the CCPA. Additionally, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. At this time, we do not collect personal information relating to residents of California, but should we begin to do so, the CCPA and CPRA will impose new and burdensome privacy compliance obligations on our business and will raise new risks for potential fines and class actions.

Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. Additionally, several states and localities have enacted statutes banning or restricting the collection of biometric information. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts. Privacy advocates and industry groups have also regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation (the EU GDPR), the United Kingdom's GDPR (the UK GDPR), Brazil's General Data Protection Law (the Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018), and China's Personal Information Protection Law (the PIPL) impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to processing of their personal data.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area (the EEA) that the European Commission does not consider to provide an adequate level of data privacy and security, such as the United States. The European Commission released a set of "Standard Contractual Clauses" (the SCCs) that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these Standard Contractual Clauses are a valid mechanism to transfer personal data outside of the EEA, but there exists some uncertainty regarding whether the SCCs will remain a valid mechanism. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense. 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.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we or our collaborators and third-party providers fail, or are perceived to have failed, to comply with U.S. and foreign data privacy and security laws and regulations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e,g,, investigations, fines, penalties, audits, inspections, and similar), private litigation (including class-related claims), additional reporting requirements and/or oversight, bans on processing personal data, orders to destroy or not use personal data, and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to, loss of customers, interruptions or stoppages in our business operations (including, as relevant, clinical trials), inability to process personal data or to operate in certain jurisdictions, limited ability to develop or commercialize our products, expenditure of time and resources to defend any claim or inquiry, adverse publicity, or revision or restructuring of our operations. 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 privacy and security laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

As a public company, we are subject to requirements of the Sarbanes-Oxley Act, the rules and regulations of the Nasdaq Global Market, the rules and regulations of the Securities and Exchange Commission. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time-consuming and costly and place significant strain on our personnel, systems and resources. Company responsibilities required by the Sarbanes-Oxley Act include, among other things, that we maintain corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Securities Exchange Act of 1934, as amended (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 legislation informally titled the Tax Cuts and Jobs Act (the Tax Act) enacted in 2017 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, legislation enacted on March 27, 2020, entitled the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) modified certain provisions of the Tax Act, and it is possible that the Biden administration and Congress may enact proposed legislation that could have an adverse effect on our operations, cash flows and results of operations and contribute to overall market volatility. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

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

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

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

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

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

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;

- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

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

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

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

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

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

We rely, in part, on license and other strategic agreements, which subject us to various obligations, including payment obligations for achievement of certain milestones on product sales. For example, with respect to SBT8230, we have licensed a cell line to manufacture a component of this product 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 ImmunoTAC conjugate SBT8230. These patents may expire prior to commercial launch of SBT8230, 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 preclinical studies, initiate and continue planned clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

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

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

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

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

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

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

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

Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

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

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

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our product candidate, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity incident) 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, CROs, 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 future clinical trials with our current and future product candidates or of our competitors;
- adverse results or delays in preclinical studies or prior and future clinical trials;
- failure to commercialize our product candidates;
- unanticipated serious safety concerns related to the use of our product candidates;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to future product candidates or clinical development programs;
- our failure to achieve product development goals in the timeframe we announce;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock;
- the expiration of market standoff or contractual lock-up agreements;
- the size of our market float;
- political uncertainty and/or instability in the United States;
- the ongoing and future impact of the COVID-19 pandemic and actions taken to slow its spread; and
- any other events or factors discussed in this report.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many immune-oncology companies. Stock prices of many immune-oncology companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. The trading prices for common stock of other biopharmaceutical companies have also been highly volatile as a result of the COVID-19 pandemic. In the past, stockholders have filed securities class action lawsuits following periods of market volatility. For example, following a decline in our stock price, a federal securities class action complaint was filed against us and certain of our officers and directors in the U.S. District for the Western District of Washington, captioned Dresner v. Silverback Therapeutics, Inc., et al., Case No. 2:21-cv-01499, which alleges violations of (i) Sections 11 and 15 of the Securities Act of 1933, as amended (the Securities Act); and (ii) Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder. Even if we are successful in defending against this action or any similar claims that may be brought in the future, such litigation could subject us to substantial costs, divert resources and the attention of management from our business, and adversely affect our business.

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

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

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

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. As of December 31, 2021, we had 35,133,934 outstanding shares of our common stock.

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

As a result of the COVID-19 pandemic and actions taken to slow its spread, as well as actual or perceived changes in interest rates and economic inflation, the global credit and financial markets have 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. In addition, government efforts to stimulate economic activity in the face of the COVID-19 pandemic have caused interest rates to fluctuate and created uncertainty as to future fluctuations. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

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

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

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

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

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

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

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

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

We are subject to securities class action litigation and may be subject to additional litigation in the future.

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

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

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

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

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

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

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

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

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

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

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

Our amended and restated certificate of incorporation designates the state courts the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, and the federal district courts of the United States of America to be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or 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.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that 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. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and 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. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations, and prospects.

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, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

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

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, share, and transmit (collectively, processing) proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and proprietary business information (collectively, sensitive information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such sensitive information. We also have outsourced elements of our operations to third parties, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions, and as a result we manage a number of third-party contractors who have access to our sensitive information. Moreover, we may share or receive sensitive information with or from third parties. Our ability to monitor these third parties' information security practice, is limited, and these third parties may not have adequate information security measures in place.

Despite the implementation of security measures, given the size and complexity and the increasing amounts of sensitive information that we maintain, our internal information technology systems and those of our third-party CROs and other contractors and consultants are potentially vulnerable to cyberattacks, malicious internet-based activity, and online and offline fraud. These threats are prevalent, continue to increase, and are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actor. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to from cyberattacks by malicious third parties (including but not limited to malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), ransomware attacks, denial-of-service attacks (such as credential stuffing), social engineering attacks (including through phishing attacks), supply-chain attacks and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), personnel misconduct or error, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats which may compromise our system infrastructure or lead to data leakage. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services. The COVID-19 pandemic and our remote workforce also poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections outside our premises. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

Any of the previously identified or similar threats could cause a security incident or other interruption. To the extent that any disruption or security incident were to result in unauthorized, unlawful, or accidental acquisition, modification, destruction, a loss, alteration, encryption, disclosure of, or access to sensitive information, we could incur liability and reputational damage and the further development and commercialization of our product candidates could be delayed.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information. We cannot assure you that our data privacy and security efforts and our investment in information technology will prevent significant breakdowns or security incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. 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.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business.

Additionally, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations.

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 preclinical studies and future clinical trials, our development plans and business.

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. In addition, we lease approximately 9,166 square feet of office space in Seattle, Washington pursuant to a lease that commenced on August 1, 2021 and expires on July 31, 2023. 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.

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

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 March 15, 2022, there were approximately eight holders of record of our common stock. Because most of our common stock is held by brokers, nominees, and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

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

None.

Use of Proceeds

On December 3, 2020, we commenced our initial public offering (IPO) 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.

The net proceeds from our IPO are held in cash and cash equivalents, primarily in treasury money market accounts, and investments, primarily in U.S. Treasury securities. Through December 31, 2021, we have used approximately $45.0 million of the net proceeds from our IPO.

The following information updates the planned use of proceeds information from our IPO that we previously disclosed in the final prospectus filed with the SEC pursuant to Rule 424(b)(4) of the Securities Act on December 4, 2020: we intend to use the remaining net proceeds from the IPO, together with our existing cash and cash equivalents, to fund the development of our SBT8230 program for cHBV, including IND-enabling studies, a Phase 1 SAD study, and a Phase 1 MAD study. We intend to use the remainder to fund our other research and development activities, including activities related to our internal discovery programs, as well as for working capital and other general corporate purposes. We may also use a portion of the net proceeds from the IPO to in-license, acquire or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

Issuer Purchases of Equity Securities

Not applicable.

Item 6. [Reserved]

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 biopharmaceutical company focused on leveraging our proprietary ImmunoTAC technology platform to develop systemically delivered, tissue targeted therapeutics for the treatment of chronic viral infections, cancer, and other serious diseases. 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. Our platform enables us to strategically pair proprietary linker-payloads that modulate key disease-modifying pathways with monoclonal antibodies directed to specific disease sites. Many potentially promising systemic therapies fail to maximize their therapeutic potential due to toxicities in healthy tissues. Our approach is designed to expand the therapeutic window and avert unacceptable toxicities by directly targeting specific disease sites where our therapeutics are locally active.

In July 2020, we initiated clinical development of our first ImmunoTAC product candidate, a TLR8 agonist conjugated to a HER2 antibody, SBT6050. Preclinical data suggested that we would be able to demonstrate a therapeutic window and advance SBT6050 through clinical development as a monotherapy and in combination with standard-of-care agents that had a complementary mechanism-of-action. Our Phase 1/1b program was designed to measure safety and tolerability, PK, PD and anti-tumor activity as monotherapy and in combination with pembrolizumab. On March 28, 2022, we made the decision to discontinue our clinical development program for SBT6050 due to limited monotherapy activity and dose-limiting adverse events when used in combination with pembrolizumab. SBT6290, comprised of the same linker payload conjugated to a Nectin4 antibody was expected to show a similar clinical profile and, therefore, we also terminated this program prior to dosing patients. We have prioritized our resources to focus on the development of SBT8230 and early-stage discovery programs.

Our understanding of TLR8 conjugates in preclinical species and in the clinic guides our interpretation of the preclinical characteristics of SBT8230, an ASGR1 antibody conjugated to a TLR8 agonist linker payload for the treatment of cHBV, which is currently in preclinical development. ASGR1 is highly expressed in liver and is restricted in its expression to this organ. Other ASGR1-directed agents, such as those used in RNAi therapies, have shown robust liver localization. SBT8230 shows biodistribution profiles in NHP consistent with these agents, which is distinct from SBT6050 and SBT6290. We believe that efficient liver targeting of SBT8230 via ASGR1 binding has the potential to lead to markedly lower serum exposures of SBT8230 in patients compared to those observed with SBT6050 in the clinic at any dose evaluated. We believe the preclinical to clinical experience for SBT6050, coupled with the NHP PK, PD, and tolerability data for SBT8230, suggest that the clinical safety, PK and PD profiles for SBT8230 has the potential to be notably different than those for SBT6050, given the large differences in serum exposures and overall conjugate disposition for SBT8230 that are expected in patients due to its efficient liver targeting. SBT8230 is designed to elicit an anti-viral immune response by targeting TLR8 activation to the liver. The anti-viral immune response is achieved through activation of myeloid cells and subsequent activation of immune cells that drive an IFNγ signal, which has been observed in the clinic with SBT6050. This has been shown by others to drive seroconversion, an important determinant of a functional cure. We see a significant opportunity in liver-localized immunotherapies as a potential way of achieving durable responses in these patients. We are focused on advancing SBT8230, our liver-targeted conjugate designed to potently activate human myeloid cells in the liver for the treatment of cHBV.

Further support for investigating TLR8 agonism for the treatment of cHBV comes from selgantolimod (GS-9688), an existing untargeted, orally administered TLR8 agonist being developed by Gilead Sciences. Selgantolimod has 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 cure, which is defined as sustained loss of HBsAg in the blood, in patients suffering from cHBV. We presented a preclinical update on SBT8230 in the fourth quarter of 2021. In the first quarter of 2022, we began a Phase 1-enabling toxicology study. We plan to complete a Phase 1 regulatory submission in the fourth quarter of 2022 and begin a Phase 1 SAD study in healthy volunteers in the first half of 2023. After completing the SAD study, we anticipate initiating a Phase 1 MAD study in patients with chronic HBV, who are virally suppressed on NRTI therapy.

In addition, our internal discovery programs are focused on evaluating and developing new antigen binding domains specific for targets of interest (including antibodies), next-generation linker technologies, and both agonist and antagonist small molecule payloads, that may be combined to create novel tissue-targeted antibody conjugates. The integration of medicinal chemistry, bioconjugation, protein engineering, bioinformatics, pharmacology, and translational medicine expertise focused on developing tissue-targeted therapies allows us to leverage key learnings from our previous clinical program to bring forward the next generation of therapeutics. We anticipate providing an update on our discovery pipeline in the fourth quarter of 2022.

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

Program	Target / Payload	Indication(s)	Preclinical Studies	Phase 1	Phase 2	Anticipated Milestones
SBT8230	ASGR1 TLR8 Agonist	cHBV				• 4Q 2022 – Phase 1 regulatory submission • 1H 2023 – Open enrollment for Phase 1 SAD study in healthy volunteers
Discovery Stage Pipeline						
Undisclosed	Undisclosed	Multiple				• 4Q 2022 – Preclinical update

ASGR1 = Asialoglycoprotein Receptor 1 (Liver Localized Protein)
cHBV = Chronic Hepatitis B Virus
SAD = Single Ascending Dose
TLR8 = Toll Like Receptor 8

We have incurred significant operating losses since our inception. As of December 31, 2021, we had an accumulated deficit of $186.2 million. Our net losses were $89.5 million and $32.9 million for the years ended December 31, 2021 and 2020, respectively. Our losses have resulted primarily from 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 we will continue to incur significant losses for the foreseeable future as we continue our development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products, seek to expand our product pipeline, invest in our organization and technology platform, as well as incur expenses associated with operating as a public company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on a variety of factors including the timing and scope of our preclinical studies and clinical trials. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses or other similar arrangements.

On March 28, 2022, our board of directors approved a corporate restructuring plan to discontinue our clinical development programs for SBT6050 and SBT6290 and to prioritize resources on the development of SBT8230 and early-stage discovery programs (the Restructuring Plan). In connection with the Restructuring Plan, our workforce will be reduced by 27%, with substantially all of the reduction in personnel expected to be completed by July 15, 2022. We initiated the reduction in force on March 31, 2022 and expect to provide severance payments, continuation of group health insurance coverage, and other benefits for a specified period to the affected employees. We currently estimate that we will incur costs of approximately $2.0 million for termination benefits related to the Restructuring Plan, all of which will be cash expenditures paid in 2022.

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.

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. 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 decrease in 2022 due to discontinuation of the clinical development of SBT6050 and SBT6290 and the Restructuring Plan. However, following 2022, we expect that our research and development expenses will begin to increase again for the foreseeable future as we continue the development of our preclinical and discovery programs, particularly as they 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 these future preclinical studies and clinical trials 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 decrease in 2022 due to the Restructuring Plan. However, following 2022, we expect that our general and administrative expenses will begin to increase again to the extent needed to support growth in our research and development activities. We also expect to continue 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, cash equivalents, and long-term investments carried at fair value, and interest expense on our borrowings.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020:

	Years Ended December 31,		Dollar Change	% Change
	2021	2020		
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 61,501	$ 24,577	$ 36,924	150%
General and administrative	28,083	8,341	19,742	237
Total operating expenses	89,584	32,918	56,666	172
Loss from operations	(89,584)	(32,918)	(56,666)	172
Interest income (expense), net	106	(29)	135	*
Net loss	$ (89,478)	$ (32,947)	$ (56,531)	172%

* *Not meaningful*

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2021 and 2020:

	Years Ended December 31,		Dollar Change	% Change
	2021	2020		
	(in thousands, except percentages)			
Direct costs:				
SBT6050	$ 15,150	$ 4,710	$ 10,440	222%
SBT6290	9,217	3,049	6,168	202
Preclinical programs	7,932	3,059	4,873	159
Total direct costs	32,299	10,818	21,481	199
Indirect costs:				
Personnel-related expenses, including stock-based compensation	23,045	9,657	13,388	139
Facility and equipment related expenses	2,972	2,426	546	23
Other unallocated research and development expenses	3,185	1,676	1,509	90
Total research and development expenses	$ 61,501	$ 24,577	$ 36,924	150%

An investigational new drug application for SBT6290 was cleared by the FDA in the fourth quarter of 2021 and we opened enrollment for a Phase 1 clinical trial of SBT6290 in the first quarter of 2022, which is now discontinued. As a result, we have separated direct costs for the development of SBT6290 from preclinical programs for the year ended December 31, 2021 and, for comparability purposes, the year ended December 31, 2020. This change had no effect on net loss, total research and development expenses, stockholders' equity, or cash flows as previously reported.

Research and development expenses were $61.5 million and $24.6 million for the years ended December 31, 2021 and 2020, respectively. The increase of $36.9 million was due primarily to an increase of $10.4 million in direct costs related to the development of SBT6050 as we continued to advance the program through a Phase 1/1b clinical trial. The increase was also due to an increase of $6.2 million in direct costs related to the development of SBT6290 as we advanced the program through FDA clearance of its investigational new drug application and prepared to initiate a Phase 1 clinical trial in the first quarter of 2022 and due to an increase in direct costs for our preclinical programs of $4.9 million as we continued to advance SBT8230 and other preclinical research efforts. The remaining increase was due to increases in personnel-related expenses of $13.4 million resulting from increased headcount during the year ended December 31, 2021 as well as increases in salaries, bonuses, stock-based compensation, and recruiting expenses. To a lesser extent, the increase in research and development expenses was due to facility and equipment related expenses of $0.5 million, and other unallocated research and development expenses of $1.5 million.

General and Administrative Expenses

General and administrative expenses were $28.1 million and $8.3 million for the years ended December 31, 2021 and 2020, respectively. The increase of $19.7 million was due primarily to an increase of $13.5 million in personnel-related expenses due to increased headcount during the year ended December 31, 2021, including executives that were new in 2020 being present for a full year in 2021, as well as increases in salaries, bonuses, stock-based compensation, and recruiting expenses. To a lesser extent, the increase in general and administrative expenses was due to an increase in professional fees of $5.4 million primarily attributable to legal, insurance, and outside consultant costs, and $0.8 million in other various general and administrative expenses as we operated as a public company for the full year of 2021.

Interest Income (Expense), Net

Interest income (expense), net was $0.1 million and $(29,000) for the years ended December 31, 2021 and 2020, respectively. The change of $0.1 million was primarily due to a decrease in principal on our notes payable and an increase in our cash balance. Also contributing to the change was the investment in higher interest-bearing assets during the period.

Liquidity and Capital Resources

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

As of December 31, 2021, we had $319.1 million in cash, cash equivalents, restricted cash, and investments. The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2021 and 2020:

	Years Ended December 31,	
	2021	2020
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (66,760)	$ (31,196)
Investing activities	(66,478)	(917)
Financing activities	614	408,506
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ (132,624)	$ 376,393

Operating Activities

During the year ended December 31, 2021, net cash used in operating activities was $66.8 million. This consisted primarily of a net loss of $89.5 million, partially offset by non-cash charges of $21.2 million and a decrease in our operating assets and liabilities of $1.5 million. The non-cash charges primarily consisted of stock-based compensation expense of $19.2 million, non-cash lease expense of $1.2 million, and depreciation expense of $0.8 million. The decrease in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses of $6.0 million. The decrease was partially offset by a decrease in lease liability of $1.1 million and an increase in prepaid expenses and other assets of $3.4 million.

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 charges of $4.4 million. The charges primarily consisted of stock-based compensation expense of $2.6 million, 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 items. The increase in prepaid expenses and other assets was primarily due to the purchase of $2.6 million in prepaid insurance.

Investing Activities

During the year ended December 31, 2021, cash used in investing activities was $66.5 million. This consisted of purchases of U.S. Treasury Securities of $65.1 million and purchases of property and equipment of $1.4 million.

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

Financing Activities

During the year ended December 31, 2021, cash provided by financing activities was $0.6 million. This was primarily driven by proceeds from the exercise of common stock options and the employee stock purchase plan of $1.5 million, which was partially offset by $0.8 million of principal payments on the term loan payable.

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 the term loan payable of $0.7 million.

Future Funding Requirements

We believe that our cash, cash equivalents, restricted cash, and investments of $319.1 million at December 31, 2021 will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2026 following the Restructuring Plan. 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 discovery, preclinical studies and clinical trials of our product candidates, and in particular future clinical trials for SBT8230;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking FDA, EMA and any other regulatory approvals;
- the costs of manufacturing our product candidates and commercial manufacturing activities;
- 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;
- our costs associated with expanding our facilities or building out our laboratory space;
- the effects of the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide from the COVID-19 pandemic; and
- the costs of operating as a public company.

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

Material Cash Requirements

Our material cash requirements include the following contractual and other obligations as of December 31, 2021:

	Payments Due by Period				
	Total	Less than 1 year	1-3 Years	3-5 Years	More than 5 years
Operating lease obligations (1)	$ 6,917	$ 1,481	$ 4,250	$ 1,186	$ —
Total	$ 6,917	$ 1,481	$ 4,250	$ 1,186	$ —

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

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, 2021 and 2020, 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 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 vendors for clinical studies, 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.

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.

Our significant accounting policies are more fully described in Note 2 to our audited financial statements appearing in Part II, Item 8 of this Annual Report on Form-10-K. Not all of our significant accounting policies require that we make estimates and assumptions that we believe are critical accounting estimates. Our estimates relating to research and development expenses, stock-based compensation, and income taxes have had or are reasonably likely to have a material impact on our financial statements and we consider them to be our critical accounting policies and critical accounting estimates.

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, 2021, we had net operating loss carryforwards for income tax purposes of approximately $160.3 million. If not used, $18.2 million of this carryforward will begin to expire in 2036 and $142.1 million has no expiration. We also have research and development tax credits of approximately $2.7 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, 2021, 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 date upon which we are deemed to be a “large accelerated filer,” as defined in Rule 12b-2 under the Exchange Act; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt securities during the prior three-year period; and (iv) December 31, 2025.

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 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, 2021 and 2020, the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the two years then ended, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years then ended 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 Company 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 31, 2022

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 254,045	$ 386,569
Prepaid expenses and other current assets	7,447	4,087
Total current assets	261,492	390,656
Investments	64,780	—
Restricted cash	250	350
Right-of-use assets	4,733	2,180
Property and equipment, net	2,212	1,618
Total assets	$ 333,467	$ 394,804
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,078	$ 2,583
Accrued expenses	11,727	5,278
Term loan payable, net	—	844
Current portion of lease liability	1,087	896
Total current liabilities	14,892	9,601
Lease liability, net of current portion	4,760	2,326
Total liabilities	19,652	11,927
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred Stock, $0.0001 par value per share; 10,000,000 shares authorized at December 31, 2021 and 2020; no shares issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at December 31, 2021 and 2020, 35,133,934 and 34,801,537 shares issued and 35,107,651 and 34,701,274 shares outstanding at December 31, 2021 and 2020, respectively	4	3
Additional paid-in capital	500,349	479,608
Accumulated other comprehensive loss	(326)	—
Accumulated deficit	(186,212)	(96,734)
Total stockholders' equity	313,815	382,877
Total liabilities and stockholders' equity	$ 333,467	$ 394,804

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,	
	2021	**2020**
Operating expenses:		
Research and development	$ 61,501	$ 24,577
General and administrative	28,083	8,341
Total operating expenses	89,584	32,918
Loss from operations	(89,584)	(32,918)
Interest income (expense), net	106	(29)
Net loss	$ (89,478)	$ (32,947)
Unrealized loss on available-for-sale securities	(326)	—
Comprehensive loss attributable to common stockholders	$ (89,804)	$ (32,947)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.56)	$ (11.33)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	34,926,403	2,907,542

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	Accumulated Other Comprehensive Loss	Accumulated	Total Stockholders' 'Equity
	Shares	Amount	Shares	Amount	Capital		Deficit	(Deficit)
Balance as of January 1, 2020	15,714,283	$ 53,174	664,431	$ —	$ 5,010	$ —	$ (63,787)	$ (58,777)
Issuance of Series B redeemable convertible preferred stock for cash, net of $76 in issuance costs (Note 8)	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 upon conversion of convertible notes	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 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
Exercise of common stock options, shares issued under the employee stock purchase plan, and vesting of early exercised common stock options	—	—	406,377	1	1,554	—	—	1,555
Stock-based compensation	—	—	—	—	19,187	—	—	19,187
Net loss and comprehensive loss	—	—	—	—	—	(326)	(89,478)	(89,804)
Balance as of December 31, 2021	—	$ —	35,107,651	$ 4	$ 500,349	$ (326)	$ (186,212)	$ 313,815

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31, 2021	2020
Cash flows from operating activities:		
Net loss	$ (89,478)	$ (32,947)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	783	637
Stock-based compensation	19,187	2,640
Non-cash lease expense	1,146	1,073
Amortization of debt issuance costs	2	31
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,360)	(3,535)
Accounts payable and accrued expenses	6,034	1,790
Lease liability	(1,074)	(885)
Net cash used in operating activities	(66,760)	(31,196)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(65,106)	—
Purchase of property and equipment	(1,372)	(917)
Net cash used in investing activities	(66,478)	(917)
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)
Principal payments on term loan payable	(846)	(700)
Proceeds from exercise of common stock options and employee stock purchase plan	1,460	177
Net cash provided by financing activities	614	408,506
Change in cash, cash equivalents, and restricted cash	(132,624)	376,393
Cash, cash equivalents, and restricted cash at beginning of period	386,919	10,526
Cash, cash equivalents, and restricted cash at end of period	$ 254,295	$ 386,919
Supplemental disclosure of cash flow information:		
Unpaid initial public offering costs included in accounts payable and accrued expenses	$ —	$ 339
Right-of-use assets and lease liabilities recognized	$ 3,699	$ —
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.

1. Nature of Business

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

Initial Public Offering

In December 2020, the Company completed its initial public offering of common stock ("IPO") of 13,225,000 shares of common stock 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. Additionally, 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") in anticipation of the IPO. 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.

Risks and Uncertainties

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

Liquidity and Capital Resources

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred net operating losses since its inception and had an accumulated deficit of $186.2 million as of December 31, 2021. The Company had cash, cash equivalents, restricted cash, and investments of $319.1 million as of December 31, 2021 and has not generated positive cash flows from operations. To date, the Company has funded its operations primarily through the issuance of redeemable convertible preferred stock, convertible notes, and the sale of common stock in connection with the IPO. The Company's currently available cash, cash equivalents, restricted cash, and investments as of December 31, 2021 are sufficient to meet its anticipated cash requirements for at least the 12 months following the date the financial statements are issued. Management considers that there are no conditions or events, in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern for a period of at least 12 months from the date the financial statements are issued.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Use of Estimates

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

The full extent to which the coronavirus ("COVID-19") pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including expenses, clinical trial 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.

Fair Value of Financial Instruments

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

Cash and Cash Equivalents

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

Restricted Cash

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

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, 2021	December 31, 2020
Cash and cash equivalents	$ 254,045	$ 386,569
Restricted cash	250	350
Total cash and cash equivalents and restricted cash	$ 254,295	$ 386,919

Investments

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

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

Concentrations of Credit Risk

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

Prepaid Expenses and Other Assets

Prepaid expenses consist primarily of operating expenses paid in advance of when services are provided.

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

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

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

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, 2021.

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

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

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 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 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, 2021 and 2020.

Comprehensive Loss

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

Net Loss Per Share Attributable to Common Stockholders

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

Emerging Growth Company Status

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

Recently Issued Accounting Pronouncements Not Yet Adopted

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

3. Fair Value Measurements

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

Level 1: Quoted prices in Active Markets for identical assets or liabilities.

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

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

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

December 31, 2021	Level	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Fair Value
Money market funds	1	$ 253,945	$ —	$ —	$ 253,945
Long-term investments - U.S. Treasury securities	1	65,106	—	(326)	64,780
Total		319,051	—	(326)	318,725
December 31, 2020					
Money market funds	1	$ 386,369	$ —	$ —	$ 386,369

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

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

4. Property and Equipment, Net

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

	December 31, 2021	December 31, 2020
Furniture and fixtures	$ 367	$ 269
Laboratory equipment	4,679	3,401
Property and equipment, gross	5,046	3,670
Less accumulated depreciation	(2,834)	(2,052)
Total property and equipment, net	$ 2,212	$ 1,618

Depreciation expense was $0.8 million and $0.6 million for the years ended December 31, 2021 and 2020, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Research and development expenses	$ 6,528	$ 2,063
Employee compensation and benefits	4,605	2,634
Professional services and other	594	581
Total accrued expenses	$ 11,727	$ 5,278

6. Leases

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

	Years Ended December 31,	
	2021	2020
Lease expense		
Operating lease expense	$ 1,452	$ 1,388
Variable lease expense	459	386
Total lease expense	1,911	1,774
Operating cash outflows from operating leases	$ 1,841	$ 1,591

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

The weighted-average remaining term on the Company's leases was 4.7 years and 1.8 years as of December 31, 2021 and 2020, respectively. To compute the present value of the lease liabilities, the Company used weighted average discount rates of 7.5% and 8.5% as of December 31, 2021 and 2020, respectively.

During the year ended December 31, 2021, there was a change in the expected lease term of the Company’s Seattle, Washington headquarters, whereby the Company became reasonably certain that it will not exercise its option to terminate the lease. As a result, the ROU asset and lease liability were remeasured using the present value of the remaining lease payments. The re-measurement resulted in an addition to the ROU asset and lease liability of $3.1 million. The change in the expected lease term has no effect on the classification of the lease.

Future minimum commitments due under the operating lease agreements as of December 31, 2021 are as follows (in thousands):

Years Ended December 31,	Amount
2022	1,481
2023	1,513
2024	1,348
2025	1,389
Thereafter	1,186
Total undiscounted lease payments	6,917
Present value adjustment	(1,070)
Total present value of lease payments	$ 5,847

7. Term Loan Payable

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

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

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

8. Stockholders' Equity (Deficit)

Authorized Shares

The Company's current Amended and Restated Certificate of Incorporation authorizes 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 in December 2020, the Company's redeemable convertible preferred stock was classified as mezzanine equity on the Company's balance sheets as the shares are contingently redeemable upon a deemed liquidation such as a change in control and in that event, there is no guarantee that all stockholders would be entitled to receive the same form of consideration. No accretion to redemption value was recorded during the year ended December 31, 2020 as a deemed liquidation event was not considered probable.

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 provided that the Company would issue, and the Series B holders would purchase, an additional 21,732,862 shares of the Company's Series B redeemable convertible preferred stock across two tranches for aggregate proceeds of $46.9 million in the event that certain agreed upon milestones were achieved or the preferred majority approved their closing. The Series B tranches did not meet the definition of freestanding instruments or the definition of derivatives, therefore, they were not accounted for separately or bifurcated.

On July 1, 2020, the Company issued 10,669,834 shares of its Series B redeemable convertible preferred stock for cash at a purchase price of $2.16 per share, resulting in gross proceeds of $23.0 million.

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

Common Stock

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

	December 31, 2021	December 31, 2020
Shares underlying outstanding equity awards	6,370,873	6,316,569
Shares available for future equity award grants	2,931,012	1,506,806
Shares underlying early exercised equity awards	26,283	100,263
Shares underlying ESPP withholdings	—	4,393
Total	9,328,168	7,928,031

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):

	Years Ended December 31,	
	2021	2020
Research and development expense	$ 8,331	$ 1,180
General and administrative expense	10,856	1,460
Total stock-based compensation expense	$ 19,187	$ 2,640

As of December 31, 2021, the total unrecognized stock-based compensation expense was $50.5 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.49 years.

Stock Option Awards

As of December 31, 2021, the Company's equity incentive plans authorized a total of 9,564,798 shares, of which 2,931,012 shares are available for future grant, and 6,370,873 shares are outstanding. Not included in the outstanding option balance are 26,283 shares pursuant to stock options that were early exercised and subject to repurchase that remain unvested as of December 31, 2021.

Stock options granted under the Company's equity incentive 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 or in full on an annual basis. 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, 2021 is as follows (in thousands, except share and per share data and years):

	Stock Options Outstanding			
	Shares Subject to Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance at December 31, 2020	6,316,569	$ 10.93		
Granted	511,773			
Exercised	(261,567)			
Cancelled	(195,902)			
Balance at December 31, 2021	6,370,873	12.82	8.58	11,385,117
Vested at December 31, 2021	1,974,776	$ 9.60	8.14	$ 4,887,808

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, 2021. The aggregate intrinsic value of options exercised during the years ended December 31, 2021 and 2020 was $7.7 million and $0.1 million, respectively.

The weighted-average grant date fair value per share of option grants for the years ended December 31, 2021 and 2020 was $22.15 and $10.50, respectively. The total fair value of shares vested during the years ended December 31, 2021 and 2020 was $17.0 million and $1.1 million, respectively.

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

	Years Ended December 31,	
	2021	2020
Expected term (in years)	6.0	6.0
Expected volatility	79%	80%
Risk-free interest rate	0.98%	0.51%
Expected dividend yield	—	—

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

Fair Value of Common Stock. Prior to the Company's initial public offering in 2020, the grant date fair market value of the shares of common stock underlying stock options was determined by the Company's board of directors. Following the closing of the Company's IPO, the fair market value of the Company's common stock is based on its closing price as reported on the date of grant on the primary stock exchange on which the Company's common stock is traded. Prior to the Company's IPO, because there was no public market for the Company's common stock, the board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair market value, which included contemporaneous valuations performed by an independent third-party, the Company's results of operations and financial position, including its levels of available capital resources, its stage of development and material risks related to the Company's business, progress of the Company's research and development activities, the Company's business conditions and projections, the lack of marketability of the Company's common stock and preferred stock as a private company, the prices at which the Company sold shares of its redeemable convertible preferred stock to outside investors in arms-length transactions, the rights, preferences and privileges of the Company's redeemable convertible preferred stock relative to those of its common stock, the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry, the likelihood of achieving a liquidity event for the Company's securityholders, such as an IPO or a sale of the company, given prevailing market conditions, the hiring of key personnel and the experience of management, trends and developments in the Company's industry and external market conditions affecting the life sciences and biotechnology industry sectors.

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

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

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

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

Employee Stock Purchase Plan

In November 2020, the Company's board of directors and stockholders approved and adopted the 2020 ESPP. 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% 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.

As of December 31, 2021, a total of 698,015 shares were reserved under the ESPP, of which 627,185 shares are available for future issuance and 70,830 shares have been issued. The weighted average per share fair value rights granted during the year ended December 31, 2021 was $15.95.

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, 2021, were as follows:

	Years Ended December 31,	
	2021	2020
Expected term (in years)	1.2	1.2
Expected volatility	81%	82%
Risk-free interest rate	0.14%	0.11%
Expected dividend yield	—	—

10. Income Taxes

The Company's effective tax rates for the years ended December 31, 2021 and 2020 differ from the U.S. federal statutory rate as follows (in thousands):

	Years Ended December 31,	
	2021	2020
Tax at the federal statutory rate	$ (18,790)	$ (6,919)
Benefit from R&D tax credits	(1,244)	(586)
Stock-based compensation	1,102	331
Non-deductible executive compensation	817	—
Other temporary and permanent differences	33	21
Change in valuation allowance	18,082	7,153
Total provision for income taxes	$ —	$ —

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

	Years Ended December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforward	33,671	18,832
Lease liability	1,228	677
R&D tax credit carryforward	2,746	1,502
Share-based compensation	2,151	227
Other deferred tax assets	237	109
Total deferred tax assets	40,033	21,347
Deferred tax liabilities - Right of use asset	(994)	(458)
Valuation allowance	(39,039)	(20,889)
Net deferred tax assets	$ —	$ —

At December 31, 2021, the Company had net operating loss carryforwards for income tax purposes of approximately $160.3 million. If not used, $18.2 million of this carryforward will begin to expire in 2036 and $142.1 million has no expiration. At December 31, 2021, the Company also had research and development tax credits of approximately $2.7 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 $39.0 million and $20.9 million for the years ended December 31, 2021 and 2020, 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, 2021 and 2020, 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 ImmunoTAC platform. The Company has paid an aggregate of $150,000 in license fees that were recorded in research and development expense when incurred.

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

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

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.

On November 5, 2021, a securities class action complaint was filed against the Company and certain of the Company's officers and directors in the U.S. District for the Western District of Washington, captioned Dresner v. Silverback Therapeutics, Inc., et al., Case No. 2:21-cv-01499. The complaint alleges that between December 3, 2020 and September 10, 2021, the Company and certain of the Company's officers and directors violated (1) Sections 11 and 15 of the Securities Act of 1933, as amended; and (2) Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Securities and Exchange Commission ("SEC") Rule 10b-5 promulgated thereunder, by making allegedly false and misleading statements in various SEC filings and press releases regarding the clinical and commercial prospects of the Company's product candidate, SBT6050, which is now discontinued. The complaint seeks unspecified damages and interest, as well as attorneys' fees and other costs. The court recently appointed lead plaintiff and lead plaintiff's counsel. The Company and the other defendants have not yet filed a response to the complaint, and do not anticipate doing so until after the filing of an amended complaint.

The Company cannot predict the outcome of this suit, and failure by the Company to obtain a favorable resolution could have a material adverse effect on its business, results of operations and financial condition. The Company's chances of success on the merits are still uncertain and any possible loss or range of loss cannot be reasonably estimated and as such the Company has not recorded a liability as of December 31, 2021.

Indemnifications

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

COVID-19

The global COVID-19 pandemic continues to rapidly evolve, and management continue to monitor the situation closely. The extent of the impact of COVID-19 on the Company's business, operations, planned preclinical studies and clinical trials, and manufacturing timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on the Company's CROs, third-party manufacturers, supply chains necessary for research and development and manufacturing, and other third parties with whom the Company does business, as well as its impact on regulatory authorities and the Company's key scientific and management personnel. For example, the COVID-19 pandemic has caused the cost of obtaining animals for our preclinical studies to increase dramatically and, if the shortage continues, could also result in delays to our development timelines.

To the extent possible, management is conducting business as usual, with necessary or advisable modifications to employee travel and some of the Company's non-lab based employees working remotely. Management will continue to actively monitor the rapidly evolving situation related to COVID-19 and may take further actions that alter Company operations, including those that may be required by federal, state or local authorities, or that management determines are in the best interests of the Company's employees and other third parties with whom the Company does business. At this point, the extent to which the COVID-19 pandemic may further 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. 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 did not match contributions made by employees through December 31, 2021. The Company began matching 4% of employee contributions in 2022.

14. Net Loss Per Share Attributable to Common Stockholders

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

	As of December 31,	
	2021	2020
Common stock options	6,370,873	6,316,569
Unvested common stock	26,283	100,263
ESPP withholdings	—	4,393
Total potentially dilutive shares	6,397,156	6,421,225

15. Subsequent Events

Subsequent to December 31, 2021 through March 31, 2022, the Company's board of directors approved the grant of options to purchase an aggregate of 1,815,926 shares of common stock at an exercise price of $4.85 per share. The unrecognized stock-based compensation expense for these grants is approximately $5.9 million. Additionally, the Company's board of directors approved the grant of 266,744 restricted stock units. The unrecognized stock-based compensation expense for these awards is approximately $1.3 million.

On March 28, 2022, the Company's board of directors approved a corporate restructuring plan to discontinue the Company's clinical development programs for SBT6050 and SBT6290 and to prioritize resources on the development of SBT8230 and early-stage discovery programs (the "Restructuring Plan"). In connection with the Restructuring Plan, the Company's workforce will be reduced by 27%, with substantially all of the reduction in personnel expected to be completed by July 15, 2022. The Company initiated the reduction in force on March 31, 2022 and expects to provide severance payments, continuation of group health insurance coverage, and other benefits for a specified period to the affected employees. The Company currently estimates that it will incur costs of approximately $2.0 million for termination benefits related to the Restructuring Plan, all of which will be cash expenditures paid in 2022.

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, 2021. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2021, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2021.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

On March 28, 2022, our board of directors approved a corporate restructuring plan to discontinue our clinical development programs for SBT6050 and SBT6290 and to prioritize resources on the development of SBT8230 and early-stage discovery programs (the Restructuring Plan). In connection with the Restructuring Plan, our workforce will be reduced by 27%, with substantially all of the reduction in personnel expected to be completed by July 15, 2022. We initiated the reduction in force on March 31, 2022 and expect to provide severance payments, continuation of group health insurance coverage, and other benefits for a specified period to the affected employees. We currently estimate that we will incur costs of approximately $2.0 million for termination benefits related to the Restructuring Plan, all of which will be cash expenditures.

Item 9C. Disclosure regarding Foreign Jurisdictions that Prevent Inspections.

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, 2021 (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 Compensation* and *Summary Compensation Table for Fiscal 2021 and 2020* 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*, *Executive Compensation*, *and Non-Employee 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	Description of Registrant's Common Stock (incorporated by reference to Exhibit 4.6 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 29, 2021).
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*¥	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).
10.11+	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).
10.12+	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.15 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 30, 2020).
10.13**	Amendment No. 1 to Cell Line License Agreement, by and between the registrant and WuXi Biologics (Hong Kong) Limited, dated January 12, 2021 (incorporated by reference to Exhibit 10.16 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 29, 2021).
10.14¥	Sublease Agreement, by and between the registrant and Delta Dental of Washington, dated July 1, 2021 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 10, 2021.
10.15+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the Silverback Therapeutics, Inc. 2020 Equity Incentive Plan.
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.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

+ 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.

SILVERBACK THERAPEUTICS, INC.

Date: March 31, 2022

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 31, 2022
/s/ Jonathan Piazza Jonathan Piazza	Chief Financial Officer *(Principal Financial Officer)*	March 31, 2022
/s/ Russ Hawkinson Russ Hawkinson	Senior Vice President of Finance *(Principal Accounting Officer)*	March 31, 2022
/s/ Peter Thompson, M.D. Peter Thompson, M.D.	Chairman of the Board of Directors	March 31, 2022
/s/ Vickie L. Capps Vickie L. Capps	Director	March 31, 2022
/s/ Robert Hershberg, M.D., Ph.D. Robert Hershberg, M.D., Ph.D.	Director	March 31, 2022
/s/ Saqib Islam, J.D. Saqib Islam, J.D.	Director	March 31, 2022
/s/ Andrew Powell, J.D. Andrew Powell, J.D.	Director	March 31, 2022
/s/ Jonathan Root, M.D. Jonathan Root, M.D.	Director	March 31, 2022
/s/ Thilo Schroeder, Ph.D. Thilo Schroeder, Ph.D.	Director	March 31, 2022
/s/ Maria Koehler, M.D., Ph.D. Maria Koehler, M.D., Ph.D.	Director	March 31, 2022

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

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

1. SUBLEASE SUMMARY.

a. **Subleased Premises**. Tenant leases to Subtenant and Subtenant leases from Tenant that portion of the Master Premises (the "Subleased Premises") consisting of an agreed area of 9,188 rentable square feet on the 6th floor(s) of the Master Premises, as outlined on the floor plan attached as Exhibit 3 (except that Tenant shall not have access to the stairwell depicted thereon) and commonly known as 400 Fairview Avenue North, Seattle, WA 98109 (Suite 600).

b. **Sublease Commencement Date**. The term of this Sublease shall commence upon the later of (i) receipt of Landlord's written consent to this Sublease in a form acceptable to Subtenant, (ii) possession of the Subleased Premises is delivered to Subtenant and (iii) Tenant's Work (cap of the stairwell) is completed (the "Sublease Commencement Date"), but this date may not occur prior to July 1, 2021 unless Subtenant agrees.

c. **Sublease Termination Date**. The term of this Sublease shall terminate at midnight on the last day of the 24th full month following the Sublease Commencement Date, or one (1) day prior to the termination date of the Master Lease, whichever is earlier, unless sooner terminated in accordance with the terms of this Sublease (the "Sublease Termination Date"). So long as Subtenant is not in default (beyond applicable notice and cure periods) of its obligations under this Sublease, Subtenant shall have the right to terminate this sublease any time following the twelfth (12th) month of the sublease term by providing at least 90 days prior written notice. Subtenant shall pay a termination fee equal to one month of rent due at the time of written notice to Tenant. So long as Subtenant is not in default (beyond applicable notice and cure periods) of its obligations under this Sublease, Subtenant shall have the option to extend the Sublease term for a period of twelve-months (the "Extended Sublease Term"). Subtenant shall provide three-months' written notice of its exercise of this option to extend prior to the Sublease Termination Date unless sooner terminated pursuant to the provisions of the Sublease Agreement. The monthly base rent for the Extended Sublease Term shall be $30,054.42.

d. **Base Rent**. Subtenant shall pay to Tenant monthly base rent (check one): ☒ $28,329.67 for the first twelve months, then $29,179.56 thereafter, or ☐ according to the Rent Rider attached hereto ("Base Rent). Rent shall be payable at Tenant's address shown in Section 1(h) below, or such other place designated in writing by Tenant. Provided Subtenant shall faithfully perform all of the terms and conditions of the Sublease, Subtenant shall not be required to pay any Rent for the first full calendar month of the Term of this Sublease. For the avoidance of doubt, the parties to this Sublease intend that this Base Rent payment is the only payment owing by Subtenant to Sublandlord for use of the Subleased Premises, and Subtenant shall not be responsible for paying any portion of the Operating Costs, utility costs or other costs owing under the Master Lease. Sublandlord at its sole cost shall timely pay Landlord for all Operating Costs, utility charges and other charges and fees owing under the Master Lease throughout the Term of this Sublease.

e. **Prepaid Rent**. Upon execution of this Sublease, Subtenant shall deliver to Tenant the sum of $28,329.67, as prepaid rent to be applied to Rent due for month 2 of the Sublease.

f. **Security Deposit**. Upon execution of this Sublease, Subtenant shall deliver to Tenant the sum of $29,179.56 (equal to last month's rent) to be held as a security deposit pursuant to Section 5 below. The security deposit shall be in the form of (check one): ☒ cash, ☐ check or wire transfer, ☐ letter of credit, or according to the Letter of Credit Rider (CBA Form LCR) attached hereto.

g. **Permitted Use**. The Subleased Premises shall be used only for office and administrative use, subject to the Master Lease, applicable zoning, and other laws, and for no other purpose without the prior written consent of Tenant (the "Permitted Use").

h. **Notice and Payment Addresses**:

Tenant: DELTA DENTAL OF WASHINGTON
400 Fairview Avenue N, Suite 800
Seattle, WA 98109
Attn: Ryan Bartlett
Email: rbartlett@deltadentalwa.com
Subtenant: SILVERBACK THERAPEUTICS, INC

Email:

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

2. PREMISES

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

b. **Acceptance of Premises**. Except as specified elsewhere in this Sublease, Tenant makes no representations or warranties to Subtenant regarding the Subleased Premises, including the structural condition of the Subleased Premises or the condition of all mechanical, electrical, and other systems on the Subleased Premises. Except for any subtenant improvements to be completed by Tenant as described in the Work Letter attached as Exhibit 4 ("Tenant's Work"), Subtenant shall accept the Subleased Premises and its appurtenances in their respective AS-IS, WHERE-IS condition, and shall further be responsible for performing any work necessary to bring the Subleased Premises into a condition satisfactory to Subtenant. By signing this Sublease, Subtenant acknowledges that it has had adequate opportunity to investigate the Subleased Premises, acknowledges responsibility for making any corrections, alterations and repairs to the Subleased Premises (other than Tenant's Work), and acknowledges that the time needed to complete any such items shall not delay the Sublease Commencement Date. However, Sublandlord shall at its cost deliver the Subleased Premises to Subtenant (i) broom clean; and (ii) with the Tenant's Work (cap of the stairwell) substantially completed. Sublandlord further agrees to work in good faith with Subtenant and Landlord to facilitate Subtenant's use of existing cabling infrastructure within the Subleased Premises (while ensuring that Sublandlord's data and network security and performance is not compromised). To Sublandlord's knowledge, all lighting, electrical outlets, and any other electrical/mechanical systems are in a fully functional condition consistent with a class A building in Seattle. Notwithstanding anything to the contrary in this Sublease, Subtenant shall have no obligation to correct any defects in the Subleased Premises (including, without limitation, any condition that is a default under the Master Lease) existing as of the Commencement Date of this Sublease, and Sublandlord shall be responsible at its cost for correcting any such defects or defaults to the extent such obligations are Sublandlord's obligation to maintain pursuant to the Master Lease.

c. **Subtenant Improvements**. The Work Letter attached as Exhibit 4 sets forth all of Tenant's Work, if any, and all improvements to be completed by Subtenant ("Subtenant's Work"), if any, that will be performed on the Subleased Premises. Responsibility for design, payment and performance of all such work shall be as set forth in the Work Letter.

3. **TERM**. The term of this Sublease shall commence on the Commencement Date and shall end on the Termination Date (the "Term").

a. **Early Possession**. Subtenant acknowledges that Tenant may need to obtain Landlord's consent to this Sublease prior to Subtenant occupying the Subleased Premises, and that Subtenant shall not occupy the Subleased Premises without the prior written consent of Tenant. In the event Tenant gives Subtenant access to the Subleased Premises preceding the Sublease Commencement Date for the purpose of installing Subtenant's furniture, telecommunications, fixtures, telephone systems and computer cabling and the performance of Subtenant's Work, if any, such access shall be fully coordinated with Tenant in advance and Subtenant shall not interfere with Tenant's Work. In no event shall Subtenant have access to any portion of the Master Premises except for the Subleased Premises. All of the terms and conditions of this Sublease, including Subtenant's insurance and indemnification obligations, shall apply during such time, except for payment of Base Rent. If Subtenant occupies the Subleased Premises before the Sublease Commencement Date specified in Section 1, then such date of occupancy shall not advance the Sublease Commencement Date or Sublease Termination Date set forth above. Subtenant shall have fifteen (15) days early access to the Premises for FF&E at no additional cost.

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

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

4. RENT

a. **Payment of Rent**. Subtenant shall pay Tenant without notice, demand, deduction or offset, in lawful money of the United States, the monthly Base Rent stated in Section 1 in advance on or before the first day of each month during the Sublease Term beginning on (check one): ☒ the Sublease Commencement Date, or ☐ ___ (if no date specified, then on the Sublease Commencement Date), and any other additional payments due to Tenant ("Additional Rent", and together with Base Rent, the "Rent") when required under this Sublease. Payments for any partial month during the Term shall be prorated. All payments due to Tenant under this Sublease, including late fees and interest, shall also constitute Additional Rent, and upon Subtenant's failure to pay any such costs, charges or expenses, Tenant shall have the same rights and remedies as otherwise provided in this Sublease for the failure of Subtenant to pay Rent.

b. **Late Charges; Default Interest**. If any sums payable by Subtenant to Tenant under this Sublease are not received within five (5) days of their due date, Subtenant shall pay Tenant an amount equal to the sum which would be payable by Tenant to the Landlord for or 5% of the delinquent amount for the cost of collecting and handling such late payment in addition to the amount due and as Additional Rent, whichever is greater. All delinquent sums not paid by Subtenant within five (5) business days of the due date shall, at Tenant's option, bear interest at the rate the Tenant would pay the Landlord under the Master Lease for an equivalent default or the highest rate of interest allowable by law, whichever is less. Interest on all delinquent amounts shall be calculated from the original due date to the date of payment.

c. **Less Than Full Payment**. Tenant's acceptance of less than the full amount of any payment due from Subtenant shall not be deemed an accord and satisfaction or compromise of such payment unless Tenant specifically consents in writing to payment of such lesser sum as an accord and satisfaction or compromise of the amount which Tenant claims. Any portion that remains to be paid by Tenant shall be subject to the late charges and default interest provisions of this Section.

5. **SECURITY DEPOSIT**. Upon execution of this Sublease, Subtenant shall deliver to Tenant the security deposit specified in Section 1 above. Tenant's obligations with respect to the security deposit are those of a debtor and not of a trustee, and Tenant may commingle the security deposit with its other funds. If Subtenant defaults in the performance of any covenant or condition of this Sublease, Tenant shall have the right, but not the obligation, to use or retain all or any portion of the security deposit for the payment of: (i) Base Rent, Additional Rent, or any other sum as to which Subtenant is in default; or (ii) the amount Tenant spends or may become obligated to spend, or to compensate Tenant for any losses incurred by reason of Subtenant's default. Subtenant acknowledges, however, that the security deposit shall not be considered as a measure of Subtenant's damages in case of default by Subtenant, and any payment to Tenant from the security deposit shall not be construed as a payment of liquidated damages for Subtenant's default. If at any time during the Term of the Sublease the security deposit delivered by Subtenant becomes insufficient to cover the amounts required under this Section 5, whether or not due to Tenant's application of all or a portion of the security deposit contemplated by this Section, Subtenant shall, within five (5) days after written demand therefore by Tenant, deposit with Tenant an amount sufficient to replenish the security deposit to the amount required in Section 1 above. If Subtenant is not in default of any covenant or condition of this Sublease at the end of the Term, Tenant shall return any unused portion of the security deposit without interest within 30 days after the surrender of the Subleased Premises by Subtenant in the condition required by Section 9 of this Sublease.

6. **MASTER LEASE**. Tenant represents to Subtenant that as of the effective date of this Sublease: (a) Tenant has delivered to Subtenant a complete copy of the Master Lease (which may contain redacted business terms), which represents all agreements between Landlord and Tenant relating to the leasing, use, and occupancy of the Subleased Premises, and (b) Tenant has not received notice from Landlord of a breach under the Master Lease that is uncured as of the date of mutual execution and delivery of this Sublease. Tenant shall not agree to an amendment to the Master Lease which would have an adverse effect on Subtenant's occupancy of the Subleased Premises or its intended use of the Subleased Premises, without obtaining Subtenant's prior written consent, which consent shall not be unreasonably withheld, conditioned, or delayed. Subtenant represents that it has read and is familiar with the terms of the Master Lease.

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

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

7. **CONSENT OF LANDLORD**. Notwithstanding anything to the contrary in this Sublease, whenever the consent of Landlord is required under the Master Lease, Subtenant shall obtain the consent of both Tenant and Landlord, but in all instances Subtenant shall first request and obtain the consent of Tenant before requesting the consent of Landlord. This Sublease shall not become effective until Landlord has provided its written consent to this Sublease. If Landlord does not consent to this Sublease within sixty (60) days of the parties' execution of this Sublease, then this Sublease shall be deemed void and the parties shall have no further rights or obligations hereunder.

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

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

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

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

11. **DESTRUCTON OR CONDEMNATION**.

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

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

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

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

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

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

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

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

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

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

14. **MORTGAGE SUBORDINATION AND ATTORNMENT**. This Sublease shall automatically be subordinate to any mortgage or deed of trust created by Landlord to the extent the Master Lease is subordinate to the same mortgage or deed of trust, and Subtenant shall attorn upon the same terms and conditions as the Tenant in the Master Lease, provided Subtenant shall enjoy the terms and conditions relating to such subordination and attornment to the same extent as Tenant under the terms of the Master Lease.

15. **HOLDOVER**. If Subtenant shall, without the written consent of Tenant, remain in possession of the Subleased Premises and shall fail to return the Subleased Premises to Tenant after the expiration or termination of the Sublease, the tenancy shall be a holdover tenancy at sufferance, which may be terminated in accordance with Washington law; provided that, upon expiration of the Master Lease, such holdover tenancy by Subtenant shall automatically be deemed a tenancy at sufferance, terminable immediately.

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

16. **NOTICES**. All notices under this Sublease shall be in writing and effective (i) when delivered in person or via overnight courier to the other party, or (ii) three (3) days after being sent by registered or certified mail to the other party at the addresses set forth in Section 1. The addresses for notices and payment of Rent set forth in Section 1 may be modified by either party only by written notice delivered in conformance with this Section.

17. **ESTOPPEL CERTIFICATES**. Upon the written request of Tenant, Subtenant shall execute and deliver to Tenant and/or Landlord or their designee a written estoppel certificate on the same terms and conditions as required of Tenant under the Master Lease.

18. **GENERAL**.

a. **Heirs and Assigns**. This Sublease shall apply to and be binding upon Tenant and Subtenant and their respective heirs, executors, administrators, successors and assigns.

b. **Brokers' Fees**. Subtenant represents and warrants to Tenant that except for Subtenant's Broker, if any, described and disclosed in Section 20 of this Sublease, it has not engaged any firm, finder or other person who would be entitled to any commission or fees for the negotiation, execution or delivery of this Sublease and shall indemnify and hold harmless Tenant against any loss, cost, liability or expense incurred by Tenant as a result of any claim asserted by any such firm, finder or other person on the basis of any arrangements or agreements made or alleged to have been made by or on behalf of Subtenant. Tenant represents and warrants to Subtenant that except for Tenant's Broker, if any, described and disclosed in Section 20, it has not engaged any firm, finder or other person who would be entitled to any commission or fees for the negotiation, execution or delivery of this Sublease and shall indemnify and hold harmless Subtenant against any loss, cost, liability or expense incurred by Subtenant as a result of any claim asserted by any such firm, finder or other person on the basis of any arrangements or agreements made or alleged to have been made by or on behalf of Tenant.

c. **Entire Agreement**. This Sublease, which incorporates portions of the Master Lease, contains all of the covenants and agreements between Tenant and Subtenant relating to the Subleased Premises. No prior or contemporaneous agreements or understandings pertaining to the Sublease shall be valid or of any force or effect and the covenants and agreements of this Sublease shall not be altered, modified, or amended to except in writing signed by Tenant and Subtenant.

d. **Severability**. Any provision of this Sublease which shall prove to be invalid, void or illegal shall in no way affect, impair or invalidate any other provision of this Sublease.

e. **Governing Law**. This Sublease shall be governed by and construed in accordance with the laws of the State of Washington.

f. **Memorandum of Sublease**. Neither this Sublease nor any memorandum or "short form" thereof shall be recorded without Tenant's prior consent.

g. **Submission of Sublease Form Not an Offer**. One party's submission of this Sublease to the other for review shall not constitute an offer to sublease the Subleased Premises. This Sublease shall not become effective and binding upon Tenant and Subtenant until it has been fully executed by both Tenant and Subtenant, and consented to by Landlord (if required by the Master Lease).

h. **Authority of Parties**. Each party to this Sublease represents and warrants to the other that the person executing this Sublease on behalf of such party has the authority to enter into this Sublease on behalf of this Sublease, that the execution and delivery of this Sublease has been duly authorized, and that upon such execution and delivery this Sublease shall be binding upon and enforceable against such party upon execution and delivery.

19. EXHIBITS AND RIDERS. The following exhibits and riders are made a part of this Sublease:
Exhibit 1: Legal Description of the Master Premises or Property
Exhibit 2: Master Lease
Exhibit 3: Outline of Subleased Premises
Exhibit 4: Work Letter
Other: Parking Rider, FF&E

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

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

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

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

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

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

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

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

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

DELTA DENTAL OF WASHINGTON, a Washington nonprofit corporation	SILVERBACK THERAPEUTICS, INC., a Delaware corporation
TENANT	SUBTENANT
TENANT	SUBTENANT
/s/ Brad A. Berg	/s/ Laura K. Mawry
By:	By:
Chief Operating Officer	Chief Exec Officer
Its:	Its:

SUBLEASE AGREEMENT

STATE OF WASHINGTON
COUNTY OF King
This record was acknowledged before me on June 24 21, by Brad A. Berg as
COO & CFO of Delta Dental of Washington
/s/ Julie Stewart
My commission expires: 3-04-2024

STATE OF WASHINGTON
COUNTY OF KING
This record was acknowledged before me on July 1st 20 21, by LAURA SHAWVER as
CEO of SILVERBACK THERAPEUTICS
/s/ Veronique Moleres
My commission expires: 4/26/25

SUBLEASE AGREEMENT

EXHIBIT 1

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

SUBLEASE AGREEMENT
EXHIBIT 2
[Master Lease]
[Omitted]

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

SUBLEASE AGREEMENT
EXHIBIT 4
[Work Letter]
[Omitted]

SILVERBACK THERAPEUTICS, INC.
RSU AWARD GRANT NOTICE
(2020 EQUITY INCENTIVE PLAN)

Silverback Therapeutics, Inc. (the "***Company***") has awarded to you (the "***Participant***") the number of restricted stock units specified and on the terms set forth below in consideration of your services (the "***RSU Award***"). Your RSU Award is subject to all the terms and conditions as set forth herein and in the Company's 2020 Equity Incentive Plan (the "***Plan***") and the Award Agreement (the "***Agreement***"), which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein but defined in the Plan or the Agreement shall have the meanings set forth in the Plan or the Agreement.

Participant:
Date of Grant:
Vesting Commencement Date:
Number of Restricted Stock Units:

Vesting Schedule: 1/4th of the Restricted Stock Units shall vest on the first anniversary of the Vesting Commencement Date. Thereafter 1/4th of the Restricted Stock Units shall vest on the second, third, and fourth anniversary of the Vesting Commencement Date (and if there is no corresponding day, the last day of such month) such that the RSU Award is fully vested on the fourth anniversary of the Vesting Commencement Date.

Notwithstanding the foregoing, vesting shall terminate upon the Participant's termination of Continuous Service.

Issuance Schedule: One share of Common Stock will be issued at the time set forth in Section 5 of the Agreement for each restricted stock unit which vests.

IMPORTANT INFORMATION REGARDING SELL-TO-COVER ELECTION

Please read this Restricted Stock Unit Grant Notice, the Agreement, the Plan, and the Company's Sell-to-Cover Election (the "***Sell-to-Cover Election***") carefully.

By accepting this RSU Award, Participant hereby agrees and acknowledges that (1) during the next "open window period" following the date hereof applicable to Participant, as determined by the Company in accordance with the Company's then-effective policy or policies on trading in Company securities, or (2) on the next date following the date hereof when Participant is otherwise permitted to trade in Company securities, Participant will execute the Sell-to-Cover Election with respect to this RSU Award and each Restricted Stock Unit granted to Participant by the Company following the date hereof (the "***Sell-to-Cover Election Obligation***").

If Participant fails to fulfill Participant's Sell-to-Cover Election Obligation, this RSU Award will be cancelled and Participant's eligibility for any future or additional benefits under this RSU Award will terminate, effective immediately as of such failure to fulfill Participant's Sell-to-Cover Election Obligation.

Additional Terms/Acknowledgements: By your signature below or by electronic acceptance or authentication in a form authorized by the Company, you understand and agree that:

- The RSU Award is governed by this RSU Award Grant Notice (the "***Grant Notice***"), and the provisions of the Plan and the Agreement, all of which are made a part of this document. Unless otherwise provided in the Plan, this Grant Notice and the Agreement (together, the "***RSU Award***

Agreement") may not be modified, amended or revised except in a writing signed by you and a duly authorized officer of the Company.

- You consent to receive this Grant Notice, the Agreement, the Plan, the Sell-to-Cover Election, the Prospectus, and any other Plan-related documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.
- You have read and are familiar with the provisions of the Plan, the RSU Award Agreement, the Sell-to-Cover Election, and the Prospectus. In the event of any conflict between the provisions in the RSU Award Agreement, or the Prospectus and the terms of the Plan, the terms of the Plan shall control.
- The RSU Award Agreement sets forth the entire understanding between you and the Company regarding the acquisition of Common Stock and supersedes all prior oral and written agreements, promises and/or representations on that subject with the exception of: (i) other equity awards previously granted to you, and (ii) any written employment agreement, offer letter, severance agreement, written severance plan or policy, or other written agreement between the Company and you in each case that specifies the terms that should govern this RSU Award.
- Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

SILVERBACK THERAPEUTICS, INC.: **PARTICIPANT:**

By:

Signature Signature

Title: _____ Date:

Date:

ATTACHMENTS: RSU Award Agreement, 2020 Equity Incentive Plan, Sell-to-Cover Election

ATTACHMENT I

SILVERBACK THERAPEUTICS, INC.
AWARD AGREEMENT
(2020 EQUITY INCENTIVE PLAN)

As reflected by your RSU Award Grant Notice ("***Grant Notice***"), Silverback Therapeutics, Inc. (the "***Company***") has granted you a RSU Award under the Company's 2020 Equity Incentive Plan (the "***Plan***") for the number of restricted stock units as indicated in your Grant Notice (the "***RSU Award***"). The terms of your RSU Award as specified in this Award Agreement for your RSU Award (this "***Agreement***") and the Grant Notice constitute your "***RSU Award Agreement***." Defined terms not explicitly defined in this Agreement but defined in the Grant Notice or the Plan shall have the same definitions as in the Grant Notice or Plan, as applicable.

The general terms applicable to your RSU Award are as follows:

1. **GOVERNING PLAN DOCUMENT.** Your RSU Award is subject to all the provisions of the Plan, including but not limited to the provisions in:
   - **a.** Section 6 of the Plan regarding the impact of a Capitalization Adjustment, dissolution, liquidation, or Corporate Transaction on your RSU Award;
   - **b.** Section 9(e) of the Plan regarding the Company's retained rights to terminate your Continuous Service notwithstanding the grant of the RSU Award; and
   - **c.** Section 8 of the Plan regarding the tax consequences of your RSU Award.

Your RSU Award is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the RSU Award Agreement and the provisions of the Plan, the provisions of the Plan shall control.

2. **GRANT OF THE RSU AWARD.** This RSU Award represents your right to be issued on a future date the number of shares of the Company's Common Stock that is equal to the number of restricted stock units indicated in the Grant Notice as modified to reflect any Capitalization Adjustment and subject to your satisfaction of the vesting conditions set forth therein (the "***Restricted Stock Units***"). Any additional Restricted Stock Units that become subject to the RSU Award pursuant to Capitalization Adjustments as set forth in the Plan and the provisions of Section 3 below, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Restricted Stock Units covered by your RSU Award.

3. **DIVIDENDS.** You shall receive no benefit or adjustment to your RSU Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment; provided, however, that this sentence will not apply with respect to any shares of Common Stock that are delivered to you in connection with your RSU Award after such shares have been delivered to you.

4. **WITHHOLDING OBLIGATIONS.** As further provided in Section 8 of the Plan, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for, any sums required to satisfy the federal, state, local and foreign tax withholding obligations, if any, which arise in connection with your RSU Award (the "***Withholding Obligation***") in accordance with the withholding procedures established by the Company. Unless the Withholding Obligation is satisfied, the Company shall have no obligation to deliver to you any Common Stock in respect of the RSU Award. In the event the Withholding Obligation of the Company arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Withholding Obligation was greater than the amount

withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

5. DATE OF ISSUANCE.

a. The issuance of shares in respect of the Restricted Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the Withholding Obligation, if any, in the event one or more Restricted Stock Units vests, the Company shall issue to you one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 above, and subject to any different provisions in the Grant Notice). Each issuance date determined by this paragraph is referred to as an "***Original Issuance Date***".

b. If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if:

i. the Original Issuance Date does not occur (1) during an "open window period" applicable to you, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities, or (2) on a date when you are otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market (including but not limited to under a previously established written trading plan that meets the requirements of Rule 10b5-1 under the Exchange Act and was entered into in compliance with the Company's policies (a "***10b5-1 Arrangement***")), *and*

ii. either (1) a Withholding Obligation does not apply or (2) the Company decides, prior to the Original Issuance Date, (A) not to satisfy the Withholding Obligation by withholding shares of Common Stock from the shares otherwise due, on the Original Issuance Date, to you under this RSU Award, and (B) not to permit you to enter into a "same day sale" commitment with a broker-dealer (including but not limited to a commitment under a 10b5-1 Arrangement) and (C) not to permit you to pay your Withholding Obligation in cash, then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day when you are not prohibited from selling shares of the Company's Common Stock in the open public market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if and only if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the shares of Common Stock under this RSU Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

c. To the extent the RSU Award is a Non-Exempt RSU Award, the provisions of Section 11 of the Plan shall apply.

6. TRANSFERABILITY. Except as otherwise provided in the Plan, your RSU Award is not transferable, except by will or by the applicable laws of descent and distribution.

7. CORPORATE TRANSACTION. Your RSU Award is subject to the terms of any agreement governing a Corporate Transaction involving the Company, including, without limitation, a provision for the appointment of a stockholder representative that is authorized to act on your behalf with respect to any escrow, indemnities and any contingent consideration.

8. NO LIABILITY FOR TAXES. As a condition to accepting the RSU Award, you hereby (a) agree to not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from the RSU Award or other Company compensation and (b) acknowledge that you were advised to consult with your own personal tax, financial and other legal

advisors regarding the tax consequences of the RSU Award and have either done so or knowingly and voluntarily declined to do so.

9. **Severability.** If any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid will, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

10. **Other Documents.** You hereby acknowledge receipt of or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Prospectus. In addition, you acknowledge receipt of the Company's Trading Policy.

11. **Questions.** If you have questions regarding these or any other terms and conditions applicable to your RSU Award, including a summary of the applicable federal income tax consequences please see the Prospectus.

* * *

This Agreement will be deemed to be accepted by you upon the signing (which may be electronic) by you of the Restricted Stock Unit Grant Notice to which it is attached or by the deemed acceptance of this Agreement, as described in the Restricted Stock Unit Grant Notice.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Form S-3 No. 333-261979 of Silverback Therapeutics, Inc. and

(2) Form S-8 Nos. 333-261980, 333-254827 and 333-251143 of Silverback Therapeutics, Inc. pertaining to the equity and option plans of Silverback Therapeutics, Inc.

of our report dated March 31, 2022, with respect to the consolidated financial statements of Silverback Therapeutics, Inc., included in this Annual Report (Form 10-K) of Silverback Therapeutics, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Seattle, Washington
March 31, 2022

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, 2021 of Silverback Therapeutics, Inc. ("the registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

5. The registrant's other certifying officer(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 31, 2022

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, 2021 of Silverback Therapeutics, Inc. ("the registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

5. The registrant's other certifying officer(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 31, 2022

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 PURSURANT 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, 2021, 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, as amended; and

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

Date: March 31, 2022 By: /s/ Laura Shawver, Ph.D.

Laura Shawver, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: March 31, 2022 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.